

to the *Bt* cotton project): transparency of the regulatory process, and IPRs.

- *Pest resistance in Bt cotton*: While pest resistance is a general issue, resistance to *Bt* crops may evolve faster than to traditional pesticides, therefore management plans need to be clearly laid out at the outset (see my response to Barwale's comments).

- *Ecological impacts and GE*: A recent review (Wolfenbarger, L. L. and Phifer, P. R., *Science*, **290**, 2088–2093) states that '... key experiments on both the environmental risks and benefits are lacking. The complexity of ecological systems presents considerable challenges for experiments to assess the risks and benefits and inevitable uncertainties of genetically engineered plants'. Therefore, rather than dismiss the potential for negative environmental impacts, regulatory procedures should ensure that the potential risks and any corrective measures are initially spelt out so that appropriate monitoring can be done, with follow-up as necessary.

- *Availability of information*: Bhatia questions my use of newspapers as a source of information after having commented on distorted facts in the media. This fact reinforces my point that information needs to be accessible: I had to use newspapers largely because other sources of information on these matters are not easily accessible to someone not directly involved in this work. I strongly urge the Department of Biotechnology and the Department of Environment to make public information on developments at various stages of the regulatory process, via a website, as done in the US by the United States Department of Agriculture (e.g. <http://www.aphis.usda.gov/bbep/bp/>) and Environmental Protection Agency (e.g. <http://www.epa.gov/fedrgstr/index.html>).

- *Intellectual Property Rights*: Bhatia notes that many Indian farmers fear the entry of multinational corporations (MNCs) into seed production in India since, to them, it spells the end of seeds as public goods (and he feels that the need to be globally competitive outweighs such concerns). The issue of IPRs is intimately tied up with the advent of MNCs, and this nexus of forces is feared by many people. These fears are likely to recur unless it is clear that the public interest is held above other interests. Contrary to common impression, there

are a few signs that the dreaded 'terminator technology' is a thing of the past (e.g. Rafi, Suicide seeds on the fast track, http://64.4.69.14/web/allpub-display.shtml?pf1=com-list-all_param), and the public should continue to be aware of such facts. Other patent-associated problems, such as surrounded carotene-enriched 'golden rice', need to be addressed: e.g. 'Enabling Technologies', at the Centre for the Application of Molecular Biology to International Agriculture (http://www.cambia.org/main/r_enab_tech.htm). All options should be explored in imaginative ways and not foreclosed in an attempt to save time.

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***Bt*-cotton: Government procedures**

Geeta Bharathan (*Curr. Sci.*, **79**, 1067–1075) has touched upon several aspects of *Bt*-cotton in India, some of which are inexact and are not based on facts. It is the intention of this note to provide clarification on the working procedures of the Government on the *Bt*-cotton trial, which are elaborated below:

- Permission for conducting contained field trials for collection of data was accorded by the Department of Biotechnology (DBT) for *Bt*-cotton hybrids containing *CryIAC* gene to M/s Maharashtra Hybrid Seeds Co Ltd (MAHYCO), Mumbai and not to M/s Monsanto. All the testing and evaluation work is being done utilizing the cotton hybrids of MAHYCO, and these hybrids are designated by the prefix of MECH with a numerical suffix, but not with the designation of Bollgard.

- There was no committee headed by V. L. Chopra that rejected the induction of the *Bt*-cotton technology at any stage. The initial negotiation for technology transfer between India and Monsanto was for a package comprising the supply of two constructs containing *CryIAC* as well as *CryIAb*, transformed *E. coli* competent to express these two *Cry* genes, and

transgenic cotton seeds of Coker-312 containing *CryIAC* gene, besides including training of Indian personnel in molecular biology relevant to cotton transformation. This negotiation broke down because of disagreement between the Government of India and Monsanto on financial terms of the technology transfer.

- MAHYCO's proposal for importing transgenic cotton seeds of Coker-312 containing *CryIAC* gene was for investigating step-by-step the basis for the insertion of the *Bt*-transgenic traits into Indian cotton cultivars by backcrossing using the Coker-312 as the parent line; establishing the stability of the back crossed cultivar; assessing the quantum of expression of *Bt* proteins in different plant parts; evaluating the efficacy of the transgenic plant parts against the target bollworm; assessing the environmental risks of the transformed *Bt* cultivars in Indian germ plasm; and evaluating the food safety of the *Bt*-cotton on experimental animals. This proposal was approved in the research mode to MAHYCO in accordance with the existing rules. This is consistent with the Indian Environment (Protection) Act (EPA 1986), and Rules 1989.

- It is, perhaps, therefore, not fair to state without full knowledge about the facts as has been mentioned by the author (p. 1069). 'The factors that led to the approval of a project that, superficially, appears no different from the first (rejected) project are not available to the public'. The following points are noteworthy: (a) if the earlier proposal could have been clinched, India would have been ahead of many countries in transgenic plant research, as contemporary knowledge and training in transgenic research would be fast forthcoming. (b) While the first field experiments on transgenic plants were carried out in USA in 1985, the *Bt*-cotton cultivars containing *CryIAC* gene were not yet approved in USA during the time when India was negotiating for procuring this technology. (c) Recombinant DNA technology applied to create transgenic plants in a wide range of cultivars, including cotton is not easy to master.

India has great skill in plant tissue culture and also has access to many transgenic constructs, with opportunities to transform the plant cells/calli into transgenic lines. Yet we have not been able to produce transgenic cotton lines,

as the transformation of the transgenic cells of cotton into fully grown plants has not yet been possible.

- The field trials conducted during kharif 1998 at forty locations by MAHYCO on its *Bt*-cotton hybrids were in a total area of about 5.164 acres only. No plantation was carried out by MAHYCO prior to its obtaining an approval for the conduct of the trials. All trials were conducted in accordance with an approved site plan, plantation plan and plan for collecting relevant information on parameters that are required to be measured to assess the safety as well as utility of the transgenic cultivars. All information on plantation and on data collection is documented.

- The information furnished in table 2 of the paper is not only misleading but is also biased, without any scientific basis. The author claims that implications of use of the gene are prone to the evaluation of resistance. The author has not given either the LD₉₅ values of any pest of *H. armigera* nor has she mentioned about the levels of expressions of CryIAc proteins in different plant parts. Without such information, how can one make assessment about emergence of resistance? The issue of development of resistance is a complex phenomenon and the minimum that is required to be known are the above. There is also a need to evolve a suitable IPM in order to enable the most effective use of transgenic *Bt* cultivars in the field and to evolve an agronomic practice suitable to a region in the context of target transgenic cultivars tested. This is a part of the evaluation strategies of the Government while conducting the biosafety evaluation. This part has not been appreciated by the author. Further, the extent of cross-pollination has also been a part of the evaluation process under practical conditions in the field. It is true that there will be seed setting by cross-pollination between the non-transgenic tetraploid compatible cultivars from the transgenic pollens of cotton in the adjacent cotton field. However, the implication of such cross-pollination needs to be understood. By providing a separation between the border rows of transgenic cultivars and the non-transgenic ones it will be possible to substantially trap the escape of transgenic pollens to an extent that may not be significant on any count. Such data are being generated through Indian trials.

- The statement of the author made in table 2 (p. 1071) that 'Regulatory process non-transparent' is not clear. She further states that there is 'Need for public information and vigilance'. The regulatory process is as transparent as it should be. All the contained open field experiments are documented with the map of a site plan, the planting pattern and the isolation distances. The protocols for conducting the experiments are approved by the Review Committee on Genetic Manipulation (RCGM). The applicant watches the experimental site. There is a full record of persons conducting the experiments. Any outsider willing to visit the experimental site is escorted to the site by the applicant or his nominee provided the person discloses his identity and the purpose of visit. Records are maintained about the persons visiting the experimental sites. Copies of the authorization letter embodying all these aspects are available with the District Collector of the State where the experiments are conducted. The State Government is fully kept informed about the experiments. In what way therefore, is the regulatory process non-transparent? In addition to the regulatory authorization for the conduct of such experiments, DBT has convened several public meetings and has given statements to the press about these experiments.

- The toxicity and allergenicity information on *Bt*-cotton was generated by MAHYCO on the basis of the directives of the RCGM as such information on ruminants (goat model) was not yet available anywhere in the world. Similarly, allergenicity information was also not available, but was generated in Brown Norway (BN) rats. The information so generated did not show any additional risks from the use of *Bt*-cotton compared to its non-*Bt* counterpart.

- The author has stated (p. 1074) that 'Recapitulating points made earlier in the paper: the protein coded by this gene' (*CryIAc*) 'is known to be most toxic to the tobacco budworm, which is not a major pest of cotton in India. In laboratory studies *H. armigera*, a major Indian pest, is known to be variably susceptible to CryIAc protein, and can very quickly evolve resistance under selection'. This point is admittedly a relevant one and therefore, Indian experiments include the elaboration of the LD₉₅ values for different Indian *H. armigera* along with the

levels of expression of CryIAc proteins at different cotton plant parts at different ages. Unless the target *Bt*-cotton plants consistently express CryIAc proteins well above the LD₉₅ values, it would not be useful to introduce such cultivars in commercial agriculture. In addition, as stated earlier, sound IPM strategies would also be built in to delay the emergence of resistance in *H. armigera*. It is pointed out in this context that management of the menace of *H. armigera* costs the country close to Rs 1100 crores annually. Strategies to cut such costs can in no way be belittled and ridiculed.

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Response:

I thank Ghosh for clarifying aspects of the regulation of the *Bt*-cotton project. It was precisely because accurate information is not readily available to the public that I presented my own understanding as gleaned from 'mere' newspaper reports of regulatory issues, and it is good to have at least a partial straightening of the public record. However, I am disappointed in the lack of answers to many technical questions raised in the paper.

- *MAHYCO vs Monsanto*: Ghosh has clarified that the major reason for non-approval of the Monsanto project was due to financial aspects. According to him, approval of the Monsanto project would have enabled India to be 'ahead of many countries in transgenic plant research as contemporary knowledge and training in transgenic research could be fast forthcoming'. He points to the absence of transgenic cotton in India as indication of a deficiency in indigenous expertise to do this. Perhaps others could comment on this statement?

- *Information in table 2*: Ghosh states that the 'information' in table 2 is misleading 'without scientific basis'. The only 'information' there is under column I (features of the *Bt*-cotton project), the other two columns containing questions