

Gene Campaign's Recommendations On The Draft National Biotechnology Regulatory Bill, 2008

Gene Campaign recommends that India needs to have a distinct law in place to oversee genetic manipulation and its implementation, which must harmonise with other laws and national and international agreements. The draft National Biotechnology Regulatory Bill, 2008 needs to achieve harmonization with international agreements such as the Biosafety Protocol, to which India has ratified. To do so, specific provisions need to be incorporated which deal with public awareness and participation, socio- economic concerns, liability and redress, inclusion of the precautionary principle etc. (dealt with in detail later).

1. A Standing Committee with functional autonomy must be set up to advise on the social and economic implications of implementing GM technology.
2. The Bill must provide for the setting up of a statutory National Bioethics Commission.
3. It must provide for a consultative and participatory process to prioritise crops and traits for genetic improvement through biotechnology with the goal of addressing the needs of small farmers and Indian agriculture.
4. The NBRA must take a strong position on research and commercialization of GM crops for which India is a Centre of Origin (eg. rice). Commercial cultivation of GM rice should not be allowed until the nature of gene flow and its impact is understood. Mexico, the country that is the centre of origin and diversity for corn has a clear- cut policy. It has imposed a ban on not just the cultivation of GM corn, but also research in GM corn. Similarly, China has a ban on the cultivation of GM soybean, for which it is a centre of origin, while Peru, which is a centre of origin for potato, has imposed a ban on GM potato.
5. Like the Protection of Plant Varieties and Farmers' Rights Act, 2001 has taken a clear-cut position prohibiting terminator technology; the NBRA must take a clear position forbidding the use of the Herbicide Tolerance trait. The Agbiotech TaskForce, chaired by Dr. M.S. Swaminathan, in its Report has stated that no technology that will displace labour should be given preference in this country. The Herbicide Tolerance trait will not only displace women as wage labourers but will also destroy sources of food, fodder and medicinal plants.
6. The law should contain provisions whereby alternatives to the GM approach could be carefully evaluated in each case before deciding on the GM route.
7. There should be provision for a mandatory cost-risk-benefit analysis conducted in public, before giving approval for a GM product.

8. The Bill should put in place protocol for vastly improved food safety tests and mechanisms for long term monitoring of human health (post GM food release).It should also have a stringent protocol to assess environmental and ecological impact.

9. The law must have sections providing for post- market surveillance and monitoring of GM products.

10. It should have a provision to deal with bio- terrorism.

11. The Bill must contain a provision requiring an annual review of all decisions on GM products to be presented to Parliament.

12. There should be a moratorium on commercial cultivation of GM crops until the regulatory system is demonstrably improved. Research on GM crops, however, should continue.

13. The draft bill should incorporate a provision, whereby producing edible vaccines and other pharmaceutical and industrial molecules is not permitted in food crops.

14. The Bill has tried to facilitate “a more uniform and consistent” approach under a single biotechnology regulatory authority, which is the National Biotechnology Regulatory Authority (NBRA). While doing so, the Bill should incorporate provisions ensuring that the Authority functions in a democratic and transparent manner and that it is answerable to the Inter- Ministerial Advisory Board and the National Biotechnology Advisory Council (NBAC). In order to achieve this, section 6 (3) should be amended with the effect that the Inter- Ministerial Advisory Board and the NBAC have the authority to intervene on product- specific decisions made by the NBRA.

15. Composition and qualifications of members of NBRA need to precisely defined:

The NBRA is the sole regulating agency on biotechnology in India; it is the body to which the data from field trials and large- scale evaluation trials are presented. The data have to be evaluated for safety and a decision taken on whether to approve or disallow a GM crop for commercial cultivation. It, therefore, stands to reason that the NBRA should be a technically competent body, strong on Risk Assessment and Risk Management of GM crops as also on Monitoring.

However, the draft Bill does not describe the composition, qualification and expertise required of its members. It is also silent about the qualifications required for the Chairperson of the Authority.

Gene Campaign recommends that people skilled in Bio safety Assessment, Environmental Assessment and Environmental Impact Assessment, should staff this Authority. A person of the highest technical competence and integrity who has experience in the regulation of GM crops should head the body.

The National Biotechnology Regulatory Authority (NBRA) should have overall responsibility for all aspects of risk assessment, risk management, risk communication leading up to decision-making about the safety of a GM crop for the environment, human and animal health and post release monitoring. It is important to ensure that there is no conflict of interest in the NBRA like there is in the present GEAC, where ICAR is a member and ICAR is also a potential applicant for several crops on which it is doing research. The rules for the NBRA should be framed in a clear and unambiguous manner so that it is not possible to stack the Agency with any particular kind of people.

16. National Biotechnology Advisory Council (NBAC) needs to have broad- based multidisciplinary membership-

Section 6(2) specifies that the National Biotechnology Advisory Council (NBAC) shall be established to provide the Authority with independent, strategic advice from various stakeholders on developments in modern biotechnology and their implications for human society. Gene Campaign recommends that the term ‘stakeholder’ used here should be interpreted as broadly as possible to include a broad based multidisciplinary membership.

As recommended by the UNEP, the following scientific disciplines should be represented in the Advisory Body:

Nucleic acid technology	Plant biology/botany
Molecular genetics	Veterinary science
Population genetics	Agronomy
Marine biology	Forestry
Ecology	Pathology
Taxonomy	Epidemiology
Microbiology	Process technology
Virology	Biochemistry
Zoology	Toxicology
and Entomology	

Apart from this scientific expertise, NBAC members must include social scientists, environmentalists, civil society groups, women farmers and members of farmers organisations, *adivasi* communities, representatives of *panchayati raj* institutions, specially from states where transgenic crops are tested and cultivated, and a legal expert.

17. Provisions for public participation and consultation-

The draft legislation totally excludes NGOs from any consultations and aspects of decision making or implementation of biotechnology. The bill has two clauses which provide an interface with the public. Neither is in the nature of public participation but merely informing the public about field and clinical trials, regulatory decisions (section 9(3)(g)) and about the mandate and programs of the Authority (section 9(3)(h)). There is no provision for ensuring that the public is provided with all information supplied by the applicant to the national competent authority, including the risk assessment report. There is also no provision for public consultation. Excluding provisions for public participation is in violation of India’s commitment in the Cartagena Protocol on Biosafety. Article 23 of the Protocol requires public consultation and participation in decision- making.

18. Precautionary Principle in Risk Assessment-

The draft Bill follows a standard western view on risk assessment, making liberal use of the 'science- based' approach promoted by the GM lobby and the U.S. Despite their being mentioned in the Convention on Biological diversity and the Biosafety Protocol, nowhere does the draft Bill acknowledge the special developing country concerns like the Precautionary Principle, especially relating to the centers of origin for crop plants, socio-economic concerns relating to small farmers and consumers and the right of the public to participate in decision- making.

The Bill should clearly state that risk assessment would be based on the precautionary principle, that is, the absence of scientific evidence or certainty does not preclude the decision makers from denying approval of the introduction of the GEO or product thereof if this may cause, or have a proven or theoretical potential (or based on reasonable scientific theory of hazards based on deductive, circumstantial as well as inductive evidence) to cause, harm to biological diversity, ecosystems, or human or animal health.

'Risk assessment' should be defined to mean the evaluation of the direct and indirect risks to human and animal health, the environment, biological diversity and to the socio-economic impacts, which may be posed by the import, contained use, deliberate release or placing on the market of GEOs or products thereof. This includes the evaluation of secondary and long-term effects.

The steps in risk assessment identify characteristics, which may cause adverse effects, evaluate their potential consequence, assess the likelihood of occurrence and estimate the risk posed by each identified characteristic of the GMO.

The *UNEP International Technical guidelines for safety in Biotechnology* outline the following steps for identifying potential impacts and assessment of risks:

- Identify potential adverse effects on human health and/or the environment
- Estimate the likelihood of these adverse effects being realized
- Evaluate the consequences should the risks materialize
- Consider appropriate risk management strategies
- Estimate the overall potential impacts that may be beneficial to human health or the environment.

These steps should figure prominently in the NBRA Bill.

The NBRA should have clear cut guidelines requiring specific information to be submitted by an applicant. This is very important as the key to the efficacy of any risk assessment process is the nature of questions asked.

Also as stated earlier, the Bill should have a requirement for mandatory cost- risk- benefit analysis, to be conducted before granting approval.

19. Inclusion of Socio- Economic Considerations -

The NBRA must include issues related to the socio- economic impact of GM crops on traditional farming, farmers' incomes and welfare, cultural practices, community well being, traditional crops and varieties, rural employment, indigenous peoples, food security, trade etc. This is required by Article 26 of the Biosafety Protocol.

This could be achieved by amending section 11(5)(b) of the Bill to the effect that a proposed undertaking would be refused if it poses an unacceptable risk to human health, animal health, environment as well as socio- economic considerations.

Moreover, under section 2, socio- economic considerations should be defined to include "the direct or indirect effects to the economy, trade, social or cultural practices, livelihoods, indigenous knowledge systems, or indigenous technologies as a result of the import, release, contained use or placing on the market of GEOs or products thereof."

20. Provision on Liability and Redress-

The NBRA must include a stringent provision for liability and redress. The Swiss Gene Technology Law has a legal framework which provides for strict conditions for the release of GMOs and a strong liability regime. Austria's Law of Genetic Engineering, Finland's Gene Technology Act, 1995, the German Genetic Engineering Act, the Gene Technology Act, 1993 of Norway are other examples of legislation which have provided for a domestic liability and redress regime.

21. Recommendations taken from Best Practices in Regulatory Systems of Australia, Indonesia and China

(i) Risk Assessment

- The risk assessment process should address the concerns of biosafety, food safety, human health and socio-economic risks.
- These concerns should be backed by adequate institutional structure (as has been achieved by the Australian and Indonesian regulation).
- There should be Joint Ministry Conference system to ensure coordination among different departments, as in the Chinese regulation.
- The Bill should have a provision requiring elaborate questionnaires to be answered by an applicant. The questions should relate mostly to scientific information (as seen in the Chinese and Indonesian regulations).

(ii) Risk Management

- The Bill should contain specific provisions for post release monitoring as well as labeling.
- The agency which has got approval to carry out activities involving GMOs should be obliged to submit periodical reports every 6 months or wherever there is an event of 'biosafety harm'.

- An applicant should be required to submit detailed descriptions of procedure to monitor survival of the GMO, likely adverse effects on their characteristics.
- Agency getting the approval for the GMO should have the obligation of labeling so as to reveal that the commodity contains GMO.
- The Bill should include a provision for appointing monitoring inspectors having adequate powers of inspection to carry out monitoring activities (as in the Australian regulation).

(iii) Decision Making Process

- The Australian and Chinese regulations require members of the different advisory/consultative committees to be skilled and experienced in their respective fields.
- There is a unique requirement in the Australian law that each committee contains at least one member from each of the other committees. This ensures coordination while considering different aspects of a problem. A similar approach is seen in the Chinese regulation in creating Joint Ministerial Committee.
- The Australian regulation has a mandatory provision for publication of notice about intentional release of GEOs involving risk. Assessment and risk management plans are available for public comments. The decision-making authority, i.e the Regulator also has the function of providing information and advice public about the regulation. The Regulator in deciding upon an application may also conduct public hearings.
- The NBRA must incorporate such provisions for ensuring better public awareness and participation.