Ministry of Environment and Forests

Decision on Commercialisation of Bt-Brinjal

I

1. The Genetic Engineering Approvals Committee (GEAC) was set up in May 1990 under the Environment (Protection) Act, 1986. While it is a statutory body under Rules 1989 of the Environment (Protection) Act, 1986 and as such it is authorised to grant approval for large-scale trials and environmental release of genetically modified organisms, on the issue of Bt-brinjal the GEAC in its 97th meeting held on October 14th, 2009 observed that

   > "*..as this decision of the GEAC has very important policy implication at the national level, the GEAC decided its recommendation for environmental release may be put up to the Government for taking final view on the matter".*

2. The GEAC, being located in the Ministry of Environment and Forests, sent its recommendations to me. After receiving the recommendations of the GEAC on Bt-brinjal, I communicated the following to the GEAC on October 16th, 2009.

   > *I have just received the recommendations of the Genetic Engineering Approval Committee (GEAC) on Bt-brinjal. I have studied the recommendations and have decided on the following course of action:*
   >
   > *The report of the Expert Committee (EC-II) submitted to the GEAC on October 8th, 2009 that formed the basis of the GEAC'as decision of October 14th, 2009 is being made public with immediate effect. It is being uploaded straightaway on the website of the Ministry of Environment and Forests (www.moef.gov.in). All previous reports and studies on Bt-brinjal are already in the public domain. Comments on this report are being sought by December 31, 2009 and I encourage their submission.*
   >
   > *During January and February 2010, I propose to have a series of consultations in different places with scientists, agriculture experts, farmers' organisations, consumer groups and serious-minded NGOs who want to engage in a responsible manner. All points of view will be represented in these consultations.*

Strong views have been expressed on the Bt-brinjal issue, both for and against. My objective is to arrive at a careful, considered decision in the public and national interest. This decision will be made only after the consultations process is complete and all stakeholders are satisfied that they have been heard to their satisfaction.

3. Between January 13th, 2010 and February 6th, 2010 public meetings on Bt-brinjal were organised by the Center for Environment Education (CEE), Ahmedabad (a Centre of Excellence supported by the MoE&F) in Kolkata, Bhubaneshwar, Ahmedabad, Nagpur, Chandigarh, Hyderabad and Bangalore. Kolkata and Bhubaneshwar were selected because West Bengal and Orissa account for 30% and 20% of India's brinjal production respectively. Ahmedabad and Nagpur were selected because Bt-cotton has been under extensive cultivation in Gujarat and Maharashtra over the past six years. Chandigarh was selected in order to allow farmers from the two agriculturally-advanced states of Punjab and Haryana to express their views. Hyderabad and Bangalore were selected because these are centres for biotechnology R&D. Almost 8000 people from different sections of society participated enthusiastically in these seven public meetings. Those who attended were farmers and farmer organisations, scientists, state agriculture department officials, NGOs, consumer groups, allopathic and ayurvedic doctors, students and housewives. A summary report prepared by the CEE based on these seven meetings is at Annex-I to the electronic version of this note available at www.moef.nic.in and video-recordings of each of these interactions will also be available very soon on the same website.[1]

[1] A wholly unjustified controversy was generated by two individuals at the Bangalore consultations on February 6th by their claim that a Gazette Notification of October 30th, 2009 exempting trade in 190 agricultural commodities from the ambit of Section 40 of the Biological Diversity Act, 2002 made these Bt-brinjal consultations a sham. This Notification has nothing to do whatsoever with the functioning of the GEAC and has absolutely no impact on genetic engineering issues. The Notification, in the making for five years, was done at the behest of the Ministry of Commerce and other organisations so that the export of these commodities is not adversely affected. In case the species listed are used as bio-resources, permission of the National Biodiversity Authority is still needed before exports take place.

4. Letters were sent to the chief ministers of West Bengal, Orissa, Bihar, Maharashtra, Andhra Pradesh and Karnataka since these are the major brinjal cultivating states accounting for 30%, 20%, 11%,6%, 6% and 4% respectively of India's brinjal production. Copies of these letters to the CMs and the responses I received from them are at Annex-II to the electronic version of this note available at www.moef.nic.in that also contains letters received from the state governments of Kerala, Madhya Pradesh and Chattisgarh. A letter received from the Chairman of the Committee on Agriculture of the Lok Sabha and other political leaders, including a former Prime Minister of India is also included in this Annex.

5. Opinions were also sought from a number of scientists both from India and abroad. These opinions are at Annex-III to the electronic version of this note at www.moef.nic.in.

6. In addition, a very large number of emails from research institutes, NGOs and concerned individuals were received. A representative sample is at Annex-IV to the electronic version of this note available at www.moef.nic.in.

II

7. I should like to make clear at the very outset that my concern is with Bt-brinjal alone[2] and **not** with the larger issue of genetic engineering and biotechnology in agriculture. *The issue before me is limited to what to do with the GEAC recommendation on the commercialisation of Bt-brinjal.*

8. **All** states which have written to me have expressed apprehension on Bt-brinjal and have called for extreme caution. Because this is extremely important in our federal framework and agriculture is a state subject, I summarise below the views of the state governments that have been submitted in writing to me by the Chief Ministers/Agriculture Ministers:

[2] I leave aside the basic issue of "why Bt-brinjal?" in the first place since there does not seem to be any over-riding food security, production shortage or farmer distress arguments favouring the enormous priority that has been accorded to it by private companies, other than the well-known argument on the need to reduce pesticide use.

- *Andhra Pradesh*: "It is clear that the data generated, the tests conducted and the information disseminated by GEAC are not sufficient for suggesting the commercial release of Bt-brinjal....Until safety parameters in terms of environment, human and animal health are clearly established, release of Bt-brinjal for commercial cultivation is to be deferred"

- *Kerala: "* Considering all this, Government of Kerala has taken a decision to prohibit all environmental release of GMOs and keep the state totally GM free. We would request the Honourable Prime Minister to reconsider the policy of GM in a national scale and declare a moratorium at least for the next fifty years".

- *Chattisgarh:"* Before giving permission for commercial cultivation of Bt-brinjal, all tests to establish full impacts, including negative impacts, on human and animal health and on the environment should be carried out".

- *Karnataka: "*The commercial release of Bt-brinjal should be deferred till the issue is thoroughly examined from all the angles by taking into account the views of all stakeholders and conducting a long-term research for its bio-safety and its consequent contributions to food security and farmers well-being".

- *Bihar: "*The Rajya Kisan Ayog is not in favour of the introduction of Bt-brinjal in the state at this point of time. The recommendation of the Rajya Kisan Ayog has been considered by the state government and the state government fully endorses the view of the Ayog".

- *West Bengal:"* I have got the report of the Expert Committee of the GEAC downloaded. I feel that the matter needs thorough examination by the experts in the field. I am requesting some members of the erstwhile State Agriculture Commission to examine the report and forward their views to the government to enable us to take a holistic view on the subject".

- *Orissa:* "The Government of Orissa does not support the introduction of Bt-brinjal at this stage and until sufficient trials are made and interests of small and marginal farmers of the state are safeguarded".

In addition, the CM of *Uttarakhand* has spoken to me and conveyed the decision to ban Bt-brinjal in that state. The Chief Secretary of *Tamil Nadu* has informed me that the state of Tamil Nadu is not in favour of commercialisation of Bt-brinjal now. The *Madhya Pradesh* Chief Minister has told me that Bt-brinjal should be introduced "only after all doubts and fears have been properly dispelled". The *Himachal Pradesh* Chief Minister has told me that the HP government will take a view after all trials have been completed and after the Government of India has decided.

9. Clearly, Bt-technology is not the only route for reducing pesticide use. That pesticide use can have deleterious public health impacts is already visible in places like Bhatinda which, as the Chief Minister of Punjab himself told me a couple of days back, has emerged as a major cancer-afflicted region. How to reduce pesticide use without compromising on food security at the macro-level and returns to farmers at the micro-level is an urgent public policy in our agriculture. In this connection, it is worth recalling that there are now close to 6 lakh farmers in Andhra Pradesh fully practicing NPM (non-pesticide management) agriculture over an area of about 20 lakh acres. I have myself been seeing this initiative over the past four years. The advantage of NPM is that it eliminates chemical pesticide use completely whereas Bt-technology only *reduces* the pesticide spray, albeit substantially. Incidentally, one of the eight missions under the National Action Plan on Climate Change is the National Mission on Sustainable Agriculture of which NPM is an integral part. On January 19th 2009 much before I became Minister for Environment and Forests, I had written to the Union Agriculture Minister on the need to evaluate the Andhra NPM experiment from the point of view of replicability on a larger scale.

10. The issue of safety tests has been raised repeatedly by critics of Bt-brinjal. The plant family *Solanaceae* to which brinjal belongs appears to be more problematic than others because it contains several natural toxins that can resurface when metabolism is disturbed. The kind of testing done, it is being said, is not specific or stringent enough to detect toxins. This is an important issue since brinjal is an item of almost daily consumption for most of us.

While there may be a debate on the nature and number of tests that need to be carried out for establishing human safety, it is incontrovertible that the tests have been carried out by the Bt-brinjal developers themselves and not in any independent laboratory. This does raise legitimate doubts on the reliability of the tests, doubts that I cannot ignore. The fact that brinjal is very largely a cross-pollinated crop[3] according to the generally accepted scientific consensus makes the threat of contamination with the use of Bt-brinjal on other varieties a particularly worrisome issue.

11. Very serious fears have been raised in many quarters on the possibility of Monsanto controlling our food chain if Bt-brinjal is approved[4]. Indeed it would not be an exaggeration to say that public concerns about Bt-brinjal have been influenced very heavily by perceptions of Monsanto itself. I have no bias whatsoever. Monsanto has made substantial investments in India, including in R&D. Many Indian-origin scientists work in Monsanto. As a country, we must learn to derive full benefit of Monsanto's expertise and capabilities, without jeopardising national sovereignty and also develop countervailing power to it. Unfortunately, we do not seem to have a large-scale publicly-funded biotechnology effort in agriculture. Had there been one, there would have been competition to Monsanto. It is true that Mahyco an Indian company is involved in the development of hybrid Bt-brinjal. But 26% of Mahyco is owned by Monsanto itself. It is also true that two government-owned agricultural universities—Tamil Nadu Agricultural University, Coimbatore and the University of Agricultural Sciences, Dharwad—have developed Bt-brinjal varieties. [5]. But doubts have been raised on how Bt-related research in these two institutions has been funded. Further, the Material Transfer Agreement between TNAU and Monsanto in

[3] A point made forcefully by Dr. Madhav Gadgil one of India's most distinguished eco-scientists.

[4] At the Bangalore public consultation on February 6th a former Managing Director of Monsanto (India) came out strongly against Bt-brinjal on this ground and on the grounds that profits should not drive seed supply. Eminent government scientists have confirmed to me that a vast proportion of Bt-cotton seed currently being used in India is controlled directly and indirectly by Monsanto.

[5] At the Bangalore consultations on February 6th, Dr. G.K. Veeresh, a former Vice-Chancellor of the University of Agricultural Sciences, Bangalore, a sister organisation of UAS, Dharwad expressed his strong opposition to the commercialisation of Bt-brinjal.

March 2005 has raised worrisome questions on ownership (both of products and germplasm) and what TNAU can do and cannot do.[6]

12. Apart from being the world's largest producer of brinjal, India is undoubtedly the country of origin as far as brinjal is concerned as testified by Vavilov in 1928. Data that has been made available to me by the National Bureau of Plant Genetic Resources of the ICAR reveals that there are 3951 collections in the Bureau and the number of diversity-rich districts is 134. The Bureau also points out that diversity-rich regions are likely to be affected by the introduction of Bt-brinjal due to gene flow. The loss of diversity argument cannot be glossed over especially when seen in light of the experience we have had in cotton where Bt-cotton seed has overtaken non-Bt seeds.

13. Bt-cotton is not comparable to Bt-brinjal no doubt but it is nevertheless necessary to review our experience with it. Undoubtedly, Bt-cotton has catapulted India into second position in the world as far as cotton production is concerned, up from number three after the new technology took root. Over 90% of cotton farmers in India cultivate Bt-cotton. It is also true that many farmers in the public consultations vociferously expressed their support to Bt-cotton on economic grounds. But a number of farmers also expressed doubts[7]. More than that, the Central Institute of Cotton Research, Nagpur has done a comprehensive review of Bt-cotton in India[8] and this review has thrown up a number of questions. The Director of the Institute (that has produced a Bt-cotton variety—*Bikaneri Nerma*—whose seeds can be kept by farmers for planting during the next season unlike hybrids where farmers have to be buy seeds every year) while

---

[6] K. Vijayaraghavan Regional Incharge of College of Agriculture and Life Sciences, Cornell University-led research programmes in the South Asian region who crafted this agreement has, however, categorically asserted that public interest has been fully protected

[7]Studies done by the Tata Institute of Social Sciences, Mumbai challenges the popular NGO belief that there is a link between Bt-cotton and persistence of farmer suicides especially in Maharashtra.

[8] This review is to be published shortly in *Current Science* but an advance copy has been made available to me and it is included in Annex-IIIA to the electronic version of this note available at www.moef.nic.in

expressing his clear support for Bt-brinjal technology, has said the following based on the Bt-cotton experience:

- *Resistance development is a very serious concern for monophagous pests. There is a need to develop baseline susceptibility data of Cry toxins on the fruit and shoot borer populations from all the Brinjal growing states in a Government Institute Laboratory known for its expertise in resistance management. The data available thus far is only from Mahyco. There is also a need to set up a main resistance monitoring laboratory to monitor the changes in baseline susceptibility changes of the fruit borer to Cry proteins after releasing the technology.*

- *Resistance Management Strategies are essentially developed based on output profiles of stochastic models which integrate toxicological, ecological, genetic and biological parameters. Stochastic models for resistance should be developed to calculate resistance risk and devise pro-active Insect Resistance Management (IRM) strategies. The structured refuge strategy of 5% conventional Brinjal within the ecosystems of Bt-Brinjal proposed by Mahyco is based on basic simplistic assumptions and not through defined algorithms and modeling.*

- *There is a need for a consolidated report on ecology, biology, genetics and population dynamics of insect pests of Brinjal that are available thus far. Based on the ecology, biology and population dynamics, simulation models should be developed so that appropriate strategies can be formulated to prevent the emergence of new pests and delay development of resistance in key pests.*

This only points to the need for more tests that are well-designed, widely-accepted and independently conducted. The *Bikaneri Nerma* also demonstrates the importance of strengthening public good research.

14. A number of doubts have been raised on the integrity of the GEAC process itself, particularly by Dr. P.M. Bhargava, one of India's most eminent biotechnologists who arguably was amongst the earliest to coin the very term "genetic engineering" and who is a nominee of the Supreme Court on the GEAC. He has provided a detailed point-by-point critique of the Expert Committee-II (EC-II) report that has formed the basis of GEAC's recommendation to commercialise Bt-brinjal. Dr. Bhargava has claimed that the Chairman of EC-II had agreed with his assessment that eight essential tests had not been conducted by Mahyco. Another fact brought to my attention is that an expert committee set up by the GEAC in 2006 (EC-I) had asked for several tests to be conducted but one-third of the EC-II members who were also members of EC-

I chose to discard the need for these studies while evaluating Bt-brinjal as EC-II. I do not propose to do a post-mortem on the way the GEAC has functioned[9]. Many have called for an independent genetic engineering regulator. A National Biotechnology Regulatory Authority has been on the anvil for almost six years now but it has yet to come into being. Such an Authority has to be professional and science-based, independent of the government that should have facilities for conducting all essential tests with integrity and impartiality. In the absence of such a body, arguments that have been made on the limitations of the GEAC cannot be ignored[10].

15. Many countries, particularly in Europe, have banned GM foods. I have spoken with my counterpart in China and he has informed me that China's policy is to encourage research in GM technology but to be extremely cautious when it comes to introduction in food crops. In any case, China's Bt-cotton is entirely indigenously developed, in marked contrast to the case in India. China has a very strong publicly-funded programme in GM technology unlike India. True, Bt-corn and Bt-soya is widely available in the USA but that is no great compulsion for us to follow suit.

16. Some scientists and civil society organisations have pointed out that the GEAC process has violated the Cartagena Protocol on Biosafety to which India is a signatory, particularly the provisions pertaining to public consultations prior to the release of GM food crops and also the broad principles governing risk assessment. It is pertinent to also recall Article 15 of the Rio Declaration on Environment and Development (1992) which echoes the precautionary principle when it states " where there are threats of irreversible damage, the lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation". Further, Section 45 of *Codex Alimentarius* "Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants" says "The location of trial sites should be representative of the range of environmental conditions under which the plant varieties would be

[9] Dr. S. Parasuraman, Director of the Tata Institute of Social Sciences, Mumbai has written to me saying that the questions he raised as member of EC-I were never answered.

[10] Apart from scientific criticisms of the EC-II report, qualified statisticians have raised doubts about it and about the biosafety dossier from a statistical point of view as well.

expected to be grown. The number of trial sites should be sufficient to allow accurate assessment of compositional characteristics over this range. Similarly, trials should be conducted over a sufficient number of generations to allow adequate exposure to the variety of conditions met in nature. To minimise environmental effects, and to reduce any effect from naturally-occurring genotypic variation within a crop variety, each trial site should be replicated. An adequate number of plants should be sampled and the methods of analysis should be sufficiently sensitive and specific to detect variations in key components." It does appear that the current standards by which the GEAC has formulated the decision to approve Bt-brinjal do not match these global regulatory norms to which India is a party.

17. I have received a number of emails from scientists in the USA, France, Australia, UK and New Zealand raising very serious doubts on Bt-brinjal and also on the way tests have been conducted in India[11]. Amongst them, I should mention communications received from (i) Professor G.E. Seralini from France who in a detailed report has pointed out several flaws in the EC-II report and concludes that "the risk on human and mammalian health is too high for authorities to take the decision to commercialise this GM brinjal"; (ii) Dr. Doug Gurain-Sherman of the Union of Concerned Scientists, Washington DC which says that "the record compiled over a 13-year period shows that the 4% yield enhancement contributed by Bt-corn varieties constitutes only 14% of overall corn yield increase. Further, Dr. Gurain-Sherman highlights serious flaws in the EC-II report on evaluation of gene flow risks from Bt-brinjal; (iii) Professor Allison Snow and Professor Norman Ellstrand of the Ohio State University that identifies several shortcomings in the EC-II report concerning gene flow from Bt-brinjal to wild and weedy relatives; (iv) Dr. Nicholas Storer of Dow AgroSciences (a private US company much like Monsanto)who does say that Bt-brinjal does not pose unreasonable adverse risks to the environment or to human and animal health but who calls for careful implementation of resistance management strategies and points out that Bt-technology should not be seen as a silver bullet to managing lepidopteran pests in brinjal; (v) Dr. Jack Heinemann of the University of Canterbury, New Zealand who

[11] 17 noted scientists from different countries have addressed a joint letter to the Prime Minister on February 8th, 2010 giving scientific reasons against the release of Bt-brinjal.

questions the consistent yield increases claimed for Bt-cotton and says that the Bt-brinjal tests conducted in India would not meet careful international standards; (vi) Dr. David Andow of the University of Minnesota, USA who says that his reading of the EC-II report is sufficient to lead him to question the adequacy of environmental risk assessment but it is not sufficient for him to conclude that the environmental risk assessment is erroneous; and (vii)Dr. David Schubert of the Salk Institute of Biological Studies, USA who says that Bt-brinjal should definitely not be introduced in India since it poses serious environmental and health risks, will increase social and political dependence on private companies and will entail higher costs at all levels of the food chain; and (viii) Dr. Judy Carman of the Institute of Health and Environmental Research, South Australia who has analysed Mahyco's biosafety dossier of 2008 in great detail and who says that her doubts and questions have not been answered at all in the EC-II report.

18. Some suggestions have been made that we could consider limited release of Bt-brinjal hybrids in limited areas and ensuring that its sale would be monitored through mandatory labelling. The President of the Indian National Science Academy, Dr. M.Vijayan of the Indian Institute of Science, Bangalore and a noted microbiologist himself has made the suggestion of limited release. My view is that while this offers a possible compromise route, it would be extremely difficult to ensure such a "quarantine". Mandatory labelling is indeed required in countries like the USA but this is somewhat impractical here because our retail market is fundamentally different than that of the USA and also because it is extremely difficult to monitor limited usage in practice[12]. Another scientist Dr. N.S. Talekar, who has worked on the brinjal shoot and fruit borer at the World Vegatable Centre, Taiwan and is now with the Mahatma Phule Krishi Vidyapeeth, while justifying the use of Bt-technology, has strongly warned against the use of Bt-brinjal in its present form saying that the manner in which the proponents of the product are recommending to farmers to use this technology is faulty and unscientific and would lead to disaster.

[12] I am informed that the Food Safety and Standards Authority of India set up under the Ministry of Health and Family Welfare is now considering the issue of mandatory labelling. The import of GM products without an accompanying declaration that they are GM products is liable to penal action under the Foreign Trade (Development and Regulation)Act, 1992.

19. Some eminent Indian scientists have written expressing their support for the commercialisation of Bt-brinjal. Prominent among them is Dr. G. Padmanabhan of the Indian Institute of Science, Bangalore who debunks several domestic and international criticisms of Bt-brinjal, makes a strong plea for commercialisation but also makes the point that we need a statutory body with regulatory authority and R&D capabilities to govern all aspects of GM crop cultivation in the country once they are released for commercialisation. Specifically, Dr. Padmanabhan argues that such an autonomous institution should address issues such as: (i) choice of GM crops and traits relevant for commercialisation in the country; (ii) registration of GM crops for a finite period and reassessment of their performance and the ground situation, before extending the registration for another finite period; (iii) inputs for determining the price of GM seeds sold to farmers; (iv) technical help and advice to farmers on a continual basis; (v) positioning of Bt crops with Integrated Pest Management (IPM) strategies and also handling of secondary infections; and (vi) education of the public on the pros and cons of the use of GM technology in agriculture. The agenda sketched out by Dr. Padmanabhan is both ambitious and necessary but will take time to implement in an effective manner. Another eminent scientist who has supported GEAC's decision to release Bt-brinjal for general cultivation is Dr. Deepak Pental, Vice Chancellor of Delhi University but he has also said that two realities must be understood—one, that as India is centre of origin of cultivated brinjal, transgenes can move to the wild germplasm though this should not unduly alarm us and two, that we will not be able to differentiate between Bt-brinjal and non-Bt-brinjal, making labelling impossible. Dr. Raj Bhatnagar of the International Centre for Genetic Engineering and Biotechnology, New Delhi has sent a highly technical communication which, in simple language, implies that there is no health risk whatsoever by eating Bt-brinjal.

20. I have had a discussion with both the Director-General of the Indian Council of Medical Research as well as with the Drug Controller to the Government of India. Both have recommended that chronic toxicity and other associated tests should be carried out independently. The parallel has been drawn with drugs where during the crucial clinical trials phase, independent testing is carried out on human beings instead of relying on just the data generated by the developer companies themselves. The DG-ICMR told me that in the face of contradictory evidence of the health

effects he would advocate more caution and further tests. Doctors for Food and Safety, a network of around 100 doctors across the country have sent a representation on the health hazards related to GM foods in general and Bt-brinjal in particular. They have drawn attention to the recommendations made by the American Academy of Environmental Medicine that GM foods have not been properly tested for human consumption and that there are substantial risks associated with the use of GM foods. I have also been informed that the Indian Systems of Medicine including ayurveda, siddha, homeopathy and unani use brinjal as a medicinal ingredient, both in raw and cooked form, for treatment of respiratory diseases and that the entire brinjal plant is used in such preparations. There is fear that Bt-brinjal will destroy these medicinal properties due to loss of synergy, differences in the alkaloids and changes in other active principles. In the opinion of this network of doctors, these factors have not been considered by EC-II.

21. The Indian Council for Agricultural Research (ICAR) and the Department of Biotechnology have also given their unqualified support to Bt-brinjal. Some farmers' organisations like the Bharat Krishak Samaj and Shetkari Sanghatana and farmers' spokespersons like Bhupinder Singh Mann and Sharad Joshi have come out fully in support of Bt-technology[13] in general and Bt-brinjal in particular on the grounds that we should not be denying modern technology to farmers and that this will improve incomes of farmers. As I have mentioned earlier, many farmers at the public consultations argued that Bt-cotton has been very profitable for them.

22. I have stressed the importance of public investment in biotechnology for agriculture. But Indian private investment in this area is already a reality. Mahyco is one example. Between 2007 and 2009, the GM crops approved for field trials by the GEAC include insect-resistant cotton and rice developed by Metahelix Life Sciences, Bangalore and hybrid-rice developed by Avesthagen, Pune, both companies run by a new generation of Indian scientists. Clearly, such science-based companies launched by Indian entrepreneurs need to be encouraged and the regulatory process

[13] Although there are farmer organizations like the Bharatiya Krishak Samaj and the Karnataka Rajya Raitha Sangha and some others from Tamil Nadu that have opposed to the commercialization of Bt-brinjal.

should not stymie such innovation[14]. Apart from this, even publicly-funded institutions like the Indian Institute of Horticulture Research, Bangalore too need encouragement since I have been informed that trials using a Bt-brinjal variety using the *Cry2A* Bt gene are at an advanced stage. Scientists at another publicly-funded institution—the Indian Institute of Vegetable Research, Varanasi---have developed Bt-brinjal using *Cry1Aaa3* gene in their own cultivar IVBL-9. These public sector products need to be introduced first, if at all, going by the Bt-cotton experience.

23. I have had the benefit of extended conversations with Dr. M.S. Swaminathan, MP who is, without doubt, India's most distinguished and senior-most agricultural scientist who was one of the scientific architects of the Green Revolution. Dr. Swaminathan, whose own research foundation is working on GM technology, has said that we need to be concerned with three issues here: (i) chronic toxicity since brinjal is an element of such frequent consumption in India; (ii) independent tests that command credibility and not depend only on data provided by the developers themselves; and (iii) the need to have an independent regulatory system that will be in a position to study all aspects of GM technology in agriculture and arrive at a measured conclusion. Dr. Swaminathan has also agreed with the view since brinjal itself contains natural toxins, we have to be extra-careful on Bt-technology. In view of his great stature both in India and abroad, I would like to place below his most recent communication to me on this subject in full:

> *Dear Jairam:*
>
> *I am glad you had wide ranging consultations, and something useful should emerge from such unprecedented churning of minds and experience. Both benefits and risks are now well known. There are unquestionable benefits in the short term, but also potential risks to human health and our brinjal heritage in the long term. What is the way forward?*

[14] I have received a representation from the Bangalore-headquartered Association of Biotechnology-led Enterprises (ABLE) arguing for the commercial cultivation of Bt-brinjal on various grounds including the fact that it is "India's first locally developed agri-biotech product".

1. ***Conserve India's genetic heritage in brinjal:***

My post-graduate thesis at IARI in 1949 was on Brinjal and non-tuber bearing Solanum species. I have studied our rich genetic wealth in this wonderful crop. What will be the long term impact of numerous local strains being replaced with one or two varieties with Cry1Ac gene from Monsanto? I suggest that during 2010, ICAR (the National Bureau of Plant Genetic Resources) along with Dr Anil Gupta of the Indian Institute of Management, Ahmedabad (he maintains a national data base on indigenous knowledge and farmers' innovations) should both collect, catalogue and conserve the existing genetic variability in brinjal. Such a collection must be carefully preserved, before we permit the extinction of the gifts of thousands of years of natural evolution and human selection.

2. ***Assess the chronic effects of consumption of Bt Brinjal:***

The second step which needs to be taken is to ask the National Institute of Nutrition, Hyderabad, and the Central Food Technology Research Institute, Mysore to undertake a careful study of the chronic effects of Bt brinjal on human health. This is analogous to the studies carried out on the impact of tobacco smoking on the incidence of lung cancer in human beings.

It will be in national interest to complete these two steps before a decision on the release of Bt brinjal for commercial cultivation and human consumption is taken.

24. It also bears mention that the Supreme Court has been hearing a PIL filed in early 2005 seeking to put in place a comprehensive, stringent, scientifically rigorous and transparent biosafety test protocol in the public domain for Genetically Modified Organisms (GMOs), for every GMO before it is sought to be released into the environment. The Supreme Court has given six Orders so far in order to ensure transparency and accountability in the functioning of the GEAC. The PIL has yet to be finally disposed and the latest Order of January 19th, 2010 asks the Union of India to respond in four weeks to the question of what steps have they taken to protect

our traditional crops. Clearly, the decision on Bt-brinjal has to take note of this PIL that has already been filed. In addition, the Supreme Court has invoked the precautionary principle as a guiding instrument in environmental decisions (A.P. Pollution Control Board vs. M.V. Nayudu<1999(2)SCC718> by relying on the following:

> *"There is nothing to prevent decision-makers from assessing the record and concluding there is inadequate information on which to reach determination. If it is not possible to make a decision with 'some' confidence, then it makes sense to err on the side of caution and prevent activities that may cause serious or irreparable harm. An informed decision can be made at a later stage when additional data is available or resources permit further research".*

25. I am also persuaded that the studies being demanded by responsible civil society groups before release of Bt-brinjal should be conducted as a measure of our sensitivity to public opinion. A couple of scientists and civil society groups have also pointed out (i) things that are problematic with the protocols of the studies already conducted; (ii) things that are problematic with the analysis of the data submitted; (iii) things that are problematic with the interpretation of the results; (iv) things that are problematic with the reporting by Mahyco; (v) things that are problematic with the procedures adopted. It is incumbent upon us as an accountable and transparent administration to respond to these concerns (presented in Annex-IV to the electronic version of this note available at www.moef.nic.in) in a serious manner.

26. Based on all the information presented in the preceding paragraphs and when there is no clear consensus within the scientific community itself, when there is so much opposition from the state governments, when responsible civil society organisations and eminent scientists have raised many serious questions that have not been answered satisfactorily, when the public sentiment is negative and when Bt-brinjal will be the very first genetically-modified vegetable to be introduced anywhere in the world and when there is no over-riding urgency to introduce it here,

<u>it is my duty 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.</u>

A moratorium implies rejection of this particular case of release for the time being; it does not, in any way, mean conditional acceptance. This should be clearly understood.

27. This decision should not, however, be construed as discouraging on-going R&D in using tools of modern biotechnology for crop improvement and for strengthening national food and nutrition security, since issues of this kind have to be examined and decided necessarily on a case-by-case basis. I hope the moratorium period will be used to build a broader consensus so that as a country we are able to harness the full potential of GM technology in agriculture in a safe and sustainable manner.

28. The moratorium period should also be used to operationalise the independent regulatory body in its entirety as being recommended by many scientists as well as civil society organizations. I also hope in the moratorium period we give serious thought to the strategic importance of the seed industry[15] and how we retain public and farmer control over it even as we encourage private investment in agricultural biotechnology. I would also recommend that the moratorium period be used to have a detailed debate in Parliament and also a comprehensive discussion in the National Development Council (NDC) on this subject.

[15] The Seeds Bill, 2004 was introduced in the Rajya Sabha in December 2004 and is awaiting Parliament's approval. Transgenic seeds needs to be looked at carefully in the context of this legislation.

29. ***I believe the approach outlined above is both responsible to science and responsive to society.*** In arriving at this decision, I have also kept in mind what the Prime Minister Dr. Manmohan Singh himself had said on this subject in his speech at the Indian Science Congress on January 3rd, 2010 at Thiruvananthapuram:

> *Developments in biotechnology present us the prospect of greatly improving yields in our major crops by increasing resistance to pests and also to moisture stress. BT Cotton has been well accepted in the country and has made a great difference to the production of cotton. The technology of genetic modification is also being extended to food crops though this raises legitimate questions of safety. These must be given full weightage, with appropriate regulatory control based on strictly scientific criteria. Subject to these caveats, we should pursue all possible leads that biotechnology provides that might increase our food security as we go through climate related stress.*

30. I expect the GEAC to take follow-up action on the matter of further studies and tests with appropriate protocols and in appropriate laboratories. I also expect the GEAC to carefully study all the material I have received and am turning over to it. I would like the GEAC to engage and interact with all those scientists, institutions and civil society groups who have submitted written representations to me. The GEAC should consult with scientists like Dr. M.S. Swaminathan, Dr. P.M. Bhargava, Dr. G. Padmanabhan, Dr M. Vijayan, Dr. Keshav Kranthi, Dr. Madhav Gadgil and others to draw up a fresh protocol for the specific tests that will have to be conducted in order to generate public confidence. Under no circumstances should there be any hurry or rush. The moratorium will continue for as long as it is needed to establish public trust and confidence**.** Meanwhile, I also intend to change the name of the GEAC from Genetic Engineering *Approvals* Committee to Genetic Engineering *Appraisal* Committee.

31. Meanwhile, in order to ensure complete transparency and public accountability, I am making my decision on the GEAC recommendation regarding commercialisation of Bt-brinjal public right away.

Jairam Ramesh
MOS(I/C)E&F; February 9th , 2010