

## ***Bt-cotton in India: Anatomy of a controversy***

*Geeta Bharathan*

*The farmers' protests against field trials of genetically engineered Bt-cotton in India highlighted the controversies surrounding genetic engineering technology in agriculture. Molecular biological, organismal, ecological and societal issues surrounding the Bt-cotton controversy are examined in order to identify the level of organization at which known and potential problems arise and, thereby, to suggest the level at which such problems are best addressed. The analysis suggests that information available to the public was incomplete, irrelevant, or obfuscated such that the technological and societal issues were neither well characterized, nor well separated; scientists have an important role in making available undistorted information to the public, thus enabling informed, democratic decision making.*

THE application of modern genetic engineering technology in agriculture, or the use of transgenic plants, is a controversial issue. The technology is strongly promoted by agricultural and other plant scientists, commercial interests, and governments of both developed and developing nations, who believe that it provides the only means of producing enough food to feed people. It is strongly opposed by environmentalist groups and several non-governmental organizations (NGOs), while greater caution in its application is advocated by others,

including many scientists. The promise and problems highlighted by discussions on the issue make up a complex set of technological and societal issues. Although societal issues are often in the forefront in developing nations, much of the debate regarding applications of genetic engineering (GE) in agriculture is conducted (especially in the media of developed countries) as if the issues involved were purely technological (i.e. molecular, organismal or ecological). There appears to be a polarization of the debate across the developing/developed nations.

Despite this apparent polarization, disparate groups across the world have united in protests against GE and seed corporations promoting GE. Monsanto, a multina-

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Geeta Bharathan is in the Department of Ecology and Evolution, State University of New York, Stony Brook, NY 11794-5245, USA.  
e-mail: geeta@life.bio.sunysb.edu

tional corporation (MNC) based in USA, was a particular target of strong protests that had one focus on the Indian *Bt*-cotton GE project. Monsanto introduced a gene coding for *Bt*, a protein in the bacterium *Bacillus thuringiensis*, into cotton using genetic engineering methods. This protein is selectively toxic to insects in the group Lepidoptera (including butterflies and moths). The cotton variety so developed, Bollgard, produces the toxin in all parts of the plant such that major insect pests of cotton are controlled, thus reducing the amount of pesticide used. Recently a decision was taken in India to test the efficacy of *Bt*-cotton using Bollgard cotton. Given the importance of cotton and the intensity of pest infestation in India, *Bt*-cotton trials were considered to be a justifiable experiment. However, this experiment led to a controversy within India that had repercussions across the world.

Aspects of the controversy are examined in this paper. First, major events directly associated with the controversy are identified in order to establish a context for the '*Bt*-cotton case'; second, the *Bt*-cotton case is analysed by listing and classifying its major features to the appropriate level of organization (molecular, organismal, ecological, or societal). Questions arising from implications of each feature are similarly classified according to the levels at which they arise, thus suggesting the level at which answers should be sought. Finally, these insights into the events surrounding the controversy and the features of the project are combined to identify gaps in public understanding of the technology. It is concluded that these gaps contributed in a major way to the controversy, and that closure of such gaps, in the public domain, will be crucial for informed public understanding of this and similar projects in the future.

## Background

### *Cotton pests*

Cotton is a traditional crop in the peninsular regions of India. In recent years, with introduction of new varieties and pesticides, its cultivation has extended beyond these regions<sup>1</sup>. Pest infestation has intensified: major pests are *Helicoverpa armigera* (American bollworm), *Spodoptera litura* (armyworm) and *Bemisia tabaci* (whitefly)<sup>2</sup>. Insect pests currently reduce cotton yields by 50 per cent, 70 per cent of all pesticide use is in cotton, and 50 per cent of production costs in cotton is in pesticides<sup>2,3</sup>. The incorporation of genes for pest resistance into cotton is a GE programme that could greatly benefit cotton cultivation in India.

### *Biosafety regulations*

The Government of India instituted regulations in 1990 that would screen, approve, and monitor projects in bio-

technology. Basic and small-scale research was to be overseen by the Department of Biotechnology (DBT), while large-scale tests and release were to be overseen by the Department of Environment, Forests and Wildlife (DOE). A reading of the regulations suggests that they were drawn up largely with genetically engineered microbes in mind<sup>4</sup>. The guidelines were modified to take into account the increased use of transgenic plants. The modified guidelines recommend that greenhouse and limited field trials in the open environment be done for 'at least one year with minimum of four replications and ten locations in the agro-ecological zone for which the material is intended'. These trials would be evaluated by the Review Committee on Genetic Manipulation (RCGM), under DBT, which would then recommend to the Genetic Engineering Approval Committee (GEAC), under DOE, whether the transgenic plant should be released for large-scale trials. Permission for up to four years for the large-scale use was linked to required monitoring of these large-scale tests<sup>5</sup>. Presumably, results of this monitoring could result in non-renewal of permission after the period of four years.

### *The Bt-cotton controversy: Sequence of events*

At least three threads are intertwined in this story: implementation of biosafety regulations and approval of the *Bt*-cotton project proposed by Mahyco (an Indian seed company partly owned by Monsanto), worldwide publicity regarding the 'terminator' gene technology, and suicides by cotton farmers in Warangal district of the southern state of Andhra Pradesh. The sequence of relevant events is summarized in Table 1.

### *Bt-cotton: Importation and biosafety regulation*

A DBT committee evaluated an application from Monsanto for permission to test Bollgard cotton in India in 1990. That committee (headed by V. L. Chopra, Indian Agricultural Research Institute, New Delhi) rejected this application for two reasons: (1) the technology fee demanded was ridiculously high, and (2) the strategy of back crossing an American variety to a local variety was rife with problems associated with traditional breeding programmes, e.g. unknown, multiple effects of unknown interactions between the genes of two different varieties. The committee felt that it would be better to introduce the *Bt*-gene directly into the local variety<sup>6</sup>.

Mahyco, a flourishing seed company located in Maharashtra, applied for permission during 1996 to import seeds of Bollgard cotton from Monsanto in order to backcross that variety into local varieties and then to test the efficacy of this *Bt*-cotton in India<sup>7</sup>. Apparently this proposal was more acceptable to the second DBT committee (of which Chopra was not a member), which

**Table 1.** Chronology of three separate sets of events that contributed to farmers' protests against field trials of genetically engineered *Bt*-cotton in India

Key events during 1990s	
<i>Bt</i> -cotton: Importation and biosafety regulation	
Monsanto refused permission to back cross Bollgard into local varieties to get <i>Bt</i> -cotton	1990
Mahyco given permission to import and backcross Bollgard into local varieties to get <i>Bt</i> -cotton	1996
Monsanto acquires 26% stake in Mahyco	April–May 1998
Mahyco given permission to plant <i>Bt</i> -cotton	27 July and 5 August 1998
<i>Bt</i> -cotton planted (in Andhra Pradesh, Karnataka, Haryana, Punjab, Maharashtra)	June–July 1998
Statements from Ministry of Agriculture: No terminator genes present in <i>Bt</i> -cotton	15 July 1998, 2 December 1998
<i>Bt</i> -cotton trials become public knowledge	16 November 1998
'Terminator' technology	
Exposure by RAFI	March 1998
Publicity in Indian press	June 1998
US files patent plea for terminator gene in India	29 December 1998
<i>Cotton farming in Andhra Pradesh</i>	
Extension into non-traditional area	1980s
Farmer suicides (Warangal district)	1997, 1998, 1999 (500 deaths by May 1999)
<i>Protests against Mahyco–Monsanto field trials</i>	
Burning of crop in <i>Bt</i> -cotton trial field, Karnataka	28 November 1998
Burning of crop in <i>Bt</i> -cotton trial field, Warangal district, Andhra Pradesh	2 December 1998

granted permission to Mahyco to do the experiments. The factors that led to approval of a project that, superficially, appears no different from the first (rejected) project are not available to the public. One factor might be the fact that a MNC made the application in the first instance, while an Indian company did so in the second. Two facts that may be relevant: one, early in 1998, Monsanto obtained permission from the Government of India to acquire 26% stake in Mahyco and was thus a direct participant in the trials (*Hindustan Times*, 10 May 1998); two, Mahyco is the world's largest producer of hybrid cotton seeds, and since 1964 has supplied the world with 300 hybrid varieties of rice, wheat, corn, sorghum, oilseeds and vegetables<sup>8</sup>. Mahyco is not a minor player in agri-business, nor, apparently, any kind of victim in this project.

Field trials of Bollgard cotton backcrossed into local cotton varieties over a period of two years were in place, in 40 plots of 1 acre each, by June–July of 1998 in Andhra Pradesh (including Warangal district), Karn

taka, Maharashtra, Haryana, and Punjab. Formal approval for the field trials was officially given to Mahyco by DBT in July–August 1998. Thus, the approval came after the GE plants already were in the field, raising questions regarding the legitimacy of the field trials<sup>1</sup>.

### *Terminator technology*

The Rural Advancement Foundation International (RAFI), an organization based in Canada, in March 1998 uncovered and publicized a new GE technology developed by the US-based Delta and Pine Land Company with funds from the United States Department of Agriculture (USDA)<sup>9</sup>. The purpose of this 'technology protection system' is that '... it protects specific plant varieties with genetically engineered desirable traits from unauthorized regeneration and ensures benefits sharing for those who accomplished the improvements' (USDA)<sup>9</sup>. In effect, this technology, dubbed 'terminator' technology by RAFI, inhibits germination of harvested seed, thus preventing farmers from sowing that seed for a second crop. In response to widespread alarm regarding the socio-economic implications of the technology (e.g. *Indian Express*, Monday, 8 June 1998) Paroda, Director-General of the Indian Council for Agricultural Research made a statement that 'We will not allow the Terminator to enter this country'. In the context of other concerns regarding GE (e.g. potential bio-safety issues such as allergenicity and 'superweed' evolution) there was a heightened sensitivity in India to issues surrounding GE applications in agriculture, in particular among activist groups (e.g. Karnataka State Farmers Association led by Nanjundaswamy) and NGOs. While the societal implications of the 'terminator' were under intense public discussion in India and elsewhere, USDA filed a patent plea for this technology in India late in December 1998.

### *Cotton farming in Andhra Pradesh*

Cotton farming was introduced in the late 1980s into Warangal district, a region that traditionally grew food crops. The area under modern varieties of cotton grew rapidly during the following period. This modernization is associated with intense pest infestation; often the combination of having to invest in expensive, certified hybrid seeds, pesticides and other chemicals places small farmers under the debt of merchants who often sell the farmers adulterated pesticides or substandard seeds. Many small farmers cannot handle such high levels of debt, and as a result many resort to suicide as a way out of insurmountable problems<sup>10</sup>. This pattern of modernization is seen across the southern states of Andhra Pradesh and Karnataka and contributes to fears of indebtedness, uncertainty, and failure often associ-

ated with the adoption of modern technology by small farmers in particular.

### *Protests against Mahyco–Monsanto field trials*

The kindling was in place towards the end of 1998: a combination of failed cotton crops in Andhra Pradesh (especially Warangal district) and Karnataka due to heavy pest infestation and ineffective, intensive pesticide applications, heightened sensibility regarding 'terminator' technology and consequent political activism against it. The match that lit the fire was struck when the existence of *Bt*-cotton field trials was revealed to the Indian public in November 1998. GE was equated with the 'terminator' technology in the public mind, and eventually this led to the destruction of *Bt*-cotton trial fields in Andhra Pradesh and Karnataka. The facts that *Bt*-cotton did not contain the dreaded 'terminator' gene and that the widely publicized suicides were not related to the trials of genetically engineered *Bt*-cotton perhaps were irrelevant in the context of the frustrations so frequently faced by small farmers in their attempts to modernize their agricultural experience. This frustration, apparently, found expression in a rage that led to conflagrations in the fields in November and December 1998. These events subsequently led to demonstrations against Monsanto by Indian farmers in Europe: the Inter-Continental Caravan of protest against the World Trade Organization headquarters in Geneva, the European Commission in Brussels and the Organization of Economically Developed Countries in Paris, during summer of 1999.

### *Bt cotton: The project and the controversy*

Can these events be used to understand the forces that underlie the controversy and those that underlie the decisions taken to adopt this particular technology? It appears, from a superficial examination, that societal factors played an important role in igniting the controversy. It is very clear that public perception of certain facts (whether relevant or not) played a critical role, and that distortion of these facts by the media may have led to exaggerated responses by the public. Does this imply that all potential problems of this and other GE technologies are societal in nature, and so must be the solutions? As noted earlier, this would be a very different view from the one prevailing in Europe, where the technology itself is perceived to be problematic. Does the public discourse on applications of GE technology capture all, or at least major, aspects of the issue?

### *Bt-cotton: Anatomy of a GE technology*

Any attempt to determine the causes underlying the *Bt*-cotton controversy inevitably comes up against a com-

plex set of underlying factors that are, nevertheless, separable into distinct, but tightly interwoven threads. In order to determine to what extent the *Bt*-cotton case was a function of societal forces and to what extent a function of biological factors, specific features of the case are analysed and summarized in Table 2. Each feature (I) is classified according to the most appropriate level of organization: molecular biological, organismal, ecological (in the wider or agricultural context), or societal. Implications of each 'originating' factor (I) are identified to their appropriate level/s of organization (II), as are further implications and associated questions or problems (III).

The 'originating' factors and associated effects and problems are used first, to reveal the complexities of the issue; second, to identify factors contributing to the *Bt*-cotton controversy; and third, to identify criteria that may have been used in arriving at particular technological decisions. It is quite possible that potential problems (III) were taken into account by the seed company, regulatory agency, or farmer as they took particular decisions that led to introduction of the technology but there is little indication, in the public domain, that it was so. Therefore, the questions raised here are relevant not only for analysis of the past, but also for guidance in the future, since the process for approval of *Bt*-cotton for commercial cultivation is a continuing one.

### *Molecular biological features*

(1) The gene obtained from *Bt*, *CryIAC*, codes for a crystal protein normally deposited in a non-toxic precursor form in the bacterial wall. It is rendered toxic to particular insect larvae on ingestion, solubilization, activation, and absorption through the gut<sup>11</sup>. This gene is one of a large family of *Cry* genes producing protein toxins that act on a range of invertebrates; *CryI* proteins act on some Lepidopteran insects. The *CryI* proteins are each active against somewhat different (often overlapping) ranges of Lepidopterans.

Laboratory tests of the purified *CryIAC* protein find a range of responses among Lepidopterans, *Heliothis virescens* (tobacco budworm) being the most, *Helicoverpa zea* (cotton bollworm) less, and *Spodoptera* (armyworm) the least, susceptible<sup>12</sup>. For instance, LCD<sub>50</sub> (concentration of *CryIAC* protein at which there is 50% mortality) for *H. virescens* was less than 10 ng/cm<sup>2</sup>, and for *H. zea* between 100 and 1000 ng/cm<sup>2</sup> (ref. 13). In *H. armigera* (American bollworm) LCD<sub>50</sub> varies between 20 and 200 ng/ml, compared to *H. virescens* with 10 to 30 ng/ml (refs 14, 15). Intraspecific variation in response is high in *H. zea*, *H. armigera* and *S. exigua*<sup>16–18</sup>. The low susceptibility to *CryIAC* observed in *S. exigua* (beet armyworm) may be extended to *S. litura* (the armyworm in India), a prediction

**Table 2.** Features of the *Bt*-cotton case and their ramifications. Each feature (I), its implications (II), and further implications and associated questions or problems (III) arising in the Indian context are classified to the appropriate level – molecular genetic (M), organismal (O), ecological, including agricultural (E), or societal (S)

I. Feature	II. Implication	III. Further implications and questions
<i>Molecular biological</i>		
<i>CryIAC</i> gene in cotton	Toxic to major pest <i>H. armigera</i> , expect small effect on <i>Spodoptera litura</i> ; no effect on <i>Bemisia</i> ; wide range of variability in response of <i>H. armigera</i> populations	<i>CryIAC</i> resistance in <i>H. armigera</i> prone to evolve; gene ineffective against other major pests: strategies to monitor, manage resistance to <i>Bt</i> ; manage outbreaks of other pests? <i>CryIAC</i> not best gene in Indian context?
(M)	(O, E)	(O, E)
<i>CryIAC</i> gene engineered to be expressed constitutively in cotton plant	Soluble protein expressed at all times in all parts has no effect on plant; continuous selection pressure of toxin on insects: expect evolution of resistance in pests (especially those with variable response)	Strategies to manage resistance to <i>Bt</i> in pest? Monitor expression of protein in plant? Cost-benefit analysis of loss of <i>Bt</i> , an effective, environmentally benign pesticide? Effect on natural populations of Lepidopterans?
(M)	(M, E)	(E, S)
<i>Organismal</i>		
Bollgard, American <i>Bt</i> -cotton variety back-crossed (over a 2-year period) into local Indian cotton variety to generate <i>Bt</i> -cotton being tested in field	Not simple case of introducing specific gene with a known effect. Sufficient period for effective screening?	Has disadvantages of traditional breeding: what advantage? Difference between Monsanto (1990) and Mahyco (1996) projects? Appropriate project design?
(O)	(O)	(O, S)
<i>Ecological</i>		
Scale of trials: 1 acre plots Period of trials: 2 seasons	1 acre tests too small? 1 to 2 seasons too short?	Appropriate project design?
(E)	(E)	(E)
Significant chance of cross-pollination 6 to 25% (up to 50%)	Transfer of pollen from crop to other varieties and wild relatives	Baseline data available? Risk assessment of gene transfer?
(E)	(E)	(E, S)
<i>Societal</i>		
No technology fee	Economic benefit to Mahyco	Other costs down the line? (cost of pest resistance to <i>Bt</i> )
(S)	(S)	(S)
Regulatory process non-transparent	Suspensions in public mind; legality in question	Need for public information and vigilance
(S)	(S)	(S)
Farmers' lack of familiarity with pests in new cotton-growing areas	Inappropriate pest management	Ineffective transfer of technology?
(S)	(E, S)	(S)

confirmed in unpublished observations cited in a recent study<sup>15</sup>. *Bemisia* (whitefly), a non-Lepidopteran insect, is not expected to be affected by the protein. The variable response of *H. armigera* to the CryIAC protein suggests a potential for rapid evolution of *Bt*-resistance in the major cotton pest, as demonstrated in the laboratory<sup>15</sup>.

Several questions arise: Has toxicity of *Bt*-cotton been tested under controlled field conditions in India? Were such tests part of the field trials approved by DBT? What can be expected of CryIAC introduced into Indian varieties via Bollgard? The initial results were contradictory: on the one hand, suggesting that *Bt*-cotton is susceptible to *H. armigera*, and on the other,

that 'initial data from the field trials in India suggested that Bollgard cotton had 14 to 38 per cent greater yield and required fewer sprayings of insecticide and pesticide'<sup>19</sup>. These results may reflect the wide range of response with a demonstrable geographic distribution noted in natural populations of *H. armigera*. It appears that *Bt*-cotton expressing CryIAC protein is neither consistently resistant to the most common pest, nor is it effective against other major pests: is it the best gene in the Indian context?

These constitute organismal and ecological level questions regarding the variability of natural populations of cotton pests, and overall effectiveness of the *CryIAC* gene.

(2) A modified version of *CryIAC* gene was engineered into cotton to produce the truncated, solubilized protein at all times and in all parts of the plant. The effect of this constitutive expression on the plant itself is thought to be negligible. There may be little chance that ingestion of large amounts of the solubilized protein (as found in *Bt*-cotton) will have an adverse effect on mammals. This proteinaceous toxin gets broken down by acidic gastric juices (as in mammals) and heat (during cooking). The *Bt* crop is therefore assumed not to pose a danger if ingested by mammals, and current testing procedures in the US apparently depend upon these facts, as well as acute high dose oral toxicity testing<sup>11,20</sup>. The US population's (involuntary) experience of ingesting *Bt* corn suggests that there are no detectable effects.

In the past, *Bt* toxin was used in agriculture in the form of bacterial sprays. It was applied at specific points in the crop cycle, and the protein mostly degraded, fairly quickly, in the soil. Thus, the Lepidopteran insects in the environment were faced with the toxin in large concentrations for short periods of time, which would make it harder for *Bt*-resistance to evolve in the insect. With GE crops, the toxin is produced at all times, thus representing a selection pressure that is continuous in time.

In the laboratory, *Heliothis* may develop resistance to CryIAC in a variety of ways, some of which confer resistance to a broad range of Cry proteins; this species is estimated to have a high frequency (1:1000) of individuals carrying a gene for resistance<sup>21</sup>. That is, the potential for evolution of resistance is higher for *Bt* than for conventional pesticides; this is likely to be higher in *H. armigera*, given reported variability of natural populations and rapid evolution of resistance in the laboratory. Appropriate strategies need to be adopted to manage resistance. The most effective strategy may be to plant non-*Bt* cotton as refuges for susceptible individuals and to ensure high levels of expression, so that hybrids are unable to survive at those doses, thus reducing the rate at which resistance evolves<sup>21</sup>. Therefore,

rather than being broken up in time (as in traditional use of *Bt*) the selection pressure is to be broken up in space through the creation of refugia, whose size would be based upon knowledge of the insect, its propensity for resistance, dosage of toxin, and other biological details. Such strategies are likely to delay the spread of resistance. As noted above, *Helicoverpa* is less susceptible than *Heliothis* to CryIAC and shows a wider range of response; therefore it is more likely to evolve resistance when faced with continuous selection pressure. Selection pressure in the form of CryIAC may render *H. armigera* resistant to other, potentially more effective *Bt* genes such as CryIAb<sup>21,22</sup>.

What mechanisms will be set in place to ensure effective management of resistance in India? The success of programmes that include the creation of refugia depends on high levels of expression of the toxin in the crop. Do the backcrossed *Bt*-cotton varieties express the protein at such high levels? Does expression differ among varieties? Has this been monitored under different conditions? If *S. litura*, a pest next in importance to *H. armigera*, is not controlled by *Bt*-cotton (see above), then it may become a major pest. What strategies are in place to prevent this from happening? Does the cost-benefit analysis take into account the potential loss in efficacy of a specific, environmentally benign pesticide such as *Bt*? Given that many of the current pest problems may be the result of indiscriminate use of conventional pesticides, the need to effectively address this serious issue has been recognized (e.g. *Businessline*, 5 January 1999), but there is little indication of how it would be addressed. What will be the effect of this continuous pressure on other Lepidopterans, both benign and beneficial?

These constitute organismal level questions regarding the amount of protein expressed, ecological level questions regarding the evolution of pesticide resistance and strategies for its management, and societal level questions regarding cost-benefit analysis.

### Organismal features

The *Bt* gene was imported into India in the form of 100 g of Bollgard seed<sup>23</sup>. The gene was incorporated into local Indian varieties through backcrossing, presumably over a period of two years starting in 1996; these back-crossed varieties were tested in the field over a period of two years (1998–2000).

The back-crossing programme of Mahyco–Monsanto for incorporating the *CryIAC* gene in Bollgard into Indian varieties represents a traditional breeding programme with the stated disadvantages of unknown, multiple effects of unknown interactions in the genome. At least some of the arguments for genetic engineering (e.g. rapid, efficient and predictable transfer of a spe-

cific gene into an established variety) do not hold in this instance. India has the technical expertise to incorporate the appropriate gene directly into local varieties: given this, what was the rationale for approving the project? Were two years of backcrossing sufficient time to evaluate stability of the back-crossed varieties before field trials began? What are the Indian varieties used in the back-crossing programme? How were these varieties chosen? There is no public discussion of these questions, although they include issues that, apparently, led the first DBT committee to reject an application from Monsanto to conduct similar tests. Was it just the fact that an Indian company (Mahyco) made the second proposal that made it acceptable in DBT's eyes, or was the second proposal substantially different from the first one?

These constitute organismal level questions regarding the rationale and efficacy of the back-crossing programme, and societal level questions regarding regulatory procedures, e.g. details of approval of the Mahyco project.

### *Ecological features*

Field trials of *Bt*-cotton were conducted on 1 acre plots in approximately 40 locations during two seasons<sup>19</sup>.

It is not known whether the size of plots and number of locations is adequate for the task of making informed decisions regarding the effectiveness of *Bt*-cotton in the field. The small-scale trials of *Bt*-cotton were found acceptable by RCGM, a committee under DBT, and Mahyco is now authorized to apply to GEAC, a committee under DOE for permission to conduct large-scale trials (*Businessline*, 1 May 2000). In a study of GE crop trials, even 100 acre trial areas in the US were considered to be too small for safe extrapolation from field trials to large-scale cultivation<sup>24</sup>. Admittedly, conditions in the US cannot be extended to those in India, but the question remains: are these trials adequate to justify approval of large-scale trials that will be the next step?

Cotton is largely self-pollinated, but 6 to 25% (and up to 50%) cross-pollination may occur<sup>25</sup>. There is a strong possibility that pollen (and with it the introduced genes) would be transferred from the GE cotton to neighbouring fields<sup>26</sup> and, possibly, to wild relatives of cotton. This possibility has not been ignored<sup>27</sup>; however, the question remains: are there sufficient baseline data to assess the conditions under which pollen transfer might occur and the consequences of such gene transfer, and to determine methods to evaluate these consequences and reduce the chances of transfer?

These constitute ecological questions regarding the design, scale, and duration of field trials, and occurrence of cross-pollination, and ecological and societal questions regarding assessment of risks associated with

cross-pollination, and measures to prevent it from occurring.

### *Societal features*

Societal features that played into the building up of the *Bt*-cotton case are numerous and complex; these are beyond the scope of this paper, but have been discussed effectively elsewhere<sup>1,10,28,29</sup>. Three features that illustrate different aspects of a complex problem are discussed here briefly. The first, the fact that no technology fee was charged by Monsanto, applies specifically to the *Bt*-cotton project; the second, the non-transparent nature of the regulatory process, applies generally to the regulation of genetic engineering in India; and the third, non-traditional cotton farmers' inexperience with cotton pests, applies to the larger problem of modernization and globalization of agriculture.

The absence of a technology fee for transfer of *Bt*-cotton is a direct economic benefit to Mahyco and, indirectly, to India in that the initial research has already been done at no cost to the government. However, as noted above, there may be other costs in the future, e.g. when resistance to *Bt* evolves in the pest. A complete balance sheet should take into account the short-term benefit of saving on pesticides versus the long-term cost of losing a valuable pesticide (*Bt*) due to evolution of insect resistance; costs to farmers who cannot afford to buy the GE seeds and whose crops in fields adjacent to the GE fields may provide refugia for the insects that cannot feed in the GE fields; and the short- and long-term benefits to the seed company that sells the seed. These factors should be considered before final approval for large-scale cultivation is given.

The consequences of having a non-transparent regulatory process are obvious. It leads to suspicion and misconceptions in the public mind, and distortions in the media. To the extent possible, decisions that affect the lives of large sections of the people should be open to scrutiny. As a result of the controversy, the application and efficacy of bio-safety regulations has been questioned. A public interest litigation against DBT, Monsanto and Mahyco has been admitted in the Supreme Court of India. The petitioner, the Research Foundation for Science, Technology and Ecology claims that bio-safety regulations were flouted starting from the initial importation of Bollgard seeds, and continuing to the, just concluded, open field trials (*Businessline*, 16 November 1999). In the meantime, DBT has permitted Mahyco to apply to the DOE for permission to conduct large-scale field trials. It is hoped that the committee will take into account the types of questions being raised here before it gives its approval.

Farmers' lack of familiarity with different types of pests in cotton contributed to inappropriate management

of pests, suggesting lacunae in the effective transfer of technology. These and other such factors, such as the circumstances that led to farmer suicides, even though not directly related to the *Bt*-cotton technology, were important in the development of the controversy. The experiences of these farmers may be the result of an insufficient base for modernization of agriculture: education, technical support, finance, and equitable markets<sup>10,28,29</sup> and may also reflect some of the problems generated by the globalization of agriculture<sup>1</sup>.

These constitute societal level questions regarding the long-term costs of pesticide resistance, procedural and legal issues in the regulatory process, and the effective transfer of new technologies.

It is possible that answers to some of the questions posed above already are available, while others can only be answered as a result of field and other trials that are still being conducted. It is important that the regulatory process be completely transparent and that the public remain alert to the entire process of testing and future large-scale trials.

#### *Bt-cotton controversy: An assessment*

Does this analysis of the *Bt*-cotton project at different levels allow an understanding of the controversy that it generated? Of the features listed in Table 2, the choice of gene, non-transparent regulatory process, and ineffective transfer of technology may be the main contributors to events that led to violent protests against Monsanto.

A fourth feature, fear of 'terminator' technology, which played a significant, possibly overriding, role in the *Bt*-cotton controversy is not listed in the table since that technology is not a feature of the *Bt*-cotton project. However, it is a technology that is intimately tied in with the application of intellectual property rights (IPRs) in biological systems and, thereby, has far-reaching implications. The chain of consequences in this case starts with a societal factor: the need to ensure that monetary benefits of GE in agriculture go to those who develop GE seeds, thus leading to 'terminator' technology. The harvested seeds do not germinate and, therefore, cannot be used to sow the next crop, thus ensuring that the desired traits are kept under the control of the GE seed manufacturer. It should be noted that this technology could be useful, ecologically, to check the spread of introduced genes when there is a chance of outcrossing. A comprehensive discussion of this technology and its implications is beyond the scope of this paper, but two points may be noted: one, a clearly identifiable societal force (need to secure IPRs) fueled the patenting of the particular technology ('terminator' technology), and two, reaction against this societal force largely fueled the protests whose target became the technology itself.

The first three features listed appear to be the only ones in Table 2 with direct effects on public perception of the technology. Non-transparency of the regulatory process and ineffective transfer of technology are general societal features that have obvious societal consequences not specific to the *Bt*-cotton project; the choice of the gene, *CryIAc*, is the only feature that is intrinsic to the *Bt*-cotton project. Recapitulating points made earlier in the paper: the protein coded by this gene 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. Susceptibility in the laboratory may or may not extend to *Bt*-cotton in the field: detailed results from the two years of field tests are not available, although newspaper reports suggest differences in response between the two years and considerable variation in response to *CryIAc* has been observed in natural populations of *H. armigera*.

Several questions arise in this context. Was pest infestation during the first year of trials due to *H. armigera* (whose susceptibility to *Bt* is known to be highly variable), *S. litura* (which may be least susceptible to *Bt*), or whitefly (which is not expected to be affected by *Bt*)? Were the two years of trials similar with regard to types and levels of pest so that they are truly comparable? Were controlled tests conducted to establish susceptibility of *H. armigera* to *Bt*-cotton in the field in India? If infestation was by *H. armigera*, was susceptibility due to variability among insect populations or to low levels of expression of the protein toxin? If, indeed, suitability of the gene has not been established for Indian conditions, then choice of this particular gene may have contributed to the apparent failure of some of *Bt*-cotton field trials. The need for vigilance against the uncritical import of particular technologies is underlined by recent reports on research in Indian agricultural institutions that is currently directed toward other *Bt* genes, *CryIAa*, *CryIAb* and *CryIF*, whose protein products reportedly are effective against *H. armigera* and *S. litura*, the major cotton pests in India<sup>30,31</sup>, and the positive experience of the use of *CryIAb* in Australia<sup>22</sup>. An overarching question emerges: why introduce the *CryIAc* gene into Indian varieties of cotton if it may not be optimal, if variability in response of the pest increases the chance of resistance evolving, and if resistance to one *CryI* gene enhances chances that the pest would also be resistant to other, potentially more effective *CryI* genes?

Several features listed (I) in Table 2 have implications leading to the possibility that the project design may be flawed at the molecular biological, organismal or ecological levels (III). In other words, some of the criteria for approval of the Mahyco–Monsanto *Bt*-cotton project may lie outside the technological considerations

explored in this analysis. This suggests that the criteria used were either other technological factors that have been (inadvertantly) overlooked here, or other societal factors not within the scope of this analysis. Answers to the questions raised here (that, no doubt, the scientists involved have considered) would allow the public to determine whether this is the case.

In conclusion, events surrounding the introduction of the *Bt* gene into Indian cotton through a programme of backcrossing generate a series of questions regarding the science, project design, and bio-safety regulations underlying the decisions that led to the adoption of the technology. These are serious questions that need to be carefully considered by scientists, policy makers, and the general public.

### Responsibility of scientists

This paper has examined both, factors underlying decisions leading to the development of a new technology and those underlying public perception of whether that technology is beneficial overall. Public perception, in part, was shaped by a small subset of the molecular biological, organismal, ecological, and societal features directly relevant to the *Bt*-cotton project; and the troubling, but not-yet-implemented 'terminator technology' that is connected with the *Bt*-cotton project only insofar as both represent a generalized 'genetic engineering' technology. Thus, public protests against the technology were based on information that was incomplete, irrelevant, distorted, or obfuscated such that the technological and societal issues were either not well characterized or clearly separated. It is imperative that assessments of the *Bt*-cotton project and future GE projects should be based on considerations in which the biological bases of the technology are clearly distinguished from societal issues such as the way, by whom, and for whom it is applied. This would be the only way to ensure a democratic decision-making process. A scientifically literate population is critically important in this process; most importantly, a socially literate population of scientists is essential to enable such democratic decision-making. There is a strong need for scientists to make specialized information readily available in an undistorted form to other scientists, the general public, policy makers, and political activists. We need to participate in the democratization of this technology by discussing it, disseminating it, and evaluating it.

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