To *Bt* or not?

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The report[1] by an Expert Committee (EC–II) and approval of *Bt* brinjal by the Genetic Engineering Approval (now Appraisal) Committee (GEAC) in October 2009 led to considerable public outcry and an ongoing debate. To promote transparency, the Ministry of Environment and Forests (MOEF), Government of India, uploaded a compendium containing details of the consultation process and various comments[2]. About 50 Fellows from six national academies met in Delhi on 1 June 2010 to briefly exchange individual perspectives on transgenics in food. Subsequently, the six academies produced a report[3] which generated considerable additional discussion. Following several criticisms (see refs 4 and 5, for example), the academies have updated their report for greater balance, and included many references[6].

It is useful and necessary for scientists (including non-biologists like me) and civil society to engage with such critical issues, with a healthy dose of scientific skepticism. Specific concerns and a critique of the approval process and the report of the academies are given below, related to *Bt* brinjal and also more generally with genetically modified (GM) crops.

Resistance

Pests are likely to develop resistance to *Bt* toxins over a period of time, which can be as short as 4 years for *Bt* brinjal[7]. A standard approach for delaying resistance is to plant refuge crops (without the toxins) along with the *Bt* crop, with the refuge crop area varying with the GM crop and location up to 50% (ref. 8). While this may be a reasonable approach for large-scale industrial farming, it appears unrealistic for the small-scale farming scenario in India. In addition, compliance with the refuge requirements has been poor even in USA[9]. Pest resistance has developed already with *Bt* cotton crops in India, demonstrating that the refuge approach may not be a long-term solution. A recent study on *Bt*-resistant target pests in South Africa notes that the originally predicted rate of pest evolution with refuge significantly underestimated reality[10].

There are additional approaches to enable further GM cropping when resistance develops, involving gene stacking, for example. However, these will lead to an ever-escalating and possibly non-sustainable scenario involving the use of next-generation GM crops and further resistance development, placing an undue (and unrealistic) faith in the ability of science and technology to keep pace on the biochemical treadmill.

Although one of the potential benefits of GM cropping is a reduction in pesticides being used currently, some studies have shown that the use of pesticide actually increases over a period of time, as noted in a recent study on *Bt* cotton grown in Karnataka from 2002 to 2009 (ref. 11). In addition, secondary pests that were not originally present develop over a period of time with GM cropping[12].

Socio-economics, sustainability and societal utility

Following the original protocol, a subcommittee recommended a socio-economic study on the impact of *Bt* brinjal[2]. Although this recommendation was accepted, such a study had not been initiated, as noted[1] in EC-II.

Since most of the brinjal is grown by small farmers[1], there is clearly cause for concern for the lack of a detailed socio-economic study and the apparently casual attitude towards this issue. There have been two recent independent evaluations of the *Bt* brinjal documentation, and they have raised serious concerns regarding the adequacy of the protocols for socio-economics, risk assessment and toxicity[7,13].

Irrespective of scientific claims and doubts, eventually the large-scale use of GM crops must be sustainable and provide societal utility. The Norwegian approach indeed requires an evaluation of these issues during the assessment of GM products[14], and this seems appropriate also for India. It is important to keep in mind that what may be sustainable and may provide societal utility in one country, may not do so in other contexts. Thus, with *Bt* brinjal, it is necessary to enquire whether the technology will benefit mostly large farmers with water and other resources over small-scale farmers in rainfed areas. This is an important issue to consider, as studies have shown that the trend towards large-scale industrial farming following GM cropping in Latin America has led to the deprivation of small rural farmers and large-scale forced migration to cities[15].

Independent studies and conflict of interest

To ensure scientific validity and inspire wider public confidence, it is necessary that studies from corporate or public entities be repeated by independent bodies and evaluated by regulators, without a conflict of interest. It is necessary for a body promoting a technology to be separated from those involved with testing and evaluating/regulating. This brings into sharp focus the need for limiting, if not eliminating, conflict of interest. Greater clarity on the roles played by scientists and others (including bureaucrats) can be provided by requiring them to give in writing any potential conflict of interest in terms of financial or other interests, and to recuse themselves from discussions where there is a potential conflict of interest. Clearly, not only must any significant conflict of interest be avoided, it must also be perceived to be precluded in the evaluation process. For example, there is a need to ensure that GEAC does not include members from other related committees in the approval process.

Balance of evidence, cost-benefit analysis

It is unlikely that one can ever be fully and completely certain that new GM crops are safe and useful. Consequently, most analyses that deal with such complex issues and risk analyses include language such as balance of evidence or cost-benefit analysis. Shorn of scientific and economic jargon, the process inherently involves value judgements, as it requires one to consider disparate factors

such as not only apples and oranges, but also cricket scores and likelihood of rain on a given day. Therefore, despite calls for decisions that are 'scientific', it is easy to recognize that small changes in values to the disparate items in a given basket can lead to different conclusions. Therefore, a holistic approach must always bear in mind the question, who pays the costs and who reaps the benefits? As an example, the GEAC approval of *Bt* brinjal would suggest that a small value was attached to socio-economic issues in the decision-making process.

Report of the national academies

In view of the controversial nature of *Bt* brinjal, the national academies did not discuss the scientific issues in detail, noting simply that there is no need to go over the material that is known. The updated report from the academies does reflect the majority opinion noted in the rather brief points of view exchanged at the meeting of the academies on 1 June 2010. Given below are specific comments to some recommendations in the report[6].

Keeping in mind the significance of national food security, the report recommends a strong push towards funding public institutions, and also a public–private partnership (PPP) for commercializing GM crops in India. While food security is essential, it is necessary to ensure that PPP does not become a euphemism for socializing costs and risks while privatizing profits. Furthermore, it is important to recognize that public institutions and nominally independent bodies are not necessarily immune to corporate pressures and inducement/sponsorship[16–18].

While the report recommends an independent high-power expert committee to oversee efforts involving transgenics, it is surprisingly silent on the need for independent testing and minimizing conflict of interest. It is difficult to visualize how a high-power expert committee can provide meaningful oversight and direction, if it has to depend on potentially tainted information arising partly from conflicts of interests and a lack of independent testing.

The report concludes that the regulatory mechanism in India is strong. It is difficult to accept this considering the lack of independent testing, potential conflicts of interest, lack of consideration of socio-economic issues before approval, and also the undue haste that seems apparent in the final stages of deliberation (the 105-page EC-II report was formally submitted on 8 October 2009, and the GEAC committee approving *Bt* brinjal met on 14 October 2009).

Three separate issues related to *Bt* brinjal are addressed.

'… the available evidence has shown, adequately and beyond reasonable doubt, that *Bt* brinjal is safe ….' This is a subjective evaluation of data and it is an overreach by assertion. At best, the limited evidence available to date suggests that *Bt* brinjal may not be unsafe. It is necessary to be aware of the broader picture where it has been shown that 'scientific findings' may be biased and wrong[19,20].

'… appropriate to release *Bt* brinjal in specific farmers' fields ….' Since all issues have not yet been adequately addressed, it is premature to consider a limited release of *Bt* brinjal. Furthermore, the purpose of such a process is not clearly defined – would this be for one year or ten years; what would be the criteria for success? Although the recommendation notes that sufficient isolation distance should be maintained, a recent study suggests that in addition to pollen transfer by insects, contamination occurs largely by inappropriate handling of seeds[21]; this clearly points to potential problems with a limited release of *Bt* brinjal in farms.

The original report of the six academies drew considerable criticism, including a call for the merging of the three science academies[22]; it is not surprising that the updated report with some cautionary notes and many references has involved essentially insubstantial changes, as it seems to have been undertaken with the presumption that the recommendations will not change. The current controversy regarding the report should be used by the academies to strengthen the process of debating, evaluating and communicating scientifically controversial issues of relevance to society. Thus, for example, the US National Academies have a published policy on undertaking studies[23], including dealing with conflicts of interest, meetings with public and concerned groups, external reviews and publication, including names of the authors of the report and reviewers, and any dissenting note; although internal discussion are confidential, most of the other information is available online.

There is a sense of urgency among groups whose work over a decade or more is not able to come to fruition in the public policy sphere[1,6,24]. It is increasingly common in science for a large number of scientists to work on 'hot' topics, and biotechnology using genetic engineering has been such a topic since the late 80s. Thus, a research scientist in India was told in the early 1990s that he would get funds only if he worked on genetic engineering[25]. However, public policy cannot and should not take into account the years spent by scientists and technologists in following a certain line of research. While *Bt* and other GM food crops appear to have potential for agricultural use, and research on this topic should be supported, it is premature and unreasonable to push for the release of such crops when there are significant doubts about the science, sustainability and societal utility, among other factors. It is also important to ensure that research funding is provided to alternate and conventional approaches to agriculture, beyond GM. We must refrain from indulging in scientific and technological hubris, as the consequences of a lack of appropriate consideration of the uncertainties may be grave for our society.

The rapid introduction of GM crops is usually advocated partly on the basis of the anticipated increase of ~ 50% in the global population from ~ 6 billion now to ~9 billion by 2050. As noted by von Braun[26] and listed in the report by the academies, the current global annual rate of agricultural productivity increase is about 2%; compounding this growth rate for 40 years leads to an expected increase in global production of ~ 120% in 2050, which is much more than the anticipated increase in population. While there is a constant need to improve productivity in view of the potential ecological and environmental challenges, and the current rate of growth may not necessarily lead to food security for all, the calculation suggests that there is no urgency to approve GM crops.

It is appropriate to close with a summary from a 2009 report from the Royal Society[27] entitled, 'Reaping the benefits: Science and the sustainable intensification of global agriculture': 'Assessment of benefits, risks and uncertainties should be seen broadly, and should include the wider impact of new technologies and

practices on economies and societies. Public and stakeholder dialogue – with NGOs, scientists and farmers in particular – needs to be a part of the governance frameworks.'

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FORM IV

Particulars of *Current Science*—as per Form IV under the Rule 8 of the Registration of Newspapers (Central) 1956.

1. Place of Publication: Bangalore
2. Periodicity of Publication: Fortnightly
3. Printer's Name and Address:
P. Balaram
Current Science Association, Bangalore 560 080
4. Publisher's Name, Nationality and Address:
P. Balaram
Indian
Current Science Association, Bangalore 560 080
5. Editor's Name, Nationality and Address:
P. Balaram
Indian
Current Science Association, Bangalore 560 080
6. Name and Address of the owner:
Current Science Association
Bangalore 560 080

I, P. Balaram, hereby declare that the particulars given above are true to the best of my knowledge.

Bangalore
1 March 2011

(Sd/-)
P. Balaram
Publisher, *Current Science*