

## INDIAN GOVERNMENT'S RESPONSE TO THE RECOMMENDATION OF THE SYMPOSIUM AND GENE CAMPAIGN'S REJOINER

The recommendations of the National Symposium *inter alia*, were sent to the Department of Biotechnology (DBT), Government of India, for consideration. The DBT, which is the key body promoting biotechnology in India, sent its comments on each recommendation, rebutting each of them. The following chart gives the recommendations from the symposium, the subsequent response from DBT and Gene Campaign's rejoinder.

	<b>Recommendations from the GM Symposium</b>	<b>Response from Government of India (DBT)</b>	<b>Gene Campaign's Rejoinder</b>
1	A distinct law should be enacted to oversee Genetic Modification Technology and its implementation. This law must harmonise with other laws and national and international agreements.	The country already has a law in place viz., Environment (Protection) Act, 1986, and Rules, 1989 wherein various guidelines are inbuilt to oversee the GM technology i.e., recombinant DNA technology and guidelines for transgenic plants. These guidelines are statutory and well harmonized with other prevailing laws like Drugs & Cosmetics Act 1940 and Rules 1942, Seed Act, Plant Variety Protection Bill, Convention on Biological Diversity, Cartagena Protocol, Patent Cooperation Treaty, and Budapest Treaty etc. etc.	<ul style="list-style-type: none"> <li>• There is no trigger in the EPA to account for GMOs. That is why legal experts want a separate law.</li> <li>• There is neither an <i>ex-ante</i> nor a <i>post-ante</i> environmental risk assessment written for the benefit of the public.</li> <li>• There was no opportunity for public comment while promulgating the Rules of 1989.</li> <li>• It is not true that the EPA along with the 1989 Rules and the Guidelines are harmonized with existing international instruments dealing with GMOs, all of which have been adopted after the promulgation of the Rules of 1989. The fact that the Rules are deficient in incorporating principles and provisions enshrined in various international instruments dealing with GMOs, is one of the grounds raised in the Public Interest Litigation filed before the</li> </ul>

			<p>Supreme Court of India, challenging <i>inter alia</i>, the constitutional validity of the Rules.</p> <p>(For information on the PIL please write to <a href="mailto:genecamp@vsnl.com">genecamp@vsnl.com</a>)</p>
2	A comprehensive biotechnology policy should be developed in consultation with all stakeholders.	The biotechnology is still in nascent stage and it is <b>not felt necessary that a separate National biotech policy should be developed</b> . The National Science and Technology Policy-2003, is already in place which covers biotechnology too and it is felt that in the Science Policy the biotechnology fits well as it is a multi-disciplinary science cutting across all scientific fields.	<ul style="list-style-type: none"> <li>• It is ridiculous to suggest there is no need for a separate biotech policy when biotechnology is being promoted as the next revolution for economic growth.</li> <li>• If biotech policy is subsumed under national S&amp;T policy, then where is the need for a separate DBT and a budget?</li> <li>• Moreover, almost everyone in the country who has an interest in biotechnology says we need a public policy on biotechnology and that includes the industry.</li> </ul>
3	A statutory National Bioethics Commission must be set up.	A National Bioethics Committee is already functional in the country involving all concerned Ministries/ Departments. Setting up of a <b>Statutory National Bioethics Commission is not felt necessary</b> .	<ul style="list-style-type: none"> <li>• If a National Bioethics Committee exists, then why are they not communicating with the public? Where are the national debates and the public fora to debate ethical issues? What is their policy?</li> </ul>
4	There should be a consultative and participatory process to prioritise crops and traits for genetic improvement through biotechnology with the goal	For genetic improvement through biotechnology of the crops, the Ministry of Agriculture has already set up a task Force to look into the issues. This task Force has a large consultative and	<ul style="list-style-type: none"> <li>• Very few people are consulted by the task force, so it cannot be said to be broad based. All these efforts are there but done only as an eyewash and not with any serious intent to garner real broad based public opinions.</li> </ul>

	of addressing the needs of small farmers and Indian agriculture.	participatory group involving government departments, seed industry, NGOs etc. and it is noteworthy that Gene Campaign has also been participating in various deliberations of the Task Force.	<ul style="list-style-type: none"> <li>• The Government has refused to respond to the concerns raised by the stakeholders. For instance, Gene Campaign has been demanding that without an understanding of gene flow in rice, no GM rice should be released, as India is a major centre of origin and diversity of rice.</li> </ul>
5	Investment in public sector research should be increased and strengthened. Novel gene discovery in crops of relevance to India should get highest priority.	The investment in public sector research has almost doubled in last three years. The public sector research institutions in agriculture have already set their priorities for the novel gene discovery in crops in the coming scenario of product patent as well as patenting of microorganisms and parts thereof. The issue has been well addressed in advance with the wisdom of agricultural scientists in the country.	<ul style="list-style-type: none"> <li>• Investment in research has not doubled in real terms. As far as “priorities for novel gene discovery” is concerned, 42% of all GM research in India are using Monsanto’s Bt gene. Most of the research in India is copy cat.</li> </ul>
6	India must develop a policy for transgenic varieties of crops for which it is a Centre of Origin and Diversity. Commercial cultivation of GM rice should not be allowed until the nature of gene flow and its impact is understood.	The issue of <b>“Policy for transgenic varieties of crops” especially the rice has already been taken care in the agri-biotech research</b> . The elite class of rice varieties like Basmati and Pusa are used only for standardization of transformation techniques and not for commercial preparation of transgenic varieties. The Indian scientists and the Government is well aware on the importance of the Indian rice germplasm protection.	<ul style="list-style-type: none"> <li>• How can issues pertaining to GM rice (for which India is a centre of origin/diversity) be said to be taken care of when no studies have been done on gene flow in wild relative of rice? The concept of gene pool contamination does not even exist in rice research being carried out today.</li> <li>• It is laughable that almost ten years have been wasted on standardizing rice transformation using Basmati when burning problems in other crop varieties are not being tackled with any urgency.</li> </ul>

7	<p>The Herbicide Tolerance trait should be subject to rigorous cost and risk benefit analysis before being considered for adoption.</p>	<p>The cost and risk benefit analysis for the crops having herbicide tolerance traits is looked into with rigor by various organizations/companies involved in such R&amp;D work or contained field trials of such crops. If such crops are not economically beneficial no farmer will buy such seeds. There is no question of adoption of such crops having herbicide tolerance traits until and unless competent authorities evaluate their safety as well as agronomic advantages.</p>	<ul style="list-style-type: none"> <li>• So far there has been no evaluation of the socio-economic impact. The Rules of 1989 do not provide for it either. In fact, developing a model for regulating the socio-economic impact of GM technology is a major challenge confronting developing countries.</li> <li>• Introduction of herbicide tolerant crops will displace wage labour (especially women) that obtains daily wages by weeding. It would also deprive rural households of free nutritious food, nutritious greens, fodder and medicinal plants.</li> <li>• There is at present virtually no methodology of risk-benefit analysis for GM crops in India. Private companies do the analysis mainly for justifying their own products. In fact, most companies have not done this analysis so far.</li> </ul>
8	<p>Alternatives to the GM approach must be carefully evaluated in each case before deciding on the GM route. A cost and risk benefit analysis must be conducted before deciding on a GM product.</p>	<p><b>The alternatives to GM approach is already in place through “organic farming”.</b> As stated earlier, the cost and risk benefit analysis is the basic fundamental of seed business and there should not be any apprehension with such GM crops. Further, the choice of GM and non-GM crop cultivation is at the will of the farmer and it is never imposed on them. Every effort is taken to make the farmer aware of the GM technology.</p>	<ul style="list-style-type: none"> <li>• ‘Alternative’ means finding another, non-GM approach to solve the problem, for instance the introduction of salt tolerant genes by conventional breeding. This has worked already. It is ridiculous to consider organic farming as an alternative to GM farming.</li> </ul>

9	Protocol for food safety tests must be vastly improved and mechanisms for long term monitoring of human health (post GM food release) be put in place.	In India no GM food crop has been released so far. However, protocols for food safety tests and various protocols for monitoring of human health for the post-release of GM food are being worked out by various public laboratories. Over and above this, there are a number of private GM testing laboratories who have built up their strength and are ready for future use.	<ul style="list-style-type: none"> <li>• There has been no public consultation in the process of developing the protocol for food safety.</li> <li>• Nobody knows what is being tested and how.</li> <li>• Are the private labs accredited? Who is going to believe what these private labs provide, when the company in question pays for tests?</li> </ul>
10	Develop a stringent protocol to assess environmental and ecological impact.	The protocols to assess environmental and ecological impact for risk assessment and risk management are already inbuilt in the EPA and they are not less stringent than anywhere in the world.	<ul style="list-style-type: none"> <li>• This is simply not true. If risk assessment and risk management is being done, then why are the protocol and the data being concealed from the public?</li> </ul>
11	There should be provisions for post-market surveillance and monitoring of GM products.	The post-marketing surveillance and monitoring of GM crops is vested with the Ministry of Agriculture and they have already constituted the mechanism for the Purpose. For r-DNA pharmaceuticals, the post marketing surveillance is always mandatory.	<ul style="list-style-type: none"> <li>• No public consultation has taken place in developing a mechanism for post-marketing surveillance and monitoring. No one knows what is being done or not being done.</li> <li>• If at all it has been developed, it has not been made public as yet. Nor has any activity report in this regard been published.</li> <li>• According to the Rules of 1989, State Biotechnology Coordination Committees and District Level Committees have been entrusted with the responsibilities of surveillance and monitoring</li> </ul>

			of GM crops. These agencies are placed under GEAC, which in turn functions under the Ministry of Environment and Forest. Hence, there seems to be a jurisdictional conflict between Ministry of Agriculture and MoEF. So far, no SBCCs or DLCs have become functional.
12	Have a policy to deal with bio terrorism urgently.	The <b>policy to deal with bio-terrorism is not a grave issue at present in our country.</b> Since biotechnology being a “dual-use” technology is always monitored through the existing mechanism of IBSC, and GEAC, we should not be apprehensive on the issue.	<ul style="list-style-type: none"> <li>• It is dangerous to claim that there is no threat from “Bio-terrorism” in India and that we should not be apprehensive of it. Recent hauls from Jammu &amp; Kashmir have indicated that the terrorists are now using less common means like chemicals for warfare.</li> </ul>
13	India must exercise caution in the IPR regime that it adopts. The current PPV-FR should be retained since it balances Breeders and Farmers’ Rights.	The issue of “Breeders’ and Farmer’ Rights” is well addressed in the existing laws especially the PVP&FR and other IPR regulations. The third patent amendment act should also take care of the patenting issues adequately falling in line with the TRIPS agreement of WTO.	<ul style="list-style-type: none"> <li>• The existing provisions of Farmer’s Rights under the PPV-FR Act, 2001 are under threat following the Government’s decision to join UPOV. Gene Campaign has already filed a PIL against this decision in the Delhi High Court. The matter is <i>sub judice</i>. (For more information write to <a href="mailto:genecamp@vsnl.com">genecamp@vsnl.com</a>)</li> <li>• Concerns have also been raised on the draft Patent (Third Amendment) Bill, which tends to dilute pre-grant opposition of patents. Definition of “Micro-organism” should also be kept very narrow in scope. Public consultation <u>must</u> take place before finalising the Bill.</li> </ul>
14	A new statutory, independent National Biotechnology Regulatory Authority must be	At this juncture the regulatory authorities for the GM products involve concerned administrative ministries	<ul style="list-style-type: none"> <li>• The present regulatory system, with GEAC as the key agency, is far from satisfactory. It lacks the</li> </ul>

	established.	under the aegis of GEAC. Since GM biotech products like Drugs & Pharmaceuticals, food & Farm products, processed food, industrial products, microorganisms, agricultural products etc. involve various administrative ministries, <b>the present functioning of the regulatory system has been well accepted.</b> A New Independent National Biotechnology Regulatory Authority would not be solution to various issues <u>faced by the industry.</u>	<p>technical competence and skills, transparency, independence and accountability.</p> <ul style="list-style-type: none"> <li>• It was "well accepted" by the <i>babus</i> and some pliant scientists. A new independent authority will deprive them of the blanket discretionary powers they exercise today.</li> <li>• Neither civil society nor the industry is satisfied with the present GM regulatory regime.</li> </ul>
15	Make GEAC more competent, transparent and accountable. Post data on research and development of GM crops and products on websites and local newspapers.	<b>GEAC is comprised of all stakeholders</b> pertaining to various administrative ministries <b>and is thus competent.</b> As far as <b>transparency is concerned, the GEAC always releases a press note after every meeting.</b> As far as <b>posting of data on R&amp;D</b> on GM crops and products on website is concerned, <b>is not a practical suggestion</b> as it is liable to IPR infringement of various organizations submitting the data to GEAC.	<ul style="list-style-type: none"> <li>• The GEAC is <i>not</i> comprised of <i>all</i> the stakeholders. It has no representation from civil society organisations or farmer organisations. The majority of its members are civil servants in their <i>ex officio</i> capacity, who lack the technical competence to grant approval to a GM crop. There are no soil scientists (to assess damage to soil microbes), no entomologists, agronomists, toxicologists and no allergy experts (to assess the possible dangers of novel proteins in GM products behaving as allergens or being toxic), no social scientists nor again any legal experts.</li> <li>• There is no transparency in decision-making. The mere release of press notes does not show transparency in the system.</li> <li>• Publishing R&amp;D data is practical, provided it does not include confidential business information (CBI). There is no IPR infringement in doing so. Other</li> </ul>

			countries make information available to the public. Nobody is asking for CBI. It would seem that the DBT is not able to differentiate between IPR and CBI.
16	An annual review of all decisions on GM products must be presented to Parliament.	<b>Submission of GEAC decisions to Parliament is not a practical exercise</b> as GEAC is a statutory body working under EPA, which is legislated through the Act of Parliament.	<ul style="list-style-type: none"> <li>• It is alarming to note that Parliament will not be involved.</li> <li>• A review of decisions of a statutory body can certainly be discussed in Parliament. When it comes to public interest, the Parliament has the mandate to discuss such matters. Given the controversial nature of GM technology and the fact that Bt cotton performance has been discussed in Parliament, DBT's contention is wrong.</li> </ul>
17	Conduct a scientifically sound study to assess attitudes and perceptions about GM technology among stakeholders in India.	The <b>perceptions and attitude</b> about GM technology of various stakeholders is more or less <b>based on the individual perceptions, rationality of mind and influence of the specific school of thought whether pro or anti-GM.</b> The study proposed by the Gene Campaign is more or less pertains to the social science and not to biotechnology. It would be prudent that Gene Campaign takes up scientific studies on their own and provide their inputs to various forums.	<ul style="list-style-type: none"> <li>• Institutions like DBT and GEAC are also comprised of individuals whose perceptions can be influenced like those of any other individual.</li> <li>• All over the world governments are involving more and more people (from all walks of life) in decision-making and policy-making processes.</li> <li>• It is pertinent to state here that Gene Campaign is neither for nor against the GM technology. It merely demands that the application of GM technology in agriculture sector be "effectively" regulated and monitored.</li> <li>• Gene Campaign would be glad to coordinate any scientific and/or socio-economic study on GM crops, involving all stakeholders including DBT. At least two things are required for this - money and</li> </ul>

			cooperation from relevant government agencies.
18	Undertake a program of awareness about GM technology to educate the public.	To educate the public, various stakeholders, research organizations, scientists involved in GM research etc. the awareness is generated through various symposia/seminars/workshops organized by the Department of Biotechnology and the Ministry of Environment & Forests regulatory throughout the country. This has generated a lot of intellectual awareness about the benefits and risks associated with the GM technology.	<ul style="list-style-type: none"> <li>• When did GEAC organize a public meeting on GMOs? The meetings referred to were those where DBT dictated its own terms and no member of the ordinary public was present.</li> </ul>
19	Organize a series of public debates across the country to elicit the views of the people, to channel it into policy making. The government should fund this exercise.	The policy making on the GM products is always channelised through public debates across the country involving CII, FICCI, ASSOCHAM, Indian seed industry, All India Biotech Association, NGOs etc. this is a continuing exercise for awareness building and updating the issues concerning GM products.	<ul style="list-style-type: none"> <li>• On the one hand, DBT says that there is no need for a separate ‘policy’ on GM, while on the other hand it again says that ‘policy’ making on the GM products is always channelised thorough public debates. Which ‘policy’ is it talking about? Or is it referring to ‘decision’ making? If so, has DBT taken into account the recommendations from stakeholders while taking final ‘decisions’?</li> </ul>
20	There should be a moratorium on <i>commercial cultivation</i> of GM crops until the regulatory system is demonstrably improved. Research on GM crops, however, should	The basic fact and fundamental to carry out R&D work in scientific fields in general is to generate a product or process for commercial use and for societal benefits. Continuation research on GM crops would be infructuous if	<ul style="list-style-type: none"> <li>• The recommendations do not seek a ‘ban’, they only seek a ‘moratorium’ until an effective regulatory regime is put in place. Till such time research on GM crops should continue. It is presumed that an ‘effective’ regulatory system would be in place before positive results are</li> </ul>

	continue.	there is moratorium on commercial cultivation of GM crops. There is no need for a moratorium on commercial cultivation of GM crops as research in this field aims at benefit to the farmers at large with benefit to the society. The regulatory procedures as they exist today) with continuous exercise of modification), are good enough to meet the biosafety requirements.	<p>obtained from GM research. So the argument that ‘moratorium’ would be infructuous to the continuation of research is not logical.</p> <ul style="list-style-type: none"> <li>• The point is that any release of GM crops <u>must</u> be properly regulated and monitored, for which the requisite systems have to be in place.</li> <li>• It is reiterated that the present system is inadequate to meet biosafety requirements or to tackle the socio-economic problems that may arise from GM technology and its application.</li> </ul>
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