



Policy Brief for Parliamentarians

THE BIOTECHNOLOGY REGULATORY AUTHORITY OF INDIA (BRAI) Bill 2013 **A threat to our Food and Farming!**

This policy brief aims at

- ◆ Introducing the BRAI Bill and its irregularities.
- ◆ Highlighting some of the weak aspects of the Bill.
- ◆ Comments of dignitaries against the BRAI Bill.
- ◆ Recommendations to improvise the irregularities of the Bill

Introduction

The Biotechnology Regulatory Authority of India Bill was introduced in the Lok Sabha on 22 April 2013 by the Ministry of Science and Technology as a promise to promote the safe use of modern biotechnology for development. However, the way the Ministry is lowering the bar for the approval of Genetically Modified/Engineered crops through this bill is highly blameworthy as it promotes modern biotechnology and its products without considering the needs and welfare of people at large. Precisely, this poses a threat to our food and farming. Several aspects of the Bill are questionable and there is an urgent need to reconsider the mechanism proposed.

This Bill is in conflict with the provisions of Cartagena Protocol which India ratified on 17 January 2003. Against the spirit of this protocol, the BRAI Bill does not make any reference to the risks associated with 'modern biotechnology' and its potentially adverse effects on biological diversity and human health.

The primary purpose of this policy brief is to expose the dangerous aspects of the Bill before Parliamentarians who must consider the potential harms to be caused by this Bill to our food and farming and prevent this fundamentally flawed piece of legislation in its current form promoting risky GMOs to become a law of the land.

Bt Brinjal in a moratorium

The debate in India on GE crops had started with Bt cotton, the only commercially approved GE crop in the country (March 2002) and had become shrillest around the approval of Bt Brinjal, the first GE food crop in India.

The fact that Government pointing at precautionary principle, finally rolled back an approval of GMOs in our country, has validated the concerns raised by many against the existing regulatory system. All these factors contribute to the moratorium.

Will GM food reduce hunger in developing countries like India?

If hunger could be addressed by technology, green revolution would have done it long ago. The fact that hunger has grown in India in absolute terms – some 320 million people go to bed hungry every night. India had a record food grain surplus of 65 million tonnes. If 65 million tonnes surplus could not feed the 320 million hungry, how will GM food remove hunger?

More than 10 state governments, covering a majority of the Brinjal growing regions have officially rejected the Bt brinjal and have written to the central government.

Several scientists have advised not to approve Bt Brinjal, and there are no independent studies apart from the company data.

More than 9000 people gave written submissions against the introduction of Bt Brinjal.

KEY PROBLEMS IN THE BRAI BILL

The BRAI Bill is a threat to our food, health, farming and environment. Every citizen in the country will be affected by this undemocratic piece of legislation and here are some of the key problems with the BRAI Bill.

1. **A bill with a Wrong Mandate:** The bill falls flat in terms of creating a credible regulatory regime as it seems more like a promotional mandate than a regulatory one. The mandate of such a regulation should be the protection of biosafety from such risky technologies than to promote the use of modern biotechnology.
2. **Conflict of interest between the BRAI and the Ministry of Science and Technology:** The BRAI Bill has been proposed by the Department of Biotechnology (DBT), under the Ministry of Science and Technology which has a mandate to promote biotechnology in the country. In this situation the promoter of biotechnology will play a major role in constituting the sector regulator

Genetically Modified Food – safety concerns

- Harmful impacts on internal organs and immune system.
- Allergic reactions produced due to novel proteins produced by the transgenic plant.
- Food and seed contamination.

and also in assisting its functioning. With the promotion and regulation of GM crops under the same ministry, there is huge conflict of interest. For instance, Section 7(1) of the bill provides the member of the selection committee for the Chairperson and the Members of the BRAI and includes the secretary-in-charge of the Department of Biotechnology and according to Section 7(2) a scientist from the same department is required to convene the meetings of the selection committee. So, the BRAI would often have to consider applications with which the Ministry of Science and Technology and the Department of Biotechnology is either directly or indirectly associated with. Therefore, the decision making of BRAI, irrespective of whether there has been any actual instance of bias, would be viewed with the apprehension of bias.

3. **Overrides State government’s role:** The State governments have been kept out of any decision making role even though agriculture and health are state subjects under the Indian Constitution. The current Bill reduces the role of the State Governments to a recommendatory capacity in the form of State Biotechnology Regulatory Advisory Committee, set up under Section 35 of the Bill. The bill does not give any powers to the State Governments to reject the introduction of any GMOs, including experimental releases through field trials, in their state.

Global Area of Biotech Crops (in million hectares)

“Genetically Modified crops have been commercialised for nearly 20 years and an analysis of the industry data indicates a rejection by majority of the countries to adopt this controversial technology. The five countries that account for 91% of the global GM production are USA, Brazil, Argentina, India, Canada.”

Nations	2010	2011	2012	Crops
US	66.8	69	69.5	Maize, Soyabean, Cotton, Sugarbeet, Papaya, Squash
Brazil	25.4	30.3	36.6	Soyabean, Maize, Cotton
Argentina	22.9	23.7	23.9	Soyabean, Maize, Cotton
Canada	8.8	10.4	11.6	Canola, Maize, Soyabean, Sugarbeet
India	9.4	10.6	10.8	Cotton
China	3.5	3.9	4	Cotton, Papaya, Poplar, Tomato, Sweet pepper
Total*	148	160	170.3	

* Includes 12 other countries such as Paraguay, South Africa, Pakistan and Uruguay.
Source: ISAAA (International Service for the Acquisition of Agri-biotech Applications.)

4. **Transparency: An option decided by the authority:** BRAI Bill have included provisions to curtail the application of RTI Act to information/bodies under them and is evident from the Section 28(1) of the Bill which places the decision to disclose information for public interest with the authority instead of the CIC or Delhi High Court as required by the RTI Act 2005. This means that once BRAI is in place the citizen's right to know about safety of GM crops is killed forever. So, the Section 28 seems entirely unnecessary as the provisions under Section 8(1) of the RTI Act are adequate to provide protection from the disclosure of information which is of the nature of commercial confidence, trade secrets, or, intellectual property, the disclosure of which would harm the competitive position of third party unless the competent authority is satisfied that larger public interest warrants the disclosure of such information; and so also Section 8(2) of the RTI Act which provides that a public authority may allow access to information, if public interest in disclosure outweighs the harm to the protected interests.
5. **Participation of Public in decision making is curtailed:** The BRAI Bill does an eyewash of public participation in the decision making process which is considered a key component in the national and international biosafety regulatory mechanism. The BRAI Bill provides for public participation in the decision making process at one stage only under section-27(5) which says that without prejudice to the provisions contained in the sub sections (1), (2), (3), and (4), the Authority shall obtain the objections or suggestions from the public in case of organisms and products. However, besides this specific provision, the Bill does not provide any other opportunity to the public to raise its concerns and to seek clarification. The Supreme Court of India in Research Foundation for Science and Technology National Resource Policy v. UOI has held that: "The right to information and community participation for protection of environment and human health is also a right which flows from Article 21 of the Indian Constitution. The Government and authorities have, thus to motivate the public participation."
6. **Inadequacies in the composition of Statutory Committees/Councils:** The committees and councils constituted under the BRAI Bill are dominated by government officials with a purely technical background. Under section 6(2) of the

bill the qualifications mentioned for persons who can be appointed as members are very limited and exclude those representing social sciences, anthropology, public health, economics, etc. Such persons bring a necessary diversity and expertise to the decision making process which ensures that a decision is based not only on science related to molecular biology, genetics or biotechnology but takes into account the social, economic and ecological realities of the area which would be affected by the decision.

7. **Makes a Mockery of Biosafety assessment:** As there is a strong body of evidence on the impacts of GM crops on human health and environment, it is essential for any regulatory mechanism for GM crops to ensure long-term, independent biosafety assessments. But BRAI bill talks nothing about long term independent assessments; on the contrary it lowers the bar by letting non accredited labs to do biosafety as given under Section 41.
8. **Socio economic assessments missing:** Socio economic studies for assessing GM crops are not part of the existing regulations. Given that GM crops come with patent tag and have been found to further corporate control on agriculture, this will have a serious impact on a country like India where the majority is dependent on the farming sector. Article 26 of the Cartagena Protocol requires parties to keep in view, while implementing obligations under the Protocol, the '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'. The Norwegian Gene Technology Act 1993 states that significant emphasis shall also be placed on whether the deliberate release represents a benefit to the community and a contribution to sustainable development.

9. **Diluted standard of Legal Liability:** Present day testing procedures of GM crops are grossly inadequate to ensure safety or ascertain environmental impacts. Despite this, the BRAI Bill has a diluted standard of liability and does not conform to principles of deterrent liability, absolute liability and polluter pays principle. Section 70(1) of BRAI Bill says "No court shall take cognizance of any offence punishable under this Act or the rules or regulations made thereunder, save on a complaint made by the Authority or any officer or person authorized by it" and Section 70(2) says "No court inferior to that of Chief Metropolitan Magistrate or a Chief Judicial Magistrate shall try any offence punishable under this Act". Thus, section 70 absolves the regulator from any deleterious decision made thus leaving no room for accountability.
10. **BRAI Kills Consumer choice:** If the current BRAI proposal is passed it would lower bar for GM food crops. Once permitted there is no way by which we can stop these crops from contaminating our regular food crops. This would ultimately kill consumer choice and every one of us would be forced to eat GM food whether we want or not.
11. **BRAI Bill in its current form is a risk to safe food!** If the BRAI is passed as an Act in the Parliament, Bt Brinjal will be back, and following it would be 71 other Genetically Modified crops which include GM maize, rice, tomato, mustard, potato, etc. It will take away the constitutional rights of the citizens and the state governments, push our farmers into the mercy of multinational seed companies, kill the citizen's choice on safe food, endanger our environment and jeopardize the country's food safety and sovereignty.

Considering the mandate of the BRAI Bill is flawed, it needs to be withdrawn and in its place there needs to be a Biosafety Protection Regime, after consultations through public hearings across the country. This was also recommended by the Parliamentary Standing Committee on Agriculture in its report "Cultivation of GM crops - Prospects & Effects", tabled on 9 August 2012.

COMMENTS AGAINST THE BILL

SATYARAT CHATURVEDI (Spokesperson, Indian National Congress and Member of Parliamentary Standing Committee on Agriculture): "The current regulatory system is shameful and calls for complete makeover, while the Government is toying with the idea of Biotech Regulatory Authority, the Parliamentary Standing Committee recommends an all-encompassing Biosafety Authority" (*The Hindu*, August 24, 2012).

BHUPENDER YADAV (Rajya Sabha MP and a lawyer): "Despite the moratorium of Bt Brinjal, there have been many attempts to cast aside concerns on GM crops and it is clear that the regulatory system proposed within the BRAI Bill is one such effort. The BRAI Bill also has no provision for the people to raise their concerns at different points of decision-making, which makes it undemocratic" (*Hindustan Times*, August 26, 2012).

PROF. ANIL KUMAR SAHANI (Rajya Sabha MP): "BRAI Bill appears to be too centralized and therefore, contradictory to the principle of increasing decentralization of governance" (Letter to PM).

DR. RAMAKRISHNA KUSMARIYA (Madhya Pradesh Minister for Farmer's Welfare and Agricultural Development): "My government would oppose the BRAI Bill if the state's authority over agriculture is violated through the Bill."

THE HINDU (Hyderabad, April 27, 2013): Sixteen MPs (including CPI Leader Basudev Acharya, Thambidurai of AIADMK, Telugu Desam Party's Nama Nageshwar Rao and Arjun Charan Sethi of Biju Janta Dal) of opposition parties, have appealed to the centre to withdraw the BRAI Bill as they pointed that the provisions of the bill showed limited public participation, no transparency, lack of safety assessments and a diluted standard of liability, all of which makes the Bill unacceptable.

FORMER JUDGES OF Supreme Court, SP JEEVAN REDDY, KULDEEP SINGH, and MH KANIA have expressed serious concerns over the introduction of BRAI Bill and said that the regulatory framework should have experts from other related ministries such as environment, agriculture, health and rural development (<http://indiagminfo.org>).

Policy recommendations

In the light of these evidences, and the likelihood of commercializing GM food, Parliamentarians should protect the right of Indian citizens to safe food and environment by demanding the Government to follow the given recommendations-

- It is suggested that the Ministry of Environment and Forests which is currently the parent ministry of GEAC be the nodal agency for the regulation of GMOs and not the Ministry of Science and Technology, to avoid conflict of interest.

- The Bill will affect issues which are on the State list such as public health and agriculture and therefore it should give certain decision making powers to States with regard to what actions can or cannot be taken in their territory.
- It is recommended that the State-level Biosafety Protection Committee headed by the chief secretary of the State or the Principal Secretary, Dept of Environment be created which will have certain decision making powers and not just a recommendatory role.
- The main focus of the Bill should be the prevention of risk arising from use of modern biotechnology as there may be threats of serious or irreversible damage associated with it. The Precautionary Approach/Principle should be the overall focus of the regulatory regime.
- It is recommended that the committees and councils constituted to regulate GMOs should also include persons who have expertise to understand the social, cultural and economic impacts of the use of modern biotechnology products like GMOs and represent the various sectors.
- As there is strong body of evidence on the potential impacts of GM crops on human health and environment, it is essential for any regulatory mechanism for GM crops to ensure long term, independent biosafety assessments before environmental release.
- There should be a need assessment of the particular GMO proposed as a first step where the Risk Assessment Unit has to ascertain whether there is any other ecologically and socially sustainable alternative for the problem that the GMO claims to solve.
- Given the wide-ranging public concern around modern biotechnology and GMOs, in any regulatory regime on GMOs, information disclosure should be made a norm and confidentiality should be made an exception. All the decisions of the all units and committees of the regulatory system should be made public as soon as possible.
- Since impacts from products of modern biotechnology, like GMOs, are far and wide, effective public participation in decision making should be a mandatory component of any regulatory regime on modern biotechnology and GM products. There should be a mechanism to take public views at every step of decision making and especially before any environmental release including experimental ones is permitted.
- The regulatory system for GMOs would have to include a clause identifying the National Green Tribunal Act as the appropriate grievance Redressal forum. Necessary amendments to the sections of the National Green Tribunal Act can be made by adding a clause in any new legislation for regulating GMOs.
- It is recommended to fix responsibilities on Environment Impact Assessment consultant and be made liable for taking suitable action (both civil and criminal) for furnishing any wrong information.
- Given the nature of damage that can be caused, the regulatory authority should include penalties which are high enough to have a deterrent effect. Absolute liability and polluter pays principle should be the cornerstones of such liability clauses on regulation of GMOs. This should be in line with the Nagoya Kuala Lumpur Supplementary Protocol that India is a signatory to.
- The Bill should have provisions for monitoring, reviewing, mitigating, preventing and if needed revoking of proposals. The regulatory Authority should impose measures to avoid adverse effects on human health, biological diversity and in general the environment, including on socio-economic conditions, arising from a genetically modified organism or a product of a genetically modified organism.
- Bill should have measures that ensures access to justice for everyone and does not create legal barriers for effective grievance redressal. The composition of bodies put in place for this should reflect the diverse aspects of scientific, social, economical, cultural and ethical ones around modern biotechnology.

HARD FACT

India's current buffer stock is nearly 2.5 times more than the Government's benchmark for buffer stocks (TOI, January 18, 2013). So, the present need is the management of food stocks by efficient distribution rather than developing more genetically modified food stock.

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