

**RESPONSE TO THE PROPOSED
BIOTECHNOLOGY REGULATORY AUTHORITY OF INDIA BILL, 2009:
WHY NOT A NATIONAL BIOSAFETY PROTECTION AUTHORITY?**

The purpose of any regulation around Genetic Engineering and related modern biotechnology applications flows from the inherent risks and hazards associated with these technologies.

India does not have a separate statute to govern the regulation of GMOs in our food and farming systems. This means that we have only executive orders/rules under the Environment Protection Act 1986 and these rules are easily changeable and altered by the regulators whereas having a proper statute would ensure that frequent, undemocratic changes in rules, guidelines and protocols will not be made too easily.

Requisite components of any biotech regulatory regime

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 principles 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
- Oversight and appellate mechanisms
- 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

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.

Almost everything listed above, as ideal pre-requisites of any statute governing modern biotechnology applications in our food and farming systems, are missing in the Indian regulatory system right now.

The lack of a proper statute and the absence of a credible regulatory regime is something that everyone is concerned about and using the opportunity of the current debate generated around Bt Brinjal, the Department of Biotechnology is trying to introduce a BIOTECHNOLOGY REGULATORY AUTHORITY OF INDIA (BRAI) BILL soon.

The following are the important concerns around this Bill.

1. The mandate of this Bill in its current version is for the "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 in order to promote the safe use of modern biotechnology by enhancing the effectiveness and efficiency of regulatory procedures".

The Bill therefore pre-supposes a clearing house/facilitator/approver role to the Authority of applications that it would receive and that is sought to be made into the main purpose of this legislation.

However, this very mandate is wrong and assumes that an inherently unsafe technology can be made safe by making the regulation effective and efficient! **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". To that extent, this Bill should be called by some other name like "Gene Technology and Biosafety Protection Act, 2010".**

It is worthwhile to remember here that 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 draft Bill sought to be introduced.

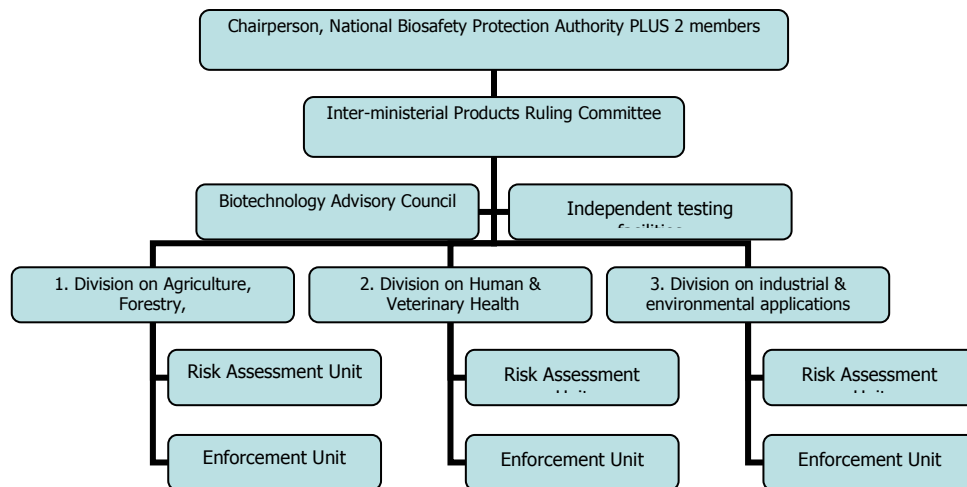
2. This so-called autonomous regulatory authority should NOT be housed under the Ministry of Science & Technology or more specifically within the Department of Biotechnology (the draft Bill emerged from the DBT). This will be a major conflict of interest in itself and if it is housed under this Ministry, the mandate itself becomes questionable. **This Authority should be under the Ministry of Environment & Forests or under the Ministry of Health & Family Welfare.**
3. **This statute should not in any way take away from the Constitutional authority that state governments have over their Agriculture and Health in the Indian federal structure.** However, the current Bill envisages ***only an advisory role for the state governments*** in the form of "State Biotechnology Regulatory Advisory Committees" with no decision-making powers. Worse, as per Section 87 (2), it ***asks for a repealing of any law in force for the time being in any State*** corresponding to this Act (including any licensing authority that the state government's concerned agencies might have under any other Law). Section 81 also expressly states that this Act will have an ***over-riding effect*** (on other Acts). **This is simply not acceptable on at least two counts:** this ignores the constitutional powers that state governments have

- over their Agriculture & Health; it also ignores and could impinge on or override the somewhat progressive legislations like Biological Diversity Act, with a mandate also to conserve and sustainably use biological diversity.
4. The proposed legislation also makes modern biotechnology regulation into only a technical risk assessment and risk management. **It ignores the bottom line set out in the Task Force report on Agri-Biotechnology and operationalising the same.**
 5. The legislation, **instead of expressly having clauses on information disclosure**, that too before decision-making and independent or public scrutiny, **has brought in clauses on retaining Confidential Commercial Information**. As past experience in India has shown, this cannot be left to the discretion of the officials in the Authority and all product development and biosafety-related information has to be pro-actively disclosed and placed in the public domain before decision-making.
 6. **It is also important to operationalise in this statute some key principles, as part of the regulations to be notified, that should be guiding decision-making in this area: (a) Precautionary principle; (b) Inter-generational equity; (c) Going in for the GM option only in case other alternatives are missing.** This third principle is what eminent molecular biologist and Supreme Court observer in the apex regulatory authority right now had proposed too, as the first parameter for assessment of a GMO. "*ascertain after careful analysis of existing information (and, if need be, relevant new information that could be generated within a short period) that there are no alternatives to the GMO and that the GMO will, if it meets the stipulated requirements, bring substantial benefit to the country and to one or more classes of its citizens. And if the GMO is truly required, carry out rigorous risk assessment*". Dr Bhargava has then gone on to lay down what such a risk assessment should consist of. Therefore, every application has to be rejected or accepted based on this main parameter right at the beginning.
 7. Final decision-making, especially in the case of environmental release cannot be left to technical experts alone. An alternate structure is proposed in Point 13 for this.
 8. **Chapter V:** Risk assessment cannot be left to the proposed three Divisions, Risk Assessment (and Enforcement Unit with its Monitoring Officers) and Products Ruling Committee for a 'science-based evaluation of the application' whether it is for import or manufacture or for any other purpose. As the Supreme Court observer had pointed out time and again, there is a need for independent testing itself and independent testing facilities. **Risk assessment should therefore consist of an evaluation of the biosafety dossier submitted by the crop/product developer including mandatory independent, public scrutiny but also independent testing for further verification of results.** Any proposed Authority should have the testing capabilities established for this.
 9. **Risk Management aspects have been neglected in the proposed legislation.** It is not enough to have an Enforcement Unit with empowered Monitoring Officers. **There should be clear clauses for reviewing of approvals and permissions, time-bound permissions in each case and clauses for revoking and cancellations of approvals.**
 10. For some inexplicable reason, a **Risk Assessment Unit** is brought into the picture for the applications pertaining to research, transport or import which is supposed to present its "clear assessment" to the Authority and further, a **Products Ruling Committee** is

brought into the picture for manufacture or use of GMOs and products thereof, for making recommendations to the Authority. This clearly assumes that import may not pose much threat and this may not be the case for large scale imports or GMOs getting imported (not just products thereof). There is no need for a Risk Assessment Unit and a Products Ruling Committee separate from each other. There can be only one Risk Assessment Unit and no Ruling should be allowed by anyone who is supposed to assess and evaluate. This Unit is only required to place its assessment report and recommendations.

11. **It would be important to make a distinction for regulation of contained use and deliberate environmental release.** There should be a sequential mode of regulation of any GMO, from contained use or containment to environment release, if at all. The environmental release should be permitted **ONLY** after biosafety has been conclusively established as per the Risk Assessment Unit.
12. **The final decision on environmental releases of GMOs (manufacture and use) should come from the Inter-Ministerial Products Ruling Committee** – the inter-ministerial body in the current proposals only has an advisory role. However, it should have the final decision-making authority, along with the Chairperson of the Authority, the three Chief Regulatory Officers who should head the three different Risk Assessment Units. Decision-making has to be from a broad-based body which studies aspects beyond technical biosafety too and should have an inter-ministerial composition for the obvious reason that GMOs in our food and farming systems have implications beyond biosafety.
13. **The following structure for the National Biosafety Protection Authority is demanded** – that all contained use applications be routinely processed by the 3-member Authority (Chairperson PLUS two members), based on risk assessment and independent testing wherever required by the concerned Division. The Enforcement Unit with its Monitoring Officers also has a role during this phase.

However, for all deliberate environmental releases, especially pertaining to Division 1 (Agriculture, Fisheries, Animals and Forestry), such approvals may come only from the Inter-Ministerial Product Rulings Committee, based on recommendations by the concerned Division on proof of biosafety, after both science-based evaluation of the applicant's data as well as **mandatory independent testing** and through public participation mechanisms in addition to consideration of other parameters that are to be evaluated (beyond biosafety).



14. The proposed legislation has no clauses on public participation. The Cartagena Protocol on Biosafety's (under the Convention on Biological Diversity) 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. **Any statute on this matter should have systemic mechanisms built for public participation in decision-making** including having representatives from credible and committed farmers' and consumers' groups in the decision-making bodies, apart from larger public consultations.
15. Chapter XIII on **Offences & Penalties**: It is not clear who Section 61 related to False or Misleading Information will be applicable to! Any person producing any document that is known to be false or misleading, it says. If this is not specifically meant for applicants to the National Biosafety Protection Authority, then this is to be construed as harassment of the public! Similarly, **Section (63) is completely objectionable and is meant to harass civil society groups concerned about the application of this hazardous technology**. This clause says: Whoever, without any evidence or scientific record misleads the public about safety of GMOs and products thereof shall be punished with imprisonment and fine!
16. In fact, **the liability clauses in this proposed legislation are very weak**. To begin with, there need not be any distinction made between companies, universities, society, trust, government departments etc. The penal clauses should apply uniformly. Two, the **legislation should have express clauses on Redressal or Compensation and Remediation or Cleaning up**. The legislation should also have a clause that makes the crop developer solely liable for any leakage, contamination and so on throughout every stage of the product development cycle. Further, the penalty of one year imprisonment and two lakh rupees fine is no deterrent and this should be made more rigorous.
17. Chapter VI pertains to provisions related to **Import of Organisms and Products** thereof. Here, apart from authorization to detain imported packages suspected to contain organisms and products thereof, there **should be an express provision for Importer's Declaration & Certification at the time of import that the**

consignment does not contain any GMOs or products thereof, for every consignment coming into India.

18. Provisions related to **Biotech Regulatory Appellate Tribunal**: As pointed out in response to the 2008 draft NBRA Bill, to appeal within 30 days after a decision is made by the Authority may not be possible for everyone and there is absolutely no reason why this provision should be incorporated into Section 42 (1). This Tribunal should be more broad based and consist of people beyond certain technical expertise. Further Section 55 (1) on Jurisdiction, Powers and Authority of the Appellate Tribunal where the Tribunal is expected to have jurisdiction over all civil cases where a substantial question related to modern biotechnology is involved is not fair for the ongoing PILs on the issue. The Appellate Tribunal should pick up cases which come in appeal to it only. Further, Section 55 (3) with its time bar of two years from the date of the cause of action for an appeal on a substantial question is not to be allowed. There should be no time bar, for the simple reason that some unpredictable effects might start showing up any time beyond two years too.
19. Section 56's clauses related to the Tribunal not being guided by Code of Civil Procedure 1908 but by principles of natural justice, not bound by the rules of evidence contained in the Indian Evidence Act 1872 and its proceedings deemed to be judicial proceedings under particular sections of Indian Penal Code and some Chapter of Criminal Procedure Code have **to be studied further by legal experts**.
20. The amendments being proposed to the Food Safety & Standards Authority (FSSA) Act 2006, so that no provisions of this Act may apply to FSSA needs to be revisited, especially given that the labeling regime comes under the FSSA and a narrow definition of GM food under FSSA will leave out many GM foods from a labeling regime.
21. Under Chapter X on **Notification of Laboratories**, it is not at all acceptable that non-accredited labs may also be notified "having regard to the emerging nature of modern biotechnology and facilities and equipment in labs". If it is such an emerging technology, one just has to wait!
22. Welcome clauses in this proposed Bill: Restriction on employment after cessation of office for different posts for at least two years from the Authority and its Tribunal etc., are welcome moves.