

Biotechnology Regulatory Authority of India Bill, 2013 (BRAI):

"Wrong Bill by the wrong people, for the wrong reasons"

– a critique by the Coalition for a GM-Free India

Background

India is a party to the Convention on Biological Diversity, and a signatory to the Cartagena Protocol on Biosafety. As per the Cartagena Protocol's Article 3, Modern Biotechnology is:

- a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
- b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

Transgenics or GMOs or Genetically Modified Organisms are created through modern biotechnology. They are created unnaturally by inserting genes, taken usually from alien organisms like bacteria, viruses, animals and other unrelated plants, for obtaining certain new 'traits' or characteristics that the new genes are supposed to bring with them and express in the GE/GM crop. This kind of insertion of "genetic constructs" of a combination of bacterial and viral genes, for instance, does not happen in Nature. In Nature, the genome of any organism gets created at an evolutionary time scale and regulation of molecular level function is a highly complex, as-yet-incompletely-understood scientific arena.

For instance, Bt cotton or Bt brinjal have been created by inserting the gene from a soil bacterium called *Bacillus thuringiensis* into cotton/brinjal to produce a new toxin inside the plant itself to kill specific pests that feed on the plant. It is claimed that this will bring down the usage of chemical pesticides that are sprayed from outside for pest control.

However, this technology is fraught with imprecision and unpredictability. Moreover, since this is a living technology (seeds have life and once released into the environment, will grow and propagate on their own), it is uncontrollable and irreversible. Insertion of new genes using the technologies used for genetic engineering results in a lot of unpredictable changes in the existing DNA of an organism and induces instability in the genome. Individual genes as well as the genetic engineering process are known to create a lot of adverse health and environmental impacts, as documented in scientific studies all over the world. Attached is a compilation (not exhaustive) of such scientific studies which have captured adverse and unintended impacts of GM crops. Given the fact that this is a controversial technology whose safety is not yet established conclusively, even as there is growing evidence of the lack of safety, a majority of the countries around the world have not opted to go in for this technology in their agriculture and to this day, more than 15 years after the first GM crop was introduced for commercial cultivation in the USA, nearly 75% of GM crop cultivation happens in just 3 countries (USA, Brazil and Argentina) even as an overwhelming majority of countries around the world have shunned this so-called gene revolution path for agricultural development.

In India, only one GM crop has been allowed for commercial cultivation – Bt cotton, that too after it was discovered to have spread illegally on thousands of hectares in 2001. At the end of nearly a decade of Bt cotton cultivation, which was brought in on the claims of reduced insecticide usage in cotton crop in India, the value of insecticides used in cotton in the country has actually increased to levels (880.40 crores of rupees in 2010) that are more than the level in 2002 (597 crores), when Bt cotton was first approved. Suicides in regions like Vidarbha have not come down after the advent of Bt cotton but have actually increased (Maharashtra's total number of farm suicides during 1997-2002 stood at 17002, with an annual average of 2833, while it was 24402 during 2003-2008 {after Bt cotton was introduced}, with the annual average being 4067, as per NCRB data).

In 2010, the nation witnessed a loud and intense debate on the first food crop that was cleared by regulators in 2009, Bt brinjal. After holding nation-wide consultations on this controversial food crop, the Minister for Environment & Forests decided to "*adopt a cautious, precautionary principle-based approach and impose a moratorium on the release of Bt brinjal, till such time independent scientific studies establish, to the satisfaction of both the public and professionals, the safety of the product from the point of view of its long-term impact on human health and environment, including the rich genetic wealth existing in brinjal in our country*".

IT IS WORTHWHILE TO REMEMBER THAT THE FOLLOWING IMPORTANT POINTS CROPPED UP DURING THE NATIONWIDE DEBATE ON THE SUBJECT, CAPTURED IN THE **GOVERNMENT OF INDIA'S BT BRINJAL MORATORIUM DECISION NOTE:**

- All state governments that were consulted and responded, expressed apprehension and called for extreme caution (so, state governments getting a space to take a stand and expressing their opposition is to be noted, from the Bt brinjal debate)
- Need - 'there does not seem to be any over-riding food security, production shortage or farmer distress arguments favoring the enormous priority that has been accorded to it (Bt brinjal) by private companies, other than the well-known argument on the need to reduce pesticide use. Bt technology not the only route for reducing pesticide use. NPM eliminates chemical pesticide use completely whereas Bt technology only reduces the pesticide spray, albeit substantially¹.
- Safety tests critiqued - Tests have been carried out by Bt brinjal developers themselves - raises legitimate doubts that cannot be ignored on the reliability of tests - threat of contamination.
- Monsanto controlling our food chain - national sovereignty concerns
- 3951 varieties of brinjal - 134 diversity-rich dists - loss of diversity argument cannot be glossed over....
- Need to review Bt cotton experience; issues of pest resistance (monophagous pest)
- Questions on the integrity of the GEAC process - NBRA needed for science-based independent testing with integrity & impartiality
- Many countries not going in for GM; US has them widely available but '*there is no great compulsion for us to follow suit*'
- Need to adhere to international protocols, agreements and guidelines like Cartagena Protocol, Rio Declaration, Codex guidelines....
- Feedback from scientists....some in favor and some against; no clear consensus within the scientific community itself
- "Limited release" suggestion not feasible, being extremely difficult to ensure "quarantine" - labeling impractical
- Precautionary principle as seen in SC judgements in the past
- Issues with the tests conducted and not conducted so far
- Public sentiment is negative
- "No over-riding urgency to introduce Bt brinjal here, the very first such GM vegetable in the world", says the moratorium decision note.

One can see from the above main points that featured in the MoEF's decision note on February 9th 2010 related to Bt brinjal, that all the above issues are very much applicable to all transgenic crops, are relevant even now and would have to be made into an integral part of a regulatory regime.

The recommendations of the Parliamentary Standing Committee on Agriculture's report on CULTIVATION OF GENETICALLY MODIFIED FOOD CROPS – PROSPECTS AND EFFECTS

The Parliamentary Standing Committee on Agriculture tabled its recommendations regarding the issue of GM crops in its report titled 'Cultivation of Genetically Modified Food Crops- Prospects and Effects', on August 9, 2012 in the Parliament. The report which was prepared after an intensive and lengthy study of the issue which spanned two and a half years, involved meetings, submissions, field visits

¹ Data from different cotton-growing states shows that even this statement is not true.

and study of reports and regulatory systems of other nations. The Agriculture Standing Committee had 31 members cutting across party lines and was headed by veteran parliamentarian, Basudeb Acharya. Eleven of the Committee members are drawn from the ruling coalition and the report of the Committee was adopted unanimously.

Some of the major recommendations of the report are (quoted from report, edited for clarity):

- **On Biotechnology regulation** - The Government has been for some years now toying with the idea of a Biotechnology Regulatory Authority. Regulating biotechnology is too small a focus in the vast canvas of biodiversity, environment, human and livestock health, etc. and a multitude of other such related issues. Therefore, an all encompassing Bio-safety Authority should be created through an act of Parliament, which is extensively discussed and debated amongst all stakeholders before acquiring shape of the law. [Para 8.120]
- **Regulatory mechanisms in other nations:** The Government should evolve such a legislation after due consultation with all stakeholders and bring it before the Parliament without any further delay. In this context the Government is to duly consult the Norwegian Law which emulates this spirit to a large extent.[Para 3.47]
- **Conflict of interest:** A delinking of interest groups/ individuals from the decision making tiers of the regulatory mechanism without the regulatory mechanism being deprived of the professional inputs of the groups/individuals in question.[Para 2.87]
- **Biosafety Authority & NBA:** Since most of the international conventions and protocols increasingly revolve around biodiversity and related matters it is imperative that the National Biodiversity Authority should be sufficiently strengthened with scientific, technical and legal human resource of best quality so that the Country's rich biodiversity is adequately safeguarded. The Committee, as an alternative, would also like the Government to explore the possibility of amalgamating the mandate of NBA with the proposed Bio-Safety Authority when it comes into being so that the multiplicity of authorities and the resultant working at cross purposes is avoided. [Para -6.153]
- **Current regulatory system:** all is not well with the regulatory mechanism put in place by the Government for oversight of cutting edge technology as sensitive as GMOs and products thereof. The regulatory mechanism definitely requires the protection and support of an Act of the Parliament which leaves no scope for ambiguity or complacency. The problem, however, is that the Government has inordinately dithered in bringing an appropriate bio-safety friendly legislation in the matter before the Parliament. [para 2.92]
- **International treaties and conventions and India:** Other than the WTO whose primary focus is facilitation of trade, all other relevant treaties, conventions, underline the protocols need and for the agreement ensuring very unambiguously biological diversity and sustainability and eliminating any risk to human health due to the use of LMOs, GMOs and products thereof; however it is appalled by the existing state of affairs in these matters in the country. While the country is a signatory to these conventions/protocols/agreements/treaties with alacrity, it has not ensured that the necessary wherewithal scientific expertise, infrastructure and manpower for ensuring compliance is also created. The Biological Diversity Authority and PPV and FRA could have played a crucial role as an advisor and regulator in several matters pertaining to safety and sustainability of biodiversity but they are just a cosmetic presence. The Committee cannot but reiterate that the Country requires an all encompassing Bio-safety Authority without any further loss of time.[para 4.34]
- **IAASTD:** The Government of India is a signatory to this path breaking effort and in the opinion of the Committee, the Government would do well if they adopt this report as the way forward for development of agriculture and allied sectors in India, in a sustainable and environmental friendly manner, and with no unwanted risks to biodiversity, human and livestock health, flora and fauna.[Para 5.52]

- **Whether GM crops should be introduced:** In their tearing hurry to open the economy to private prospectors, the Government should not make the same fate befall on the agriculture sector as has happened to the communications, pharma, mineral wealth and several other sectors in which the Government's facilitative benevolence preceded setting up of sufficient checks and balances and regulatory mechanisms, thereby, leading to colossal, unfettered loot and plunder of national wealth in some form or the other, incalculable damage to environment, biodiversity, flora and fauna and unimaginable suffering to the common man. [Para 3.48]
- **On GM crops and food security:** Faulty procurement policy, mismanagement of stocks, lack of adequate and proper storage, hoarding and lopsided distribution, massive leakages in the public distribution delivery system, etc. are more responsible for the present worrisome situation. If these shortcomings and problems are attended to along with liberal financial assistance to agriculture and allied sectors, proactive measures are initiated to arrest the decreasing trend in cultivable area and farmer friendly and sustainable agricultural practices are put in use, there would not be any compelling need for adopting technologies which are yet to be proven totally safe for biodiversity, environment, human and livestock health and which will encourage monoculture, an option best avoided. Therefore, the Government to come up with a fresh road map for ensuring food security in coming years without jeopardizing the vast bio-diversity of the Country and compromising with the safety of human health and livestock health.[Para – 7.71]
- **On preparedness to handle GM crops:** The socioeconomic factors and the impact to the seed diversity of cotton and the case of India being a centre of origin were not satisfactorily looked into before Bt cotton was approved. Hence, an indepth probe may be carried out to track the decision making involved in commercial release of Bt. cotton right from the initial stage. [Para 6.146]
- **Impact on exports:** The negative impact of genetically modified crops on the country's agricultural exports is another important aspect that needs to be factored in while taking a decision in regard to introduction of genetically modified crops. The Committee desire the considered views of the Government in the matter.[Para 6.151]
- **Field trials:** Considering the flaws and the shortcomings noticed in the functioning of the regulatory mechanism meant for the purpose, the lack of preparedness of various agencies who should ideally be involved in various oversight and both, pre and post commercialization surveillance responsibilities in the context of transgenic crops, the still unclear ramifications of transgenic crops on bio-diversity, environment, human and livestock health and sustainability, the Committee desire that for the time being all research and development activities on transgenic crops should be carried out only in containment, the ongoing field trials in all States should be discontinued forthwith.[Para 7. 21]
- **Bt brinjal:** A thorough probe into the Bt. Brinjal matter from the beginning up to the imposing of moratorium on its commercialization by the then Minister of Environment and Forests (I/C) on 9 February, 2010 by a team of eminent independent scientists and environmentalists. [Para 2.79]
- **Bt cotton in food and feed:** Information with regard to post marketing surveillance, health safety, food and feed safety of the cotton seed oil and other products like cotton cake extracted from Bt.cotton and whether the manufactures of the cotton seed oil and cotton cake derived from Bt. cotton have complied with all relevant laws and regulations laid down for production and marketing of products derived from transgenic materials. [Para- 7.61]

The current regulatory system and origins of BRAI

In India, unlike in many other countries, there is no express statutory regulatory regime governing the regulation of transgenics. The Environment Protection Act's 1989 Rules govern the regulation as of today and since there is no separate statute, it is often found that major changes in the regulatory systems are being made at the regulators' level. The regulatory bodies are also infamous for their lack of independence and scientificity, and generally lack credibility in the eyes of the public as the Bt brinjal debate has shown.

It was in 2003-04 that the idea of an independent regulatory authority, termed then as the National Biotechnology Regulatory Authority was formally mooted for the first time in the report of a Task Force set up by the Ministry of Agriculture, Government of India, headed by Dr M S Swaminathan. This Task Force recommended the following as the bottom line for any biotechnology regulatory policy: *the safety of the environment, the well being of farming families, the ecological and economic sustainability of farming systems, the health and nutrition security of consumers, safeguarding of home and external trade and the biosecurity of the nation.*

This Task Force report, accepted by the Agriculture Ministry in 2004, also had the following recommendation: "transgenics should be resorted to when other options to achieve the desired objectives are either not available or not feasible."

Chapter II. Application of Biotechnology in Agriculture - Point 1.6²:

- *Biotech applications, which do not involve transgenics such as biopesticides, biofertilizers and bio-remediation agents, should be accorded high priority. They will help to enforce productivity in organic farming areas*
- *Transgenic approach should be considered as complimentary and resorted to when other options to achieve the desired objectives are either not available or not feasible*
- *Transgenic research should not be undertaken in crops/commodities where our international trade may be affected*
- *Such areas of biotechnological applications, which can reduce employment and impinge on the livelihood of rural families, should be avoided. (4. Choice of Research Problems)*

Task Force also cautions against transgenics for crops for which we are the Centre of Origin/Diversity (like Rice, Pigeonpea, Brinjal etc.).

In 2008, the Department of Biotechnology in the Ministry of Science & Technology floated the NBRA Bill for the first time and sought public feedback and held consultations in select locations with select invitees. Both the process and the content of the Bill were severely criticized and objected to, with the main objection being to the wrong mandate of the proposed Act and the promoters of GM crops becoming the regulators. Written feedback was provided by civil society with concerns and objections related to fundamental flaws in the Bill, which could not have been addressed with clause by clause amendments! It was obvious even at that stage that the Bill had to be scrapped and a new Bill for Biosafety Protection had to be evolved.

Another version of BRAI was created in 2009, the 'secret document' of which was leaked out in March 2010 – there was much furore over this Bill since there was even a Section (63), which sought to muzzle opposition to GM by seeking to impose fines and imprisonment on voices raising concerns on GM crops! **IT WAS VERY APPARENT THAT THIS BILL DID NOT IMPROVE ITSELF BASED ON THE FEEDBACK IN 2008, BUT ACTUALLY WAS BEING SHAPED IN A WORSE FASHION.** The clauses in this version of the Bill were clearly those put in by a GM-proponents-side which was on the backfoot and needed a lax regulation to aid faster clearances without adequate scientific basis and without comprehensive impact assessment, in an undemocratic, secretive fashion.

² <http://agricoop.nic.in/TaskForce/chep2.htm>

After the debate in 2010 on the draconian BRAI Bill version at that time, no other version was available for public debate. However, it was indicated that some improvements and changes were being brought about, as per media statements available from time to time; the Environment Ministry and Health Ministry are supposed to have raised objections to the 2010 BRAI version and the MoEF engaged with the MoST in revising the Bill to include additional clauses like the creation of an Environment Appraisal Panel etc. Further, a cosmetic change in the form of Department of Science & Technology replacing the DBT was made, in a completely inadequate answer to the criticism around conflicting interests.

While the Task Force did not look at the issue of constitutional authority of state governments over their agriculture or the Gram Sabha's authority over their natural resources, this issue has been brewing right from 1998 onwards, when the first trials of Bt cotton began in the country and Karnataka and Andhra Pradesh governments took a strong objection to these secret trials and expressed their unhappiness about it to the Centre. However, it is only recently that the authority of state governments has been recognized in the regulatory norms governing field trials of GMOs in India, when the Chief Minister of Bihar objected to trials being held in his state without the knowledge or consent of the government there; earlier, when Kerala declared a GM-Free policy for itself, this was acknowledged as a valid approach in the Parliament.

THE CURRENT BRAI BILL³

On April 22nd 2013, the BRAI Bill was introduced in Lok Sabha by the Minister for Science & Technology, Government of India. In the meantime there has been vociferous opposition to the Bill from all quarters including many MPs cutting across party lines.

It is pertinent to point out that at the time the Bill was introduced, only 3 states in India had given a go-ahead to open air field trials. Earlier, during the Bt brinjal debate, 13 states had objected to approval for its commercial cultivation. Meanwhile, hundreds of villages across the country are also declaring themselves GM-Free and numerous cases of regulatory incapacities and apathy abound.

Post introduction the Bill was referred to the Standing Committee on Science & technology, Environment & Forests. The process that led to the Bill being referred to the Standing Committee was contentious too. The Minister for Science & Technology, who tabled the Bill wanted the Bill to be sent to a Joint Committee of both Houses, given the fact that this is a vast subject spanning Agriculture, Health, Commerce and so on. But it was referred to the Standing Committee on Science & technology, Environment & Forests. The Standing Committee has since then notified that public feedback can be provided on the Bill for 30 days, starting from June 10th 2013.

Limited time and scope for public feedback: The BRAI Bill, affects every citizen in the country and encompasses issues related to human and animal health, food and environmental safety, livelihoods in the farming sector, trade security and above all, food and seed sovereignty. Therefore, it is imperative that before making recommendations, ample time and opportunity is provided for wide dissemination of the Bill and also sufficient time is granted for people to respond.

But the Committee has provided a scant 30 days for the public to provide written feedback; the Committee proposes to call a few stakeholders for consultations in Delhi. The advertisement of the feedback notification appeared only in English and a few local language dailies. The Bill has not even been translated into all languages and made available to the public. The feedback has also been solicited only in English and Hindi, thereby leaving out a large segment of the population from being

³ <http://www.prsindia.org/billtrack/the-biotechnology-regulatory-authority-of-india-bill-2013-2709/>

able to provide effective feedback. There is also no proposal for holding public consultations in different parts of the country.

To limit the feedback from the public on an issue of such deep import is not acceptable and does not forebode well for our food and farm safety. It is not enough that a few members/groups, chosen by the S&T Committee, are invited to give oral deposition, citizens should be able to express their views and hear other views in a transparent public hearing process, held across the country. Recently the National Advisory Council has also suggested that all draft Bills should be proactively be made available in the public domain for at least 90 days, after which a consultation process involving all stakeholders should be carried out. This they said would be based on the principles of "transparency, equity and inclusiveness".

WHY IS IT IMPORTANT TO ENGAGE WITH THIS BILL?

- It is apparent that we need to engage with the debates around agricultural technologies, since unlike other technologies, these are going to leave a larger impact for the simple reasons that most land is put under agriculture, most people in this country have their livelihoods associated with agriculture and most importantly, all of us consume food that is derived from agriculture. Within agriculture, it is also apparent that we need to engage with a technology like transgenics since it is a living technology that is known to be imprecise, unpredictable, uncontrollable and irreversible.
- It has to be remembered that our Food becoming unsafe and toxic is a distinct possibility with the advent of GM crops/food – our health is closely linked to the quality of our food, and therefore, to the regulatory regime that is shaping up in India through this Bill.
- The livelihoods of millions of farmers will depend on the claims being made about GM crops and the actual reality of these new seeds and plants in the growing conditions and socio-economic milieu of our smallholders and others. Any degradation of the environmental resources and serious changes in crop ecology because of GM crops will have a direct impact on their livelihoods since livelihoods are intrinsically linked to the state of these resources.

A regulatory regime that does not pay attention to these issues, biosafety-related as well as issues beyond biosafety, will only benefit the industry and fail our vast majority of poor.

OUR CRITIQUE OF BRAI BILL AND WHY IT SHOULD BE WITHDRAWN

The BRAI Bill is a blatant attempt to bulldoze through the public (reflected in state governments') resistance and genuine concerns about Genetically Modified (GM) crops, and to deny state governments their Constitutional authority over Agriculture and Health. It continues to be a 'wrong bill by the wrong people for the wrong reasons' even in its 2013 version.

This BRAI mechanism makes the regulatory system even weaker than the existing GEAC mechanism. As the nation remembers, the Bt Brinjal public hearings process saw state governments, farmer organizations, scientists, environmentalists, health experts and rest of civil society come out with huge concerns about GM crops, and the Government through its moratorium decision admitted the failure of GEAC regulatory mechanism and promised to strengthen the regulatory system. How can the same Government bring in a regulatory mechanism which is actually much weaker than GEAC and which overrides the state governments, local governments and public inputs?

First and foremost, it has to be noted clearly that regulation of modern biotechnology is much more problematic than regulation in other sectors like telecom or electricity (where the government tries to regulate markets, its players, prices, competition, or gives out scarce resources to market players etc.), because this pertains to a living modified technology. The fundamental basis of regulation lies in the risks associated with modern biotechnology. Therefore, there should only be one primary mandate or objective to this statute: to prevent risks to the health and safety of people of India, its environment and its biological diversity in particular, from the development, handling, transport, use, transfer and release of any living modified organisms. Given such a mandate, this Bill should be

introduced not by the Ministry of Science and Technology but by the Ministry of Health or Ministry of Environment & Forests. The current Bill is objectionable on such fundamental grounds apart from its other failings.

Such fundamental flaws (wrong mandate and wrong ministry) cannot be addressed by a Standing Committee to which it got referred to in a contentious manner. When the demand around withdrawing the Bill started building up, the Minister for Science & Technology, Mr Jaipal Reddy, wrote to the Speaker of Lok Sabha recommending that the Bill be referred to a Joint Committee. However, this Bill has ended up with the Department Related Standing Committee on Science & Technology and Environment & Forests. It is this Committee which is now studying the Bill and seeking feedback from the public.

DETAILED CRITIQUE OF THE BRAI BILL 2013

- 1. Wrong Ministry introducing it with wrong objectives:** As mentioned above, there should be only one reason why this Bill should be enacted and that should be to uphold the biosafety of the people of India and its environment from the risks of modern biotechnology. Further, if a technology is inherently unsafe, no amount of regulation can make it safer as is the case with the use of Genetic Engineering in our food and farming systems and therefore, we have also referred to the policy directives already present to some extent. Given that this statute is trying to replace the current regulatory regime as governed by the EPA's 1989 Rules which have been expressly formulated to protect health, Nature and environment from the risks of modern biotechnology, there should be a strong, rational reason why the same will not be the objective for BRAI. What new scientific evidence or other evidence has emerged since then that this objective is being changed to also introduce fast-track clearance systems in the name of 'effective and efficient' regulatory procedures? The main purpose of Biotechnology Regulation should be "*to protect the health (human and animal) and environment of India from the risks posed by modern biotechnology and its applications*". Therefore, we need a National Biosafety Protection Authority.
- 2. Objectionable conflict of interest being under the Ministry of Science & Technology:** This so-called autonomous regulatory authority should NOT be housed under the Ministry of Science & Technology, given that this is a Ministry with a mandate to promote biotechnology. It is apparent that replacing DBT with DST is only a cosmetic change and top bureaucrats of this biotech-promoting ministry are going to be key regulators in this proposed legislation. If BRAI is housed under this Ministry, the mandate itself becomes questionable; it is not in any doubt that every legislation draws its mandate from the Ministry it is housed under and housing this under MoST is objectionable and does not fulfill the mandate of protecting the health and environment of Indians. This Authority should be under the Ministry of Environment & Forests or under the Ministry of Health & Family Welfare or under both. Given that the BRAI Bill in its Preamble declares that it is consequent to India's commitments at CBD and the Cartagena Protocol that this Bill is being brought in, it is only pertinent to point out that the nodal ministry for these international commitments is the Ministry of Environment & Forests and not Ministry of Science & Technology.
- 3. Over-riding state governments' authority over their agriculture and health:** This Bill has an expediency clause in the very first chapter (Section (2)) which seeks to keep the regulatory control in the hands of Union Government, in the name of "public interest". This is unconstitutional and retrogressive, especially given the recent change in regulatory norms in India, rightfully so for the first time, allowing state governments to have a greater say in the deployment of modern biotechnology (or against such deployment) especially in the context of field trials/environmental release of GMOs.

This statute proposes to take away from the Constitutional authority that state governments have over their Agriculture and Health in the Indian federal structure. The proposed Bill envisages *only an advisory role for the state governments* in the form of "State Biotechnology Regulatory Advisory Committees" with no decision-making powers.

Section 35 details the constitution of State Biotechnology Regulatory Advisory Committee where it is provided that it will be headed by Secretary or head or Commissioner of Biotechnology. This is again an attempt to keep all the committees under the ambit and control of the Science & Technology Ministry, which reflects two incorrect approaches – that promoters can be regulators and that modern biotechnology is primarily a matter of S&T and experts. The role of this committee is to be the nodal agency between the state and the BRAI, to facilitate, coordinate and take up capacity building. The only relevant role that is remotely being considered is for this committee to work with the enforcement unit. The committee has no powers to enable the state government to take any decisions pertaining to implementation or introduction of modern biotechnology in the state.

Section 87 states that if there is any law in any state corresponding to this Act it shall stand repealed when this Act comes into being. Ironically enough, it goes on to add (Section 87 (3)) that despite the law being repealed any licenses issued under that will continue to be in force till date of expiry. This is a clear effort to over-ride state's authority to govern issues related to health and agriculture.

4. **No Needs Evaluation:** One of the fundamental recommendations of the Task Force on Agricultural Biotechnology led by Dr.Swaminathan was that "transgenics should be resorted to when other options to achieve the desired objectives are either not available or not feasible." The BRAI doesn't talk about any needs evaluation and assessment of alternatives, which was also stressed by the Government in its Bt brinjal moratorium decision – and assumes that all biotechnology and GM crops are a *fait accompli*. In fact, in countries like Norway, the Gene Technology Act there requires the applicants and regulators to answer satisfactorily some fundamental questions like: "is the deployment of the technology ethically and socially justifiable"?
5. **Lack of democratic functioning - No mechanisms for public participation:** The proposed legislation has no clauses on public participation, other than one small mention through Section 27 (5) that public feedback will be obtained. The Cartagena Protocol on Biosafety (under the Convention on Biological Diversity) under Article 23.2 says that 'Parties...shall consult the public in decision-making process regarding living modified organisms...' and India is a signatory to this.
6. **No mechanisms for transparency – Worse yet, bypassing the citizens' Right to Information:** This Bill, despite the enormous criticism being heaped on the current regulatory regime for its opaque functioning, does not have any pro-active measures and mechanisms to institutionalize a transparent regulatory regime. It does not pro-actively propose that data at various stages of decision-making would be put out in the public domain for independent scrutiny, for instance. Worse yet, this Bill, through Section 28, expressly seeks to classify some information as Confidential Commercial Information and leaves it to the discretion of officials of the Authority to share or not share this information. This once again is regressive, given that the Bt brinjal controversy saw express Supreme Court orders to the regulators asking them to put out all the biosafety data in the public domain (this and the CIC orders earlier to that have more than established the principle that no biosafety data can be confidential commercial information and such data has to be put out in public interest). India has already seen how regulators in the Ministry of Science & Technology would rather withhold information for protecting the industry

than share the data for independent scrutiny. What is the point in incorporating a component of obtaining public feedback through Section 27 (5) if the biosafety data is not put out in the public domain⁴? This is completely objectionable and it is a surprise that the UPA government which touts the RTI Act as a flagship legislation, is allowing clauses like this to creep into this Bill.

Further, the BRAI Bill has clauses on Oath of secrecy (Section 9 (2), for instance) – it immediately raises questions on the sensitivities involved in the deployment of the technology – what is being protected, what information is being withheld and to benefit who? It is archaic that the Authority Chair and Members will subscribe to an oath of secrecy as if the role is to keep things away from the public whereas governance is moving towards greater transparency and public accountability. Why is modern biotechnology and its deployment a secret affair, unless there is something to hide from the public? How can this Authority be trusted to act in the best interest of Indians with such clauses built in?

7. Appearance of numerous bodies yet centralized and narrow decision-making process:

The Bill essentially proposes that a 3-member Authority, with support from 2 other part-time members will take decisions, even though certain new mechanisms like the Environment Appraisal Panel have been introduced, compared to the last version of the Bill seen in 2010. However, this narrow-based technical Authority has been vested with all powers to decide, even while it is proposed that the Authority will look at the recommendations of Risk Assessment Unit and Products Ruling Committee. The proposed legislation also makes modern biotechnology regulation into only a technical risk assessment function. It ignores the bottomline set out in the Task Force report on Agri-Biotechnology and operationalising the same. The Authority is narrow in its outlook conceptually where it examines modern biotechnology through the narrow prism of “science based risk” and procedurally by controlling the decision-making within 3-5 people.

Under **Section 15**, a 18-member Inter-ministerial Governing Board is envisaged - however there doesn't seem to be any concrete decision-making role for this body and in any case, this is proposed to be headed by Secretary, Dept of Science & Technology (senior bureaucrat of modern biotechnology-promoting Ministry). The role envisaged for this body is “coordination” amongst various ministries. Under **Section 16** a large Biotechnology Advisory Council (BAC), with 16 people selected from a reasonably large cross section, is envisaged but here again their role is to merely “advise” the Authority on relevant practices on matters related to modern biotechnology, products, their uses etc. The Chair of the BRAI is the Presiding Officer of the BAC and would also nominate the Convenor of the BAC, in a further centralization of functions. There are members from private sector who could be part of this body however no clauses are envisaged to avoid any conflicting interests and undue influence over the Authority.

- 8. Toothless Environment Appraisal Panel:** Under Section 26, an Environment Appraisal Panel is mooted, consisting of seven members. This once again is a cosmetic change, which lays down no norms and procedures for the Panel's selection or functioning saying that it may regulate its own procedures (26 (2)). This Panel's 'opinion' will be sought in case of organisms and products having environmental impact, as may be referred by the Authority. This already leaves a discretionary space with the Authority for such referrals. Worse, 26 (4) clearly gives an over-riding power to the Authority over the Environment Appraisal Panel in case of difference of opinion. This effectively makes the Environment Appraisal Panel, created to appease the MoEF because of the objections raised to the BRAI 2010 version, into a toothless body.

⁴ Section 18 (3) (i) only talks about informing the public of all applications and decisions taken for instance

9. **Decision-making standards diluted:** There are clauses which prevent invalidation of the proceedings of the Authority by mere vacancies (sic) etc., in this Bill (this is ironic given that there are only 3 full-time members in any case!). **Section 13** further reinforces that no act or proceeding of the Authority will be made invalid due to vacancy in the constitution of the Authority or defect in the appointment of a person as a member of the Authority which further vitiates the quality of decision-making within the Authority.

Despite the numerous bodies like the Inter Ministerial Board, Biotechnology Advisory Council etc, essentially the process of decision-making involves recommendations of the risk assessment unit comprising of scientific officers (whose qualifications, conditions of employment or conflict of interest conditions are not specified) who will do a "science-based" risk assessment for applications which will be then forwarded to the product rulings committee (in case of applications for commercial release) for recommendations on the "safety of the organisms and products". In addition the Authority will seek opinion from the Environmental Appraisal panel where it thinks the organism will have an environmental impact.

10. **Compromise of Bio-Safety & Risks –** For a long time now, a serious objection to the parallel testing of GMOs in open air conditions (amounting to environmental release) even as biosafety assessment is going on, especially on the health front, has been raised by various sections. It is clear that in the name of research, Risk Assessment Unit will permit open air trials based on the application submitted by the crop developer ("science based evaluation of the application"). This is objectionable.

There are no improvements being made in terms of open air trials not happening before biosafety is thoroughly, independently and democratically assessed, despite numerous instances of violations during field trials, showing the abject failure of regulators on this front. It is a completely specious argument provided by the current set of regulators that cultivation of GMOs in open air conditions is required for testing biosafety in labs; for such testing, the crop developers should be restricted to growing the GMO only in contained conditions like glasshouses. Using quaint terms like 'environmental release' for actual commercial cultivation and using other terms like field trials for open air releases even though they are environmental releases too, the proposed Bill has no improvements to suggest to address the serious lacunae with field trials which are making state government after state government reject the possibility of any open air trials taking place in their state.

There is no cognizance of contamination of native cultivars or biodiversity through the open air release of untested, unpredictable and unknown GMOs and the proposed bill does not at any point discuss this very important issue. Overall, it is completely lacking at examining issues of bio safety, environmental safety and providing safeguards for proven issues like contamination by GMOs.

11. **Independent testing is not part of the Bill:** There are no proposals at all for independent testing which is a great problem witnessed time and again in the current regulatory regime too. This has been an important factor in the decision-making related to Bt brinjal moratorium; however, this has not been incorporated within BRAI. Worse, there are proposals of notifying labs under this Act that have not even been accredited (Chapter X, Section 41)!

12. **No risk management mechanisms:** The fact that BRAI Bill is being seen only as a clearing house is apparent from the fact that no risk management clauses have been proposed in this Bill – there is no mention of conditional approvals, periodic reviews, review and monitoring mechanisms

(there is a vague mention of Monitoring Officers in Chapter IX on Enforcement of Provisions of Act but no specific functions mentioned), no revoking mechanisms etc.

13. **Conflict of Interest potential not fully removed:** Even though the proposed Bill has apparent clauses that seemingly rid the proposed regulatory system of conflicting interests by placing restrictions on employment after cessation of office etc., the restrictions are not absolute, a careful reading of Section 10 (1) (a) reveals otherwise (within the so called 2 year cooling off period). Further, this removal of conflict of interest has not been thought of during the period preceding the appointment in BRAI. The classic cases of regulatory compromises in the USA through revolving doors have often happened in this method (pre-appointment associations with the applicant agency in some way or the other).

There are no restrictions to prevent or check such revolving door practices before joining the Authority and therefore, nothing to prevent some appointee getting a hefty sum before joining the authority and then clearing applications in the corruption-laden systems all around us; similarly, no such restrictions for the officials in the Bio safety Assessment Units or Product Rulings Committee etc., are missing, even though they would be doing the recommendations that would form the basis of decision-making later on!), the entire authority of decision-making rests with this small group of scientists!

14. **Weak penal clauses:** The Bill has very weak penal clauses (**Chapter XII** on Offences and Penalties) and in fact does not address liability issues at all: without a liability regime in place, no regulatory regime is complete on this issue. The polluter pays principle has to be an integral part of the regulatory regime for GMOs. The Liability should put the onus of violations on the crop developer primarily and not the users. Further, liability should cover criminal and civil liability as well as redressal/compensation to affected parties like farmers in addition to remediation for damage caused.

On one hand no mechanisms are provided for prevention of contamination, and on the other, no liability regime is in place. In addition under **Sections 67, 68, 69** it is promised to the offender entity that if they can assure that offense was committed "without their knowledge" and "all due diligence was exercised" they will not attract punishment. ***Combined with the fact that offenses in this category can't be taken to normal courts (save on a complaint made by the Authority!) and can be tried only with the appellate tribunal and offending entity would be a powerful corporation or government department against a small time farmer or some such complainant (who would be injured party), the scales of justice seem awfully imbalanced.***

Section 63 that deals with unapproved field trials lays down that whoever conducts field trials without approvals will be penalized with a minimum six months imprisonment and a fine and a repeat offense would attract a longer imprisonment and higher fine. However there is no provision to bar such a company/university/organization for a stipulated period from doing open air releases (through field trials) for endangering bio diversity and causing contamination and possible loss of business or livelihoods to other farmers. Lack of such a provision to bar them for a period is detrimental to bio safety and livelihood security of farmers as there is no strong deterrent for companies or organizations not to violate rules (as we have seen many times in the past).

15. **Biotechnology Regulatory Appellate Tribunal** (Chapter XI): There are many clauses which are objectionable and raise serious concerns in this chapter and the way the appellate system is

being proposed in this Bill. The Tribunal members are drawn only from judicial and technical backgrounds whereas issues of appeal could be related to livelihoods, trade etc.

Appeal to the Appellate Tribunal (Section 43 (1)) says that any person aggrieved shall appeal within thirty days from the date on which a decision/order/direction is communicated to him – this obviously means that complainants can only be applicants to the Authority and not the general public!

Under **Section 56** (“substantial question relating to modern biotechnology”) the Appellate Authority should be approached with a case within two years when the cause of action first arose. This is an arbitrary cut-off time limit as problems with GMOs, products etc., can arise at any point. Where would that point of “when it first arose” be decided?

It is unacceptable that the Bill has a clause (**Section 70**) which says that no court shall take cognizance of any offence punishable under this Act save on a complaint made by the Authority or any officer or person authorized by it! What is the rationale for this other than to protect offenders?

Equally objectionable is **Section 77** which prevents civil courts to have jurisdiction on any matter which the Appellate Tribunal under the Act is empowered to determine, wherein there is a bar on any injunction to be granted by any court in respect of any action taken by the Authority.

Section 57 (1) says that the Appellate Tribunal shall not be bound by the procedure laid down by the Code of Civil Procedure 1908 but shall be guided by the principles of natural justice and shall have the power to regulate its own procedure. It shall also not be bound by the rules of evidence contained in the Indian Evidence Act, 1872. It is very unclear why such powers have to be vested with this Appellate Tribunal?

All these sections together undermine the right of the public and affected parties to get justice. Again on this count the proposed bill is unconstitutional as it limits the public’s access to justice. The Authority is trying to make itself an entity very much on the lines of the now discredited SEZs which could not be governed by laws of the territory. (At this juncture let us not forget the infamous Bayer Liberty Link rice case where the company claimed due diligence and said that the contamination was an “act of god”, it was only the lawsuit in a court which saved the affected farmers).

16. **Over riding effect on other laws:** It is also objectionable that this Act will have an over-riding effect over other laws in force since this Bill is indeed inconsistent with legislations like the Biological Diversity Act. In addition, there is further confusion with two contradictory statements under two sections of the proposed Act. **Section 81** of the proposed Act states that “save as otherwise provided provisions of the act shall have effect notwithstanding anything inconsistent therewith contained in any other law for the time being in force, whereas the **Section 86** of the proposed act states that “the provisions of this act shall be in addition to, and not in derogation of, any other law for the time being in force”. Clearly these two sections contradict each other and will cause confusion as there are legislations like the Biological Diversity Act which have existed prior to this proposed which will be undermined by the actions of a new Act promulgated by a different Ministry. For instance, Section 36 (4) of the Biological Diversity Act says that “the Central Government shall undertake measures:

(i) wherever necessary, for assessment of environmental impact of that project which is likely to have adverse effect on biological diversity, with a view to avoid or minimize such effects and where appropriate provide for public participation in such assessment;

(ii) to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology likely to have adverse impact on the conservation and sustainable use of biological diversity and human health.

17. **GMO imports not dealt with:** Section 33 of the proposed BRAI bill barely talks about the processes of dealing with GMO imports and how to ensure that no unapproved GMOs come into the country and approved GMOs follow a labeling regime that is sorely missing etc. The BRAI bill is silent on importation and issues related to it: including but not limited to – sampling and analysis, independent safety testing, labeling till the retail end, imposing liability clauses where rules are violated etc.

DEMAND IS FOR A NATIONAL BIOSAFETY PROTECTION AUTHORITY

Any regulatory regime around GMOs should have the primary mandate of protecting health of people and the environment from the risks of modern biotechnology. It should necessarily have the following components as cornerstones of the legislation:

- Precautionary Principle as the central guiding principle
- Going in for the GM option only in case other alternatives are missing
- Separating out very clearly the phases of contained research and deliberate release and distinct regulatory mechanisms for both, in a sequential fashion
- No conflicting interests to be allowed anywhere in the regulation and decision-making
- Transparent functioning: information disclosure and public/independent scrutiny
- Democratic functioning including public participation – even here, data to be put out in the public domain and public participation included before the decision-making process and not just informing after a decision is made
- Risk assessment – (a) prescribing rigorous, scientific protocols and asking the crop developer to take up studies and then do independent analysis of the dossier supplied by the crop developer and evaluate/review of the same; (b) to also take up independent testing by having all facilities and institutional structures in place for the same and evaluating the results
- Risk management – including monitoring, reviewing, revoking of approvals
- Liability – including penal clauses, redressal and remediation
- Labeling regime for informed choices – this covers traceability and identity preservation requirements, including for imports legally allowed
- Oversight and appellate mechanisms that are simple, affordable and accessible by affected parties and ones who can approach in public interest
- In the case of India, given that it is a federal structure and given that Agriculture is a state subject, special clauses which allow the state governments to form their own regulatory systems and mechanisms
- On-going Post Market monitoring of every GM crop

Further, the law should be governed by principles like Polluter Pays, Inter-generational equity (a key principle in environmental jurisprudence now which covers conservation of options, conservation of quality and conservation of access, for present and future generations) etc. In countries like Norway, the law also has provisions to answer questions like “Is this ethically and socially justifiable?”, before a GMO is cleared. That would automatically include socio-economic and ethical concerns within the regulatory regime.

It is worthwhile to reiterate here again that the need for an independent and credible regulatory regime was articulated by the 2004 Task Force Report on Agricultural Biotechnology and this report clearly pointed out that the following should be the bottom line for any biotechnology regulatory policy: *the safety of the environment, the well being of farming families, the ecological and economic sustainability of farming systems, the health and nutrition security of consumers, safeguarding of home and external trade and the biosecurity of the nation*”. These important aspects or cornerstones do not find any place in the BRAI Bill 2013. **The Coalition for a GM-Free India rejects the BIOTECHNOLOGY REGULATORY AUTHORITY OF INDIA (BRAI) Bill 2013 – it is a wrong Bill drafted by the wrong people for the wrong reasons. What India needs is a Biosafety Protection Authority. We urge the Standing Committee to recommend the same.**