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*The following is the response of the FBAE to the Interim Report (IR) of the Technical Expert Committee (TEC) appointed by the Supreme Court of India (SCI). Some issues were also aired by the FBAE in the articles published in the Indian Express, Bangalore and the Deccan Chronicle, Hyderabad, both of November 5, 2012, which were circulated, and also sent to the Members of the TEC.*

There is enormous literature on the science, technology, biosafety regulation, efficacy, biosafety and socio-economic benefits of genetically engineered (GE) crops based on about 25 years of research and regulatory experience and over 16 years of commercial cultivation and consumption in 29 countries and long use as food and/or cattle feed of biotech crops and products in another 31 countries (James, 2011). This vast literature, which even teams of scientists find difficult to cope up, is the evidence of the current global understanding of biotech crops and combined global expertise and wisdom. While many references are cited in this response, it is impossible even to list all the important publications on biotech crops. Some publications are basic to the understanding of the subject. For example, the book by Glare and O'Callaghan (2000) is a monumental compilation of 60 years of research from 8,000 publications on the biology, ecology and safety of *Bacillus thuringiensis*, where answers to most questions raised by the activists and repeated by politicians, could be found. Thirty one articles by international experts addressed diverse aspects of transgenic crops for food security in the context of their development, safety and benefits, at a study week of the Pontifical Academy of Sciences (Potrykus and Ammann, 2010). The question 'Why genetically modified crops?' was adequately answered by Jones (2011). However, the IR sounds as though only its authors and the anti-tech activists know better.

1. Fifty nine per cent of global GM crops contain the herbicide tolerant (HT) genes and the whole of global GM soybean is HT, constituting 47 per cent of GM crops cultivated in 2010 (James 2011). HT crops derived from conventional techniques like mutation breeding have been in cultivation without a question against them. The objections to the more precise and efficient rDNA derived HT crops, which are cultivated and/or consumed in many countries for years (James, 2011), is unscientific.
2. The HT trait when stacked with insect tolerance (IT) traits would be ideal for the Indian farmers. Globally, gene stacked GM crops constituted 26 per cent in 2010. Genuity SmartStax corn with eight stacked genes, six for IT and two for HT, which is an intellectual feat, proved to be extremely efficient.
3. HT technology is scale neutral and helps farmers of all sizes of land holding as it does in Argentina, Brazil and China. HT GM crops are very much needed in Indian agriculture now more than ever before, as over 33 per cent pre-harvest loss in agriculture is on account of weeds and this has to be stemmed.



4. Manual weeding is laborious, largely inefficient and expensive. There is an acute shortage of farm labour, which often migrates to other States for better wages. This unorganized sector acutely suffers from the seasonal underpaid employment that leaves them without income for half of a year.
5. As the biosafety and environmental safety of HT crops have been well established (Ammann, 2005), TEC's objection to HT crops seems to be more on socio-economic grounds such as affecting rural employment opportunities, which were never an issue when barbers and washer men were displaced from their traditional occupations. Biotech mega-countries China, Brazil and Argentina also have similar concerns about the welfare of the agricultural labour but deployed on a large scale HT cotton, maize, soybean and canola. Opposition to HT crops is only in the interests of the big landlords who want to retain the cheap labour force as their permanent slaves, also the reason behind lukewarm efforts in improving rural education.
6. Any agricultural seed and crop raised on it should be routinely monitored for performance and to solve problems that may arise, but conventional seed and crop never undergo any such overseeing. In their own interest GM seed developers and distributors monitor the performance of their seed continuously which involves heavy time and financial inputs. There may be some lapses which can be remedied. Oddly, TEC favours post-release monitoring and banning all open field trials in the same document.
7. No technology in any sector can be guaranteed to be absolutely risk-free and expecting GM crops alone to be so is a severely biased stand. The objective of the regulatory regime is to ensure identification, estimation and mitigation of risk, if any and so regulation should be pro-active and not block all progress. Management deficiencies should not be used to castigate technology as a whole.
8. The choice of methods of event selection, its location and timing should be left to the scientists involved in the R&D of GM crops. It is an unsound policy for others to sit in judgment, without understanding the underlying complexities of regulatory evaluation of products of modern agricultural biotechnology.
9. Ammann *et al.*, (2003) have reviewed the methods for risk assessment in transgenic crops. Biosafety tests needed for GM crops are not the same for all crops, but should be determined on a case by case basis. Only internationally standardized 'need to know' toxicity studies must be done and not the 'nice to know' tests. It is unreasonable to insist that all tests should be conducted on all the crops irrespective of the need. For example, Catchpole, *et al.*, (2005) did not find any more benefits from hierarchical metabolomics than from substantial equivalence (Kameswara Rao, 2009a) established by conventional means. Conducting unwarranted tests, many of which are technically involved and expensive, without concurrent benefits, is a waste of time and money which adds to farmer/consumer costs.
10. Conducting biosafety tests after the event selection is a logical option. Doing lab tests ahead of event selection would lead to a waste of money and time. Conducting



biosafety prior to field trials would be a serious weakness in the regulatory oversight. Open field trials are needed to gather comprehensive agronomic and biosafety data as the conditions in the green house and open field trials are not similar. More importantly the stability of the introduced trait can be demonstrated more convincingly during the open field trials.

11. The TEC wants to impose on GE crops chemical toxicology tests such as Ames test used to determine the potential to cause cancer and micronucleus test used to determine the extent of genetic damage. Considering all suggestions in the IR, it looks that TEC recommends about 39 tests to be conducted on all GE crops irrespective of relevance or need. This surpasses even the 31 tests most of which are unwarranted but insisted upon by the science face of Indian anti-tech activism. The concern is not the number of tests being demanded but their relevance and science based need to establish biosafety and environmental safety. Under the practice of Event-based approvals, transgenic with the same Event that was approved for cultivation, such as *Bt* cotton, the number of tests and period of field trials could be reduced.
12. Long term inter-generational safety test are more a slogan than a scientific need. Presently, the toxicity and allergenicity tests are done in India as per international practices and are more than adequate. Snell *et al.*, (2012) reviewed the literature on the health impact of GM plant diets in long-term and multigenerational animal feeding trials and found nothing of concern. It is easy to recommend '*long-term and inter-generational feeding studies with small rodents*' without defining the type of study, its duration and the need for the study.
13. Currently, feeding studies for 90 days are the global norm as recommended by the *Codex Alimentarius*, the World Health Organization (WHO) and the Food and Agricultural Organization (FAO), which are also followed in the USA, Canada, Australia, Argentina, Brazil, etc. The ninety day period in the life of a laboratory mouse is equivalent to 24.5 years of human life and beyond 90 days of feeding studies no new data would emerge (see Sesikeran, 2010). A history of safe consumption should help in the choice of toxicity tests actually needed in each case (Sesikeran, 2010).
14. Over 350 million people in North America and elsewhere have been consuming GE crops containing diverse transgenic products, for over 16 years. Millions of meat cattle have been fed on GE maize and soybean, and their meat consumed by people in different parts of the world for over one and half decades. None of this resulted in any proven adverse effects either in humans or cattle. This actually constitutes the largest long term transgenic food safety evaluation, with normal daily quantities of consumption in normal combinations with other foods. This does not suffer the disadvantage of overdose caused by exclusive forced feeding of pure constituents of the transgenic crops.
15. Activists repeatedly project GE soybean containing genes for methionine from Brazil nuts and the *Bt* corn containing Cry 9c gene as evidence for allergenicity of GE crops. Both were clinically demonstrated to be baseless claims (Kameswara Rao, 2009b).



The two crops were withdrawn and serve as examples of self-regulation by the industry.

16. If the isogenic were not allergenic, there is no need for allergenicity tests as the transgenes (HT, BT or other) have not been clinically proven to be allergenic in 16 years of consumption (Kameswara Rao, 2009b). Somehow the activists forget about 120 conventional foods, which were clinically proven to be allergenic often with serious consequences to consumers (Kameswara Rao, 2009b).
17. There are comprehensive guidelines to conduct field tests under BRLI and BRLII issued by the DBT based in an international consensus, with the objective of strict monitoring of safety standards. A strict compliance of these guidelines is more than adequate to establish biosafety.
18. The TEC seems to have overlooked the fact that appropriate internationally accepted statistical analyses are built into the processing of regulatory data.
19. Wherever RCGM and GEAC are located, it is bound to be questioned by someone or the other. As the RCGM deals with all the three streams (agricultural, medical and industrial) of biotechnology and as DBT formulates policy on biotechnology, RCGM is conveniently located in the DBT. Otherwise the three streams have to be split and placed under the respective Ministries which would cause problems with policy formulation and implementation, without eliminating the element of mistrust. The GEAC is located in the MoEF as it was constituted under the provisions of the Environment Protection Act of the MoEF and GEAC is the only statutory body which can approve release of biotech products into the environment including commercialization, with the prime concern of environmental safety of products in all the streams. Nevertheless, GEAC has extended its sweep to other areas such as technological, agronomical and safety as food and feed.
20. TEC's view that the RCGM and GEAC have limited expertise does not reflect an objective assessment. No Committee, including the TEC, can have the whole range of expertise required to do its job. Additional expertise would have to be invited when needed, as was done when three Expert Committees were constituted to evaluate *Bt* brinjal dossiers. It is possible to have some fulltime members appointed expressly for the work of the RCGM or GEAC, but not whole Committees.
21. Conflict of interest and vested interest are double edged and can also be used against those who oppose technology from different platforms. Only people who have hands on experience with some aspect of GM technology and/or agriculture would be of any use on Committees and any of them can be branded as having a conflict of interest or vested interest.
22. People without any scientific background relevant to the functions of the RCGM or GEAC or BRAI, have no place on them, except when they are *Ex-officio* representatives of some Ministry or Department. Inducting all stakeholders, who have no background to understand science and technology and its implications for



Indian agriculture, into any of these bodies defeats the purpose of objective and scientific decision making as most stakeholders only want to block the technology. Placing permissible regulatory documents (other than confidential business information) relating to proposals, decisions, etc., on designated websites for public viewing and comment for a period three weeks as is done in many countries would contribute to transparency.

23. A complete overhaul of the existing regulatory system is the basic objective behind proposing the Biotechnology Regulatory Authority of India (BRAI) legislation and so no interim measures need to be considered as they are not only wasteful but would cause confusion.
24. Activists frequently invoke the bogie of contravention of the provisions of the Convention on Biological Diversity (CBD) and the Cartagena Protocol to the CBD (CPB), only to inflame public opinion against biotech crops. India, as a member of the CBD does not attract any additional burden to hinder GM technology. Other Member Nations of CBD such as the USA, Argentina, Brazil, Canada, and China are leaders in the adoption of GM crop technology. The CBD only commits Member Nations to balancing the benefits and risks of utilization of biological resources. The CPB is concerned only about transboundary movement of GM crops and products, to ensure that importer's rights to the safety of GM crops and/or products are protected.
25. In the past, European countries which banned trade in GM crops and products attracted censure from the World Trade Organization (WTO). If India bans GM technology and related trade, that will actually violate her obligations under WTO.
26. No provision of either the CBD or the CPB is meant to prohibit, or intentionally impeded new agricultural technologies. The Precautionary Principle, much misinterpreted and misused by the activists, is about moving cautiously but not an excuse to hinder technological development.
27. Applicants for GM field trials and commercial release invariably address issues related to the possible impact of environmental release of GM crops on biodiversity. Thousands of open field trials have been conducted for over 25 years and no evidence of adverse effects on the environment has emerged.
28. Transgenes cannot spread to all '*other organisms*' as stated in the IR, but possibly only to the other varieties of the crop and more rarely to its related species, only if there were no reproductive barriers (Kameswara Rao, 2008b, c).
29. That there are over 100,000 varieties of rice, 75,000 of wheat, 70,000 of potato, and thousands of varieties of other crops is an adequate testimony that any gene flow among the varieties of each crop was negligible, and so is the fact that different varieties of the same crop have been grown in the neighbouring fields for decades and that the farmers have never complained that the crop did not breed true.
30. Ammann (2005) reviewed the impact of agricultural biotechnology on biodiversity. Biosafety and environmental safety of transgenic crops have been reviewed in a





number of other publications (Ramessar *et al.*; 2007, Sanvido *et al.*, 2007; OECD, 2007; Brookes and Barfoot, 2012). The safety of *Bt* proteins to bees (Glare and O'Callahan, 2000), bumble bees (Barbendrier *et al.*, 2008), butterflies (Sears *et al.*, 2001) and parasitoids (Chen *et al.*, 2008) was also demonstrated.

31. The activist terms 'gene contamination' and/or 'gene pollution' are a scientific travesty, used to instill fear among the public, and to castigate technology and its regulation. The contention that GM crops will 'contaminate' biodiversity has no scientific basis.
32. That transgenic crops do not become super weeds was established by a 10-year experiment long ago (Crawley *et al.*, 2001). The impact of transgenic crops on biodiversity depends on gene flow (Kameswara Rao, 2008b, 2008c, 2010), which transgenic technology does not change. There is no evidence of free gene flow among the conventional varieties of any of the crop that is being used to develop transgenics in India. The much touted case of gene flow from transgenic maize into native varieties of maize in Mexico was disproved (Ortiz-Garcia *et al.*, 2005).
33. The contention that transgenic crops should not be permitted in the countries that are the centres of origin is political and not based on scientific evidence (Kameswara Rao, 2010). That India is the country of origin of important crops such as brinjal, rice, etc., is an emotional argument rooted in outdated publications and is not supported by recent science. All evidence points to the fact that issues of centers of origin and centers of diversity and domestication are inconsequential where there is no pollen mediated gene flow. Twenty five years of regulatory research and over 16 years of commercial cultivation of several transgenic crops in the world have not produced even an iota of evidence for free gene flow that would affect the native germplasm of any of the crops or biodiversity.
34. No foreign expertise or documentation commissioned by anti-tech activist groups should be allowed to dictate our policy as India has sufficient number of competent scientific experts. Some foreign experts who have intervened in GM issues in India and elsewhere have recently been officially discredited by the international scientific community and agencies.
35. The most scientifically unsound, even unethical, recommendation of the TEC is that all field tests, including the currently progressing studies, be banned for 10 years, was fortunately not accepted by the SCI.
36. The performance of *Bt* cotton in India and the benefits derived by the country's farmers over the past decade have been repeatedly evaluated. *Bt* cotton was even shown to suppress cotton bollworm in the neighboring non-*Bt* cotton fields in China (Wu *et al.*, 2008).
37. Manjunath (2007, 2011) provided answers to a large number of questions that are being asked and also to questions that are likely to be asked, about *Bt* cotton. A similar publication by Kranthi (2012) also provides answers to questions on *Bt* cotton.



38. The claims of the death of farm animals and farmer suicides, both mischievously linked to *Bt* cotton, have been dispelled (Kameswara Rao, 2008a, Gruere *et al.*, 2008, Gruere and Sengupta, 2011).
39. Many *ex-ante* socio-economic studies were conducted on *Bt* brinjal (Krishna and Qaim, 2007; Kolady and Lesser, 2005, 2006, 2008; Kumar *et al.*, 2010) and there is a large number of similar studies on *Bt* cotton in India (Rao and Dev, 2009; Gruere and Yan, 2012; Brookes and Barfoot, 2012). For future crops, such studies should be done parallel with the open field trials as field data are needed to assess socio-economic impact.
40. A number of baseless charges were made by activists against GM crops in general and *Bt* brinjal in particular. This activist prescription was adopted by the Minister for Environment and Forests (MoEF) while imposing an indefinite moratorium on *Bt* brinjal and the same issues were extrapolated by the TEC in the IR. These charges were adequately answered (Padmanabhan, 2009; Kameswara Rao, 2010, 2011 and Kameswara Rao *et al.*, 2011).
41. The TEC slams on us its belief that '*the problematic issues TEC found, which are similar to those that have been pointed out in the case of Bt brinjal by others, including international experts*', have contributed to the declaration of a moratorium on *Bt* brinjal. *Bt* brinjal biosafety and other data were examined by the RCGM, the GEAC and two Expert Committees, all of which have recommended its commercial release. Political opportunism trashed this collaborative recommendation based on concurring scientific judgment.
42. That the moratorium on *Bt* brinjal had no safety or environmental concerns should be evident from the following statements of the former MoEF: a) '*It is for the political system to decide whether to introduce Bt brinjal*' (The Hindu, January 10, 2011); b) '*If I said yes to Bt brinjal, the civil society would have jumped on me*'; c) '*I had a personal bias*'; d) '*If 90% of the GM seed is going to be controlled by one company...*' (b,c and d: Malhotra, 2011, Current Science). When public-private partnership is widely encouraged by the Central Government, prejudice against the private sector is unbecoming of a Minister of the same Government.
43. The Deputy Chairman of the Planning Commission was reported to have said that '*many of the NGOs in India protesting against Bt brinjal were associated with and funded by European NGOs*', and b) '*the public consultation process on Bt brinjal initiated by Jairam Ramesh is one sided*' (Dinesh Sharma, India Today, September 3, 2011). Moratorium was imposed on *Bt* brinjal on account of activists' scaremongering and political pandering, unmindful of the damage caused even to the public sector.
44. No technology would benefit all the stakeholders. For example, *Bt* and/or HT cotton benefit the farmers while Golden Rice is a consumer product and only diabetics need GE insulin, but none negatively impacts the other stakeholders. Technology should be chosen on the basis of larger benefits to the society and not by keeping specific stakeholders in mind.



45. The activists and the politicians aver that most countries, particularly those in the European Union (EU), are vehemently against GM crops and products. While there has been significant activism against GM technology in the EU, which also funds and foments more rampant activism in India, the EU countries have actually planted *Bt* maize on 114,507 hectares in 2010 (James, 2011). Over 40 million tonnes of GM soybean and 10 million tonnes of GM maize, or their products, are annually imported into the EU, as cattle feed and/or for industrial use.
46. A report of the on EU funded GMO research in the decade of 2001-10 stated that '*The main conclusion to be drawn from the efforts of more than 130 research projects, covering a period of more than 25 years of research and involving more than 500 independent research groups, is that biotechnology, and in particular GMOs, are not per se more risky than conventional plant breeding technologies.*' (European Union, 2010).
47. The EU had spent Euro 300 million (Euro 200 million in the past decade), on GM crop research (European Union, 2010). EU researchers have been working on 350 different GE crop Events, most of them now under field trials. Europa Bio (2012) estimated that regulatory delays in the past decade in adoption of GM crops have caused a cumulative loss of 44.6 years of time for the EU countries. In the face of negative attitude of the TEC and the Parliamentary Standing Committee on Agriculture, India would most likely suffer a similar fate.
48. On December 10, 2012, David Cameron, the British Prime Minister, urged the EU '*to take decisions on scientific evidence and to speed up roll-out of GM crops to let more farmers grow them in the UK*'. The same day, the British Environment, Food and Rural Affairs Secretary Owen Paterson said that '*a) there are real environmental benefits to GM technology, b) public concerns about genetically modified food were unfounded, c) consumer opposition to the technology is 'complete nonsense', d) there is not even a single piece of meat in London restaurants that did not come from bullocks fed on GM corn and so fears over Frankenstein Foods are 'humbug', and e) GM foods should be grown and sold widely in Britain*'.
49. The following international scientific Academies, Societies or bodies have recommended the deployment of biotech crops, particularly in the developing countries, to ensure future food security: a) the US National Academies of Sciences (1987, 1989), b) Research Directorate of the European Union (81 studies, 2001), c) the French Academy of Science and Medicine (2002), d) the Royal Society, UK (2003), e) the British Medical Association (2004), f) the Union of German Academies of Science and Humanities (2004), g) the Food and Agricultural Organization (2004), h) the Advisory Committee on releases to the environment, UK (2007), i) Pontifical Academy of Sciences (2010), j) European Union (2010), k) Indian Inter-Academy Panel (six Indian Academies of science, agriculture, engineering and medicine, 2010; interestingly one Member of the TEC seems to be batting for both the sides), and l) American Association for Advancement of Science (2012). Only hypocrisy can motivate trashing this combined global expertise and wisdom (see Miller, 2012).





50. The Prime Minister of India made several statements in support of GM crops during 2012, one of them in an interview for the international journal Science, recognizing the importance of crop genetic engineering to enhance food production and ensure food security in India (PM's Interview, 2012). He had also acknowledged that anti-tech activism in India is supported by US and Scandinavian agencies.
51. In October 2012, the Prime Minister's Scientific Advisory Council emphasized the importance of GM crops for India, and sought a boost for public sector research and development in this area.
52. On October 11, 2012, the Union Minister of Agriculture (MoA) requested the Chief Ministers to permit field trials and not to block GM research as opposition to GM crops must not be based on unfounded apprehensions and that any hasty decision to block the progress of science will have a long-term implications for our country which will have to be borne by the next generation.
53. On November 27, 2012, the MoA informed the Lok Sabha in a written statement that '*from the inception of Bt cotton, there has been a sustained objection from some of the NGOs besides civil society, technical expert committee constituted by Supreme Court, Parliamentary Standing Committee, etc. The objections have been very speculative and confusing, without any reasonable assessment of the technological strengths of Bt cotton. There is no scientific evidence to show that Bt cotton has adversely impacted the biodiversity or human/cattle health.*' It is significant that the MoA has mentioned the TEC in this statement.
54. The TEC should respect the opinion of the scientists and the relevant Ministries, not just the MoEF and activists, and take a more objective view of the whole scenario of GM crops in India, keeping in mind the benefits that would accrue to the farmers, consumers and the country on their large scale adoption.
55. If the TEC makes any new recommendations in the final report, they should be applicable only prospectively and not retrospectively.

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