

THE NATIONAL BIOTECHNOLOGY DEVELOPMENT STRATEGY : PRESENT VERSION UNACCEPTABLE

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A draft biotechnology policy has been framed after just two meetings of the Expert Committee constituted for the purpose; one was the inaugural meeting, followed by one other meeting. There was one other sub committee meeting in addition. No minutes of any of the meetings were circulated to the Expert Committee and suddenly the draft “National Biotechnology Development Strategy” appeared on the DBT website with a 6 week period for comments. There were protests at the inadequate amount of time granted for public comments and that the website of the DBT would be the only place to post such comments. The DBT relented by organizing two hearings for selected members from civil society, one at Chennai and the other at Delhi. The outcome of these hearings is unknown, as is the status of the policy document. It is to be found in the original draft form on the DBT website.

A suitable time frame for comments and public consultation would be a year, during which a genuine effort could be made to tell people in this country what biotechnology is, what it offers, its upside and its downside, how people can participate, where they can get information and so forth. There should be no inordinate rush to frame the policy given that the DBT and ICAR (Indian Council of Agricultural Research) have been running their biotechnology program for the last several years. Now when a policy is finally being framed, it must be done with maximum consultation and in a transparent manner.

The National Biotechnology Development Strategy is framed with a clear emphasis on what the industry wants, both with respect to agriculture and pharmaceuticals. The Policy Recommendations lists human resource development for academic and industry needs as the number one priority. The industry focus continues all through the report with other priorities being flagged as ‘creating science and technology leaders for the industry’ and creating enabling conditions for scientists to undertake industry oriented research. There is little in the report that would indicate that the policy document is being developed to fulfill public needs, specially in the critical area of food and agriculture, nor has the public been asked what its needs are; there is alarmingly little evidence of caution in charting the way ahead specially given the fact that this technology is relatively new in India and there is insufficient understanding of how carefully it needs to be implemented. In a situation where violations are rampant, even by premier research institutions, the draft policy instead of trying to improve the regulatory system, removes almost all regulatory control, leaving the floor to the industry to put out products in the market with as little testing as possible.

The other striking feature of the draft report is the total exclusion of NGOs from any aspect of decision making or implementation of biotechnology. A single reference exists to the farming community (included in an inter-ministerial group) but NGOs are not involved in any way. Shutting the door on the public is not surprising given the track record of the Department of Biotechnology and the cloak of secrecy under which all matters relating to biotechnology, especially agricultural biotechnology are being handled in the country today. Apart from the fact that excluding the public from decision making constitutes undemocratic governance, it is also a violation of the Cartagena protocol on Biosafety. The Biosafety Protocol, to which India is a signatory, requires that the public be consulted in decision making in matters related to GMOs (genetically modified organisms). On the practical front, excluding NGOs deprives the government of a valuable and critical source of information and analysis, since civil society usually has better and quicker access to information and developments in the field of Agbiotech than government departments in India.

The most problematic parts of the National Biotechnology Development Strategy relate, to the most contentious areas of biotechnology, agricultural biotechnology, regulatory mechanisms and public participation. Here was an opportunity to demonstrate confidence and inclusivity by bringing in a fresh view on an old controversy and open the doors to consultations, but the report does not even make a hint of an effort in this direction. It has elected instead to tow a clearly a pro-industry line on Agbiotechnology and regulation and a typical government line on excluding stakeholders from any decision making.

Along with the distinct industry bias, the draft policy contains some positive elements but these either do not go far enough or are presented in diluted versions. There is a reservation against producing edible vaccines or vaccines in fruits like tomatoes and melons but rather than proscribe this approach, the report takes a mild view saying it should not be encouraged. After the contamination of corn engineered to produce pig vaccine was detected in food corn in the US, there have been strong views against pharmaceutical molecules being produced in edible plants. In India, the mix up of vaccine fruit with fruit meant for food is not just likely, it is a certainty. Many have suggested that keeping in mind public safety, this line of research should be abandoned.

It is welcomed that the report has included a mechanism to monitor the performance of GM crops in international markets and assess the potential of organic crops as compared to GM crops with respect to trade. The Inter-ministerial Agriculture Biotechnology Board constituted to undertake this task is at present composed largely of bureaucrats. It can be made more efficient by a greater representation of agencies and institutions that could contribute relevant information like traders and exporters as well as research organizations working on agricultural trade.

The draft report makes an assertion that the existing regulatory system is sound and adequate. It also states that “there is consensus” that existing legislation is efficient, when nothing could be further from the truth. There is certainly no consensus on the efficiency of the legislation nor the guidelines derived from it. None of the suggestions made in other places, including the Swaminathan Committee Task Force Report, for overhauling the regulatory system to make it more technically competent, transparent and accountable have been taken on board. India’s regulatory system for biotechnology has been criticized by a large number of stakeholders as being ad hoc, lacking in the technical skills required and without adequate provisions to deal with violations and unexpected situations. At a national stakeholder consultation organized by Gene Campaign in 2003, there was an almost unanimous view that the regulatory system was technically incompetent and nontransparent. The consensus was that it needed a radical overhaul to change its overbearing bureaucratic composition and the largely ex officio nature of the membership. The view on the incompetence and inadequacy of the regulatory system was shared equally by those opposed to Agbiotech as those strongly in favor of it.

In its recommendations, the biotech strategy report follows a standard western view on risk assessment, making liberal use of the ‘science-based’ approach promoted by the GM lobby and by the US. Despite their being mentioned in the Convention on Biological Diversity and the Biosafety Protocol, nowhere does the draft biotechnology strategy report 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.

India is a biodiversity rich region from where major crop plants like rice have originated. It is therefore an important center of origin, where unique genetic wealth and diversity is found. There is global concern on GM crops being grown in their centers of origin and diversity because of the threat to this unique gene pool from contamination by foreign genes. Such contamination has already been found in Mexico’s corn and the

authorities there are scrambling to find a way to contain the problem. The draft biotech report is silent on this crucial issue of particular relevance to India and ultimately to the world, since rice is the staple food of almost half of mankind. Similarly, there is no acknowledgement of other concerns being discussed on international platforms, for instance socio-economic impact of GM crops. It is recognized that there can be social and economic impacts on farmers, especially small farmers resulting from the application of GM technology in agriculture.

The section on Agbiotech policy is one that raises the most concerns. The draft makes recommendations that are irresponsible and potentially dangerous to the environment and human health. Far from adopting a precautionary approach, as advocated even by international treaties like the Biosafety Protocol, the report makes a departure from the established principles of biosafety and risk assessment that are practiced in other countries. A truly alarming recommendation is to do with the introduction of foreign genes into different kinds of crop plants. The draft strategy document recommends that “an event that has already undergone extensive biosafety tests should not be treated as a new event *even if it is in a changed background...*” This essentially means that once a gene like the Bt gene is tested for biosafety in cotton, it need not be tested when it is put into another crop like tomato or rice or cauliflower. According to this recommendation, Bt rice or Bt cauliflower (both in the pipeline in India) would not have to undergo any biosafety tests before being released to farmers for cultivation.

This kind of carte blanche to the producers of GM products, putting at risk not just farmers’ livelihoods but also the environment and the health of consumers, is unprecedented. It defies all understanding of how biological systems and genetic engineering work. Genetic transformation is a rather imprecise technology because there is no control over where the foreign gene is inserted in the host plant nor how many copies of the gene have been able to integrate into the host genome. The genetic background of the host plant plays a crucial role in both the process of genetic engineering and the actual expression of the foreign gene in the new host.

There are complex interactions between the foreign gene and the genetic background of the host plant it enters; these interactions will be different in the case of different plants and there is no way of predicting the interactions or their outcome. That is why biosafety tests must be conducted every time a new plant is genetically engineered. That is also the reason why the regulatory systems in all responsible countries require biosafety assessments to be done every time a gene is put into a new plant. This clause dispensing with safety testing reduces the biosafety process to a complete farce.

More reckless recommendations follow with respect to biosafety. The biotech policy document states that even if the foreign gene has been changed and modified and then inserted into a new host plant, there is no requirement to conduct tests for allergenicity and toxicity if there is ‘*no significant modifications in protein conformation*’. This would mean for instance that if the existing Bt gene were changed to make it a different gene and the new gene was put into say, tomato, there would be no need to conduct allergenicity and toxicity tests for the genetically engineered tomato, if the protein produced by the new gene was not “significantly” different. It could be different but not significantly so and what will be considered “significant” is anybody’s guess. This second carte blanche to the producers of GM products has the potential to seriously jeopardize human health because it does not require testing for new allergens and toxins that could be produced when a plant is engineered with the new genes. Such an approach flies in the face of known genetic principles that have shown that genes will behave in different ways and produce different proteins in different backgrounds. If even small changes are made to genes, the products (proteins) they produce can change substantially.

If the human genome project has taught us one thing, it is that the complexity and sophistication of biological reactions rests not on a large number of genes, (humans are estimated to have just 30,000 genes) *but on the subtly different ways in which genes interact with one another in changing situations to produce new proteins*. Nothing in such a context can be considered 'insignificant' because a change that is not radical can have radical outcomes. Specially with respect to allergens and toxins in crop plants, it is well understood that the creation of new allergens and toxins is a complex affair influenced by a number of micro factors. Acknowledging this, the WHO and FAO are compiling an atlas of the known allergens in food plants so that these can be monitored when genetically modified plants are created and used as food.

In the case of the allergy inducing GM Starlink corn, for instance, it was found that the allergic action was seen when the gene was tested in a particular background but not in another background. Food safety, allergenicity and toxicity in connection with alien genes in GM crops and foods is only now being investigated and understood. In this uncertain backdrop, it is insupportable that the national strategy report makes the astonishing recommendation of dispensing with testing for the presence of allergens and toxins.

The biotech policy that is being proposed by the report will be more lax and negligent than anything that exists elsewhere in the world. This is even more frightening when one thinks that this is being proposed in a country where agriculture and food are sensitive issues, where small farmers are vulnerable and where the agricultural research system and the regulatory systems have large question marks hanging over their performance. A premier agricultural research institute in Delhi was hauled up not long ago for large scale biosafety violations with a GM crop and its test plants had to be destroyed. The regulatory system has failed to check the spread of illegal varieties of Bt cotton for the last five to six years.

There is far too much interference by the DBT in all aspects of the biotechnology strategy document. This is unhealthy since there is a clear vested interest which could lead to a bias. The policy and its implementation must be entrusted to a competent autonomous body with the DBT playing a supporting role. The draft says that the DBT (not any stakeholders) is of the view that there is no reason for the regulatory bodies like the Genetic Engineering Approval Committee (GEAC) to ask for large scale field trials. This need not be the normal practice, since ICAR will take the responsibility for the trials but the GEAC or whatever the revised regulatory body is ultimately called, must not be deprived of that right. It is the GEAC that takes the ultimate decision to grant or refuse permission for the commercial release of a variety. They must continue to have the right to order a large scale trial if they are uncertain about the results.

Although there is a reference to the Agbiotech Task Force report in many places, and the Task Force report is quoted to say that "*the priorities in Agbiotech would be based on social, economic, ecological, ethical and gender equity issues*", the proposed policy has little relation to the letter or spirit suggested in the Task Force report. The proposal to do away with large scale field testing of transgenic crops, retaining only the agronomic testing is risk ridden; it paves the way for the producers of GM crops to by pass safety tests and take their crops to the field in the shortest possible time, regardless of whether the crop is safe or not.

GM crops that could have harmful social or economic impacts for farmers and consumers, those that are frivolous and those that will displace labor and impact rural livelihoods must be banned in this country. On this critical subject, the draft policy merely says that "*public funding should be avoided to research areas of low priority or those that could reduce employment and impinge the livelihood of rural families*". Why should just the public sector be restrained? Why not the private sector as well? In keeping with its pandering to the GM seed industry, the draft report finds it fit to leave the field open for the companies. They can go ahead and produce crops that reduce employment and impinge the livelihood of rural families.

Those in the government who speak for the GM industry offer the peculiar explanation that one can lay down policy for the public sector but how can one tell the private sector what to do, after all, they argue, it is their money. Not everyone subscribes to this perverse logic. A national policy applies to all sectors and its goal has to be to achieve the greatest public good, not create concessions for the private sector. In the case of the seed legislation called the Protection of Plant Variety and Farmers Rights Act, the decision was taken that the Terminator technology would not be allowed in India and the law expressly forbids the use of this technology by the private and public sector alike. The reticence in government circles to forbid the private sector to use GM technologies that will hurt rural families and ultimately the nation, needs examination at the highest level; the people responsible for such decisions need to be recognized and the factors that influence their decisions should be scrutinized.

The report is silent on several crucial issues like fixing liability for biotech products that end up causing damage. The signal to the biotechnology industry is that it is open season in India and producers of biotechnology seeds and other products can come and do things here that no other country will allow. In a report that panders so unashamedly to the industry, it is not surprising that there is no mention of bioethics nor what ethical principles will guide the practice of various scientific pursuits and implementation of research results. The National Biotechnology Development Strategy is deeply flawed if not directly dangerous. Its bias is evident and its neglect of public interest equally so. Its blatant attempt to practically dismantle biosafety and regulation in a field that is known for its violations rather than sound, ethical practices is not just reckless; it is devoid of responsibility and morality. This draft policy is in need of a comprehensive revision if it is to contribute to a safe and equitable development of this sector. Biosafety, the precautionary principle and public interest must constitute the cornerstone of a national policy and several neglected areas need to be spelt out. There must be sufficient time for an open discussion for people to understand the contents of the document and express their views on it.

Dr Sahai has been a member of the Expert Committee formed to frame the National Biotechnology Policy