

BEFORE THE APPELLATE AUTHORITY, NEW DELHI

(Set up under the Rule 19 of the "Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-organisms, Genetically Engineered Organisms or Cells, 1989" notified under the EP Act, 1986)

Appeal No. 2/2002

BETWEEN

Research Foundation for Science, Technology and Ecology,
at A-60 Hauz Khas, New Delhi - 110016
through its Director Dr. Vandana Shiva

APPELLANT

AND

1. Union of India through
 - (i) Ministry of Science and Technology
Department of Biotechnology
At Block-2, CGO Complex, Lodhi Road,
New Delhi - 110 003, through its Secretary
 - (ii) Ministry of Environment and Forests,
CGO Complex, Paryavaran Bhavan, New Delhi,
through its Secretary
 - (iii) Ministry of Agriculture
Krishi Bhawan, New Delhi through its Secretary
2. M/s Maharashtra Hybrid Seeds Co. Ltd.
having its registered office at 19, Rajamahahal
84, Veer Nariman Road, Mumbai- 400 020
(through its Managing Director)
3. Monsanto MAHYCO Biotech (India) Pvt. Ltd.,
221/224, "Midas", Sahar Plaza, M. Vissanji Marg,
Andheri (East) Mumbai - 400 059
(through its Managing Director)

RESPONDENTS

DATE: 8th OCTOBER, 2003

Counsel for Appellant(s): Shri Prashant Shushan, Advocate, Ms. Vandana Shiva,
Director, Research Foundation for Science, Shri Afsar H. Jafri,
Shri Narendra Verma, Advocate.

Counsel for Union of India (Respondent 1) : Shri Navin Chawla, Advocate

Ministry of Science and Technology : Dr. T. V.Ramanaiah, Scientist 'F' and
Dr. K.K. Tripathi, Scientist 'G'

Ministry of Environment & Forests : Dr. Ranjini Warriar, Addl Director

Ministry of Agriculture : D. P .Singh, Joint Manager
(Seed Division DAC) and
D.S. Mishra, Asst., Director,

Counsel for Respondents 2 & 3 : Dr. A.M. Singhvi, Sr. Advocate,
Shri H.S. Chandhoke Advocate,
Amit Bhandari, &
Prashant Pakhiddey, Advocates.
Dr. Usha Barwale, Sanjay Deshpande
(Mahyco)Dr. M.K. Sharma, MMB, Mumbai
Dr. Manjunath

ORDER

1. The appellant, the Research Foundation for Science, Technology and Ecology filed this Appeal on 12/12/2002 under Rule 19 of 'The Rules for the Manufacture, Use, Import, Export and Storage of hazardous Microorganisms, Genetically Engineered Organisms or cells 1989,' (henceforth referred to as 'The Rules 1989') against the order dated 5th April 2002 of the ' Genetic Engineering Approval Committee (GEAC) granting conditional clearance to MIS Maharashtra Hybrid Seeds Co. for three transgenic Bt hybrid cotton varieties namely Bt MECH 12, Bt MECH 162 and Bt MECH 184. There are three respondents 1. The Union of India through the Ministries of Science & Technology, Environment & Forests & Ministry of Agriculture. 2. M/s Maharashtra Hybrid Seeds Co Ltd. 3. Monsanto MAHYCO Biotech (India) Pvt. Ltd.

2. Prior to the filing of this appeal, the appellant through an IA before the Hon'ble Supreme Court sought amendment to Writ Petition (c) No. 71 of 1999 by challenging the letter dated 5.4.2002 sent by the Additional Secretary, GEAC to the Managing Director, Maharashtra Hybrid Seeds Co. This amendment application was opposed by the respondents who urged that the appellant has a remedy before the Appellate Authority under Rule 19 of The Rules 1989. As this was not disputed by the appellant, the Hon'ble Supreme Court declined to allow the amendment application. The senior counsel of the respondents stated before the Hon'ble Supreme Court that in case the appellant files an appeal before the Appellate Authority, the respondents would not raise any objection as regards the delay in filing the appeal or the 'maintainability of the appeal. The Hon'ble Supreme Court directed on 13/11/2002 that in case the appellant files an appeal within four weeks, the Appellate Authority shall entertain and decide the same on merits. As already stated the appellant in the above matter, filed an appeal before this Authority on 12/12/2002, which is now being considered.

3. The appellant and the respondents have in support of their appeal and replies filed voluminous papers and documentation. After going through the papers on record, it was decided to frame a set of issues in consultation with the learned counsels of the appellant and respondents. Consequently, the following four sets of issues were framed:

(i) Is the decision of the GEAC dated 26.03.2002 (communicated by letter dated 5.04.2002) allowing the Maharashtra Seeds Company (MAHYCO) to commercially release three varieties of transgenic Bt cotton seeds based on adequate assessment of likely hazards and consequences to the safety and health of the environment.

(ii) The Genetic Engineering Approval Committee's (GEAC's) decision of 26.3.2002 was preceded by permissions dated 27.07.98 & 05.08.98 given by the Review Committee on Genetic Manipulation (RCGM). Was the RCGM authorized to give permission for large scale field trials? If not, what effect will this have on : the decision of the GEAC dated 26.3.2002.

(iii) Would it be correct to describe the performance of the BT cotton crop in parts of Maharashtra, Gujarat and Andhra Pradesh as a 'failure' If so, does this imply that proper testing and evaluation was not carried out on the three Bt cotton seed varieties before permitting their commercial release.

(iv) Are the existing safety guidelines, procedures and monitoring mechanisms adequate for ensuring compliance with the conditions of approval for the release of genetically engineered seeds into the environment.

4. Issue No (i): The appellant has stated that because of the inherent uncertainty in the commercial application of genetically modified organisms, the grant of permission to respondent No. 2 has violated the precautionary principle. Specially, as the GEAC showed undue haste in granting permission to respondent No. 2 in contrast to it's earlier order dated 18.10.2001 through which it ordered that the entire standing crop of transgenic Navbharat-151 be destroyed on account of safety factors. The appellant has referred to some laboratory tests in other countries, which have pointed to gene flow into animals and insects through ingestion of genetically modified foods.

4.1. It has been stated that the approval of the GEAC 'is not based on any direct information or data collected from the ground level through testing or evaluation by any independent authority' An

independent evaluation is necessary as this would be impervious to the pressure of commercial interests to promote Bt cotton.

4.2. The appellant has stated that field trials in question with regard to Bt cotton 'have been conducted in an unscientific and unsafe manner. The so called isolation distances have been arbitrarily fixed and are totally inadequate to prevent pollen escape'. 'The 5 ms distance is definitely not a safe and clear isolation either in the context of preventing genetic pollution, through gene flow through pollination or preventing genetic pollution through entry in the food chain'

5. Respondent No. I has stated 'The existing regulatory framework in India with regard to the hazardous transgenic organisms is adequate and is amongst the stringent in the world. The Rules and guidelines are in consonance with the rules prevailing in other countries'.

5.1. The concerns expressed by the appellant and the reference to certain studies are not relevant to the present issue as they refer to laboratory experiments in which genetically modified foods were fed to animals and insects and those tests are not relevant to the present matter which is concerned with Bt cotton.

5.2. Respondents have submitted that amongst others, the Indian Council for Agricultural Research (ICAR) and Monitoring cum Evaluation Committee (MEC) set up under the Revised Guidelines for Safety in Biotechnology evaluated the reports emanating from tests/trials conducted on Bt. cotton which were spread over a period of six years. These tests/trials covered molecular characterization and stability of the Cry 1 Ac gene, gene flow studies and cross ability, aggressiveness studies, food/feed safety issues, allegercinity studies, agronomic benefits etc.

5.3. According to Respondent No.1, evaluation of all these studies/tests reveal that Bt cotton is safe for the environment and its use will reduce the insecticide load on the environment. 'Though 8t cotton has been approved for commercialization in several developed/developing countries for the past several years, yet the Government has deemed it appropriate to satisfy itself of the bio safety and agronomic benefits of the same before granting approval for commercialization' Approval was given by Government after evaluating tests/trials spread over a period of 6 years. Thus, there is no question of any haste in according approval and violating the precautionary principle.

6. This Authority has examined the view-points put forth by the learned counsels for the

appellant and respondents in the form of documentation and oral averment on the basis of which a decision is given on this issue.

6.1. In India 'The Rules 1989,' provide the legal and institutional framework for granting approvals for testing and commercialization of genetically engineered organisms. Rule 4 provides for the setting up of six competent authorities as indicated below;

4(1) Recombinant DNA Advisory Committee (RDAC)

This committee shall review developments in Biotechnology at national and international levels and shall recommend suitable and appropriate safety regulations for India in recombinant research, use and applications from time to time. The committee shall function in the Department of Biotechnology.

(2) Review Committee on Genetic Manipulation (RCGM)

This committee shall function in the Department of Biotechnology to monitor the safety-related aspect in respect of on-going research projects and activities involving genetically engineered organisms/hazardous microorganisms. The Review Committee on Genetic Manipulation shall include representatives of (a) " Department of Biotechnology (b) Indian Council of Medical Research (c) Indian Council of Agricultural Research (d) Council of Scientific and Industrial Research (e) other experts in their individual capacity, Review Committee on Genetic Manipulation may appoint sub groups.

It shall bring out Manuals or guidelines specifying procedure for regulatory process with respect to activities involving genetically engineered organisms in research, use and applications including industry with a view to ensure, environmental safety. All ongoing projects involving high risk category and controlled field experiments shall be reviewed to ensure that adequate precautions II and containment conditions are followed as per the guidelines.

The Review Committee on Genetic Manipulation shall lay down procedures restricting or prohibiting production, sale, importation and use of such genetically engineered organisms of cells as are mentioned in the Schedule.

(3) Institutional Biosafety Committee (IBSC)

This committee shall be constituted by all occupier or any person including, research

institutions handling microorganisms /genetically engineered organisms. The committee shall comprise the Head of the Institution, Scientists engaged in DNA work, a medical expert and nominee of the Department of Biotechnology. The occupier or any person including research institutions handling micro organisms/genetically engineered organisms shall prepare with the assistance of the Institutional Biosafety Committee (IBSC) an up-to-date on-site emergency plan according to the manuals / guidelines of the RCGM and make available copies to the District Level Committee / State Biotechnology Co-ordinating Committee and the Genetic Engineering Approval Committee.

(4) Genetic Engineering Approval Committee (GEAC)

This Committee shall function as a body under the Department of Environment, Forests and Wildlife for approval of activities involving large-scale use of hazardous microorganisms and recombinants in research and industrial production from the environment angle. The Committee shall also be responsible for approval of proposals relating to release of genetically engineered organisms and products into the environment including experimental field trials.

The composition of the Committee shall be

- (i) Chairman - Additional Secretary, Department of Environment, Forests and Wildlife.
Co-Chairman - Representative of Department of Biotechnology
- (ii) Members: Representatives of concerned Agencies and Departments, namely, Ministry of Industrial Development, Department of Biotechnology, and the Department of Atomic Energy.
- (iii) Expert Members: Director General - Indian Council of Agricultural Research. Director General - Indian Council of Medical Research. Director General - Council of scientific and Industrial Research, Director General Health Services. Plant Protection Adviser. Directorate of Plant Protection. Quarantine and storage, Chairman, Central Pollution Control Board and three outside experts in individual capacity.
- (iv) Member Secretary: An official of the Department of Environment Forest and Wildlife. The committee may co-opt other members / experts as necessary.

The committee or any person/s authorized by it shall have powers to take punitive actions under the Environment (Protection) Act.

(5) State Biotechnology Co-ordination Committee (SBCC)

There shall be State Biotechnology coordination Committee in the States wherever necessary. It shall have powers to inspect, investigate and take punitive action in cases of

violations of statutory provisions through the Nodal Department and the State Pollution Control Board/Directorate of Health/Medical Services. The Committee shall reviews periodically the safety and control measures in the various industries/institutions handling genetically engineered Organisms/Hazardous microorganisms. The compositions of the Coordination Committee shall be:

- | | | |
|--|---|------------------|
| (i) Chief Secretary | - | Chairman |
| (ii) Secretary, Department of Environment | - | Member Secretary |
| (iii) Secretary, Department of Health | - | Member |
| (iv) Secretary, Department of Agriculture | - | Member |
| (v) Secretary, Department of Industries and Commerce | - | Member |
| (vi) Secretary, Department of Forests | - | Member |
| (vii) Secretary, Department of Public Works/
Chief Engineer, Department of Public Health Engineering. | - | Member |
| (viii) State Microbiologists and Pathologists | - | Member |
| (ix) Chairman of State Pollution Control Board | - | Member |

The Committee may co-opt other members/experts as necessary.

(6) District Level Committee (DLC)

There shall be a District Level Biotechnology Committee (DLC) in the districts J wherever necessary under the District Collectors to monitor the safety regulations in installations engaged in the use of genetically modified organisms/ hazardous microorganisms all its application ill the environment.

The District Level Committee/or any person/s authorized in this behalf shall visit the installation engaged in activity involving genetically engineered organisms, hazardous microorganisms, formulate information chart, find out hazards and risks associated with each of these installations and coordinate activities with a view to meeting any emergency. They shall also prepare an off-site emergency plan. The District Level Committee shall regularly submit its report io the State Biotechnology Co-ordination Co/11miltee/Genetic Engineering Approval Committee. The District Level Committee shall comprise of:

(i)	District Collector	-	Chairman
(ii)	Factory Inspector	-	Member
(iii)	A representative of the Pollution Control Board	-	Member
(iv)	Chief Medical Officer (District Health Office!)	-	Member (Convener)
(v)	District Agricultural Officer	-	Member
(vi)	A representative of the Public Health Engineering Department	-	Member
(vii)	District Microbiologists / Pathologist (Technical expert)	-	Member
(viii)	Commissioner Municipal Corporation	-	Member

The Committee may co-opt other members/experts as necessary.

6.2. It is seen that these authorities have a wide representation of scientists, experts and others. The Rules 1989 and the mechanisms set up under them are designed to ensure compliance to a procedure with prescribed tests and evaluations prior to granting any permission for commercialization of genetically engineered organisms (GEO).

6.3. The reference to the orders of the GEAC directing destruction of the entire standing crop of transgenic Navbharat-151 is not relevant, as these Bt cotton seeds were being sold illegally. The references to ingestion of genetically modified foods by insects and animals in laboratory tests in other countries cannot override the results of specific tests/trials on Bt cotton varieties that were carried out in accordance with the directions of the RCGM and GEAC. The appellant has expressed concern about a 5m refugia not being adequate for preventing pollen escape. This has to be seen in the light of 'Cotton pollen grains are sticky and heavy, hence wind pollination does not occur. Cross pollination occurs by insects mainly honey bees and bumble bees' (Cotton Breeding Dr. Phundan Singh). Tests on pollen flow through wind in the present case have shown that it has traveled less than the 5m which has been prescribed as a safe limit. It would thus appear that for the purpose of determining cross pollination in cotton plants' insect activity is more relevant. The purpose of refugia is to create an area where non Bt Cotton is allowed to grow alongside or within a field of Bt cotton so that resistance build up to Bt is reduced. While it has been averred by the learned counsel for respondents that the need for refugia in India is low because of small holdings and diverse crop combinations, it is noted that one of the conditions of approval to Respondent No.2 is to annually

monitor susceptibility of bollworm to the Bt gene and for this purpose Respondent No.2 has entrusted this task to the Central Institute of Cotton Research (CICR).

6.4. Respondent No.1 has filed a copy of the Recombinant DNA Safety Guidelines 1990, Revised Guidelines for Safety in Biotechnology 1994 and the Revised Guidelines for Research in Transgenic Plants and Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts 1998. The appellant has not been able to establish that the above referred to tests were carried out in violation of these guidelines or that these guidelines were scientifically deficient. In the present case, Respondent No.2 was required to carry out a number of tests/trials which covered aspects such as molecular characterization and stability of the Cry 1 Ac gene, gene flow studies, crossability, aggressiveness studies, food/feed safety issues, allergenicity studies, agronomic benefits, etc. Permission for commercialization of three varieties of Bt cotton seed was granted after various studies/assessments which primarily addressed safety issues and after tests spread over a period of six years, involving agencies such as Indian Toxicology Research Centre, some State Agriculture Universities, Directorate of Biological Control (ICAR), Indian Institute of Management, Ahmedabad, Centre for Genetic Manipulation of Crop Plants, Central Avian Research Institute, Central Institute of Fisheries Education, College of Veterinary Sciences, Gujarat University and the ICAR amongst others. Prior to grant of permission by the GEAC it also considered the evaluation reports of the ICAR and MEC. The Department of Biotechnology was also closely involved with the tests through the RCGM and concerned IBSC's. None of these reports or evaluations have given any adverse findings on the safety related aspects of the three approved varieties of Bt cotton.

6.5. It is thus not established that the GEAC ignored the precautionary principle, or that such evaluations were unscientific and were the outcome of commercial pressures to promote Bt cotton. Having considered these aspects, this Authority holds that the GEAC gave its approval to Respondent No.2 for commercializing three varieties of Bt cotton after an adequate assessment of likely hazards and consequences to the safety and health of the environment.

7. Issue No (ii). The appellant has stated that under The Rules 1989, permission for release of GEO's into the environment and permission for conducting open field trials (which lead to release into the environment) as well as permission for its import can only be given by the GEAC. The permissions dated 27.7.98 and 5.8.98 granted by the RCGM and the proceedings which culminated in such permission to conduct multicentric open field trials at 25 locations in 9 States is in violation of the Rules 1989. During averments learned counsel for the appellant has invited attention to Rules

7-12 of The Rules 1989 and in particular Rules 9 & 10. It has been stated that even the Recombinant DNA Safety guidelines 1990 and Revised Guidelines for safety in Biotechnology 1994 indicate that the approval of the GEAC is required for experimental field trials.

7.1. Respondent No.1 has stated that in the meeting of the RCGM held on 6.12.1993 in which a representative of the Ministry of Environment and Forests was also present, the points of distinction in the work responsibilities of the GEAC and RCGM were discussed. 'It was agreed in this meeting that all research work including laboratory and small field experiments would be permitted and monitored by the RCGM. The RCGM was also to design the open field experiments in conditions to control the escape of transgenic seeds into the open environment. It was further agreed that only large-scale research trial in open environment would be directly controlled by the GEAC.' It has been stated that 'In the context of formally bringing the "Revised Guidelines for Research in Transgenic Plants-1998" to the notice of the GEAC in its 19th meeting held on 08.03.1999, the issue of demarcation of work between RCGM and GEAC on research in transgenic crops were also discussed and GEAC had reiterated the earlier decision taken on 06.12.1993 by the RCGM, demarcating the functions between the RCGM and GEAC as working procedures' Respondent No.1 has stated that the Revised Guidelines for Research in transgenic Plants and Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts 1998 which were issued under Rule 4(2) clearly indicate that the RCGM can authorize limited field trials in multi locations.

7.2. This Authority notes that The Rules 1989 provide a comprehensive legal framework to regulate all aspects relating to GEO's including import, export, manufacture, research, handling and laboratory tests as well as field trials. The Department of Biotechnology and the Ministry of Environment & Forests have a major and complementary role to play in the areas covered by the Rules 1989. The RCGM is responsible for monitoring safety related aspects of on going research/activities involving GEO's, bring out safety guidelines and review of high risk category and controlled field experiments to ensure that adequate precautions and containment conditions are followed as per the guidelines. The RCGM is also empowered to lay down procedures prohibiting import, production or sale of GEO's. It is however noted that subsequent to the issue of The Rules 1989, the RCGM with the concurrence of the representative of the Ministry of Environment and Forests agreed to a division of duties between the RCGM and the GEAC to the effect that the former would look at approvals involving small scale imports of GEO's and grant permission for small scale field trials, whilst the GEAC would process applications for large scale

imports and large scale field trials. This was further clarified by the Revised Guidelines for Research in transgenic Plants and Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts 1998 which were issued under Rule 4(2) and noted in the 191h meeting of the GEAC held on 8.3.1999. It is also noted that the Department of Biotechnology has been giving approvals since 1994 for contained field trials for various transgenic crops such as mustard, tomato, brinjal, tobacco, cotton and cauliflower etc. Similarly permission for import of transgenic seed materials/plants was given to a number of institutions.

It is noted that the Order of the Government of India (Allocation of Business) Rules, 1961 (as amended up to April 10th, 2003) shows that amongst other responsibilities, the Department of Biotechnology is responsible for;

2. Identifying specific programmes of Research and Development and manufacturing in biologicals and *biotechnology and oversee the initiation and pursuit of related research and manufacturing activities.*
4. Act as a screening, advising and approving agent of the Government with regard to import and transfer of new technologies for the manufacture of biological and biotechnological products and their intermediates.
6. To act as the central agency for the import of genetically manipulated materials. culture, cells, specimens, tissues and biotech products including DNA and RNA of any type or size and for promoting their production in the country.
12. Serve as the authorised department of the Government in respect of legislative and Parliamentary requirements in all areas mentioned under Allocation of Business for the Department. '

7.3. The Allocation of Business Rules 1961 envisage the Department of Biotechnology as the central agency 'for the import of genetically manipulated materials.' Para 8 of the Recombinant DNA Safety Guidelines 1990 states that the RCGM will issue permits 'authorizing the import or receipt of regulated materials for research (e.g. toxin genes, hybridomas, cell cultures, organelle)'... whilst' large scale imports for industrial use are regulated by Genetic Engineering Approval Committee'

7.4. In view of the overlapping and complementary roles of the Department of Biotechnology

and Ministry of Environment and Forests (MoEF) envisaged in The Rules 1989, the MoEF may like to define the distinctions between the roles and functions of the RCGM and GEAC more clearly in The Rules 1989.

7.5. Looking at the overall responsibilities assigned to the Department of Biotechnology under the Allocation of Business Rules, the overlapping of certain responsibilities between the Department of Biotechnology/Ministry of Environment and Forests under The Rules 1989 and that the GEAC gave its approval dated 5.4.2002 after it had considered the evaluations of large scale field trials conducted by Respondent No. 2 vide the directions of the GEAC dated 30.06.2000, 22.06.2001 and 22.08.2001, this Authority holds that the permissions dated 27.7.98 & 05.08.98 given by the RCGM do not vitiate the GEAC's decision of 26.03.2002 issued vide letter dated 05.04.2002.

8. Issue No (iii). The appellant has stated that 'the massive failure of the Bt cotton is an indication that adequate testing was not done before giving permission to the Respondent for commercial release of cotton'. It is stated that 'Bt cotton is reported to have failed due to new diseases and pest emergence in Madhya Pradesh and Maharashtra where Bt cotton was commercially introduced for the first time'. It has been stated that in Khargaon (MP) 'BT is a total failure' with the same story being repeated in Vidharbha (Maharashtra). Dr. Venugopal ex project coordinator of the Central Institute for Cotton Research has been quoted as having said while some private hybrids and varieties released earlier were resistant to curl leaf virus (LCV) Bt cotton was found susceptible to LCV. The appellant has also referred to a report from NDTV entitled 'Bt cotton a failure in Andhra Pradesh', a copy of letter from one V. S. Rao Joint Agriculture Commissioner Mahubnagar (AP) has been filed, as also a copy of a report from Greenpeace India entitled 'The real story on Bt cotton'. The appellant has stated that it i.e. Research Foundation for Science, Technology & Ecology conducted an independent study in Andhra Pradesh, Maharashtra and Madhya Pradesh. According to the appellant, this study showed that Bt cotton is not resistant to bollworm and requires higher pesticide use, pest occurrence in Bt was higher than non-Bt cotton and Bt cotton does not give higher yields.

8.1. Respondents have denied the contention of the appellant that there has been a large-scale failure of Bt cotton in India. Respondent No.2 has submitted that credence could not be placed on a study conducted by the appellant as no details had been furnished about its peer review or that it was conducted according to established standards. According to Respondent No. 1 'the performance of Bt cotton plantings were monitored by appropriate committees in various States where it was

planted' According to these repolls the performance of Bt cotton was satisfactory in terms of boll worm infestation and reduction in use of pesticides spray. Reports of visits by these committees to the States of Gujarat, Maharashtra, Madhya Pradesh and Andhra Pradesh have been filed. A study conducted by the Central Institute for Cotton research has also been filed.

8.2. This Authority has examined the documents filed by the appellant and I'. respondents on this issue. The report of Greenpeace which attempts to throw doubts on the veracity of some of the interviews with farmers during a visit by a committee of the GEAC on the 10/11 November in Andhra Pradesh does not substantiate a 'failure' of Bt cotton. As regards the study conducted by the appellant, no information or details of any peer review have been provided or the names and credentials of those who conducted this. A reading of the reports of the monitoring committees of the GEAC which visited areas in Andhra Pradesh (11-12 November 2002) Maharashtra (2-3 October 2002) Madhya Pradesh (17-18 November 2002) and Gujarat (7-8 October 2002) and Status Report on the performance of Bt cotton (SR CICR) by the Director CICR do not point to any failure of Bt cotton. A perusal of the reports of these committees and SR CICR shows the year 2002-2003 suffered a severe drought. In the surveyed areas 75% of farmers expressed satisfaction with the performance of Bt cotton. With moderate levels of pests the BT hybrids performed better than non-Bt hybrids. The number of sprays were also less in the case of Bt cotton. However in 25% cases severe parawilt was evident and farmers showed 'utter dissatisfaction', as wilting was more evident in Bt hybrids particularly in parts of Madhya Pradesh and the Vidharbha region. The problem of wilt being more in evidence in Bt plants in some areas appears to have been due to water scarcity under rain fed conditions rather than the presence of the Cry 1 Ac gene. There is also an opinion on record by Director of CICR that parawilt malady is not restricted to Bt cotton and can be universal to all hybrids. This problem needs to be addressed as suggested by the CICR by transferring the Bt gene to hardy parental lines with sufficient sucking pest tolerance. There is also a necessity for wider awareness creation as to the specific protection that Bt cotton seed provides, In view of these reasons, this Authority holds that, unsatisfactory performance of Bt cotton against parawilt etc in some rain fed areas in a period of drought does not justify a conclusion that Bt cotton was a failure. It is germane that no evidence has been produced that in the areas where performance was not satisfactory, this had an impact on the safety and health of the environment, which is the primary concern that the GEAC is required to address under The Rules 1989 prior to grant of permission for commercial release of GEO's.

9. Issue No (iv): A perusal of the Rules 1989 shows that an elaborate framework and

institutional mechanism has been created under the Rules 1989 which consists of six competent authorities with a representation of national institutions, scientists, specialists and others. Each of authorities have been assigned a *role* with responsibility for review of developments in biotechnology at national and international levels, recommendation of safety guidelines in recombinant research and application, monitoring safety aspects of research and activities involving genetically engineered organisms, preparation of on site emergency plans, review and inspection of installation as well as powers of investigative action and authority to initiate punitive action in case of violation of statutory provisions. The final link in the complement of competent authorities is at the district level in the form of the DLC. Till date, three sets of Guidelines for recombinant safety have been issued by the Department of Biotechnology as part of an ongoing process. So far only one approval for commercial release of genetically engineered seeds into the environment has been given.

9.1. Both the appellant and respondents have referred to the matter of Navbharat 151 cotton seed though in differing contexts. This points to the need for an early warning system which can detect illegal trade in genetically engineered seeds. As the field of genetic engineering in biotechnology is a complex and evolving one, there is need for both continuing vigilance on the part of concerned regulatory authorities and capacity building as the quantum of work in this area increases. This is an issue, which the GEAC may like to address.

9.2. Respondent No.1 has stated that when the Department of Biotechnology gave permission to MAHYCO to import 100 gms of transgenic seed on 30.3.1996 information was given to the Chairman of the Maharashtra SBCC and the DLC of Jalna district. When permission was given by the OBT on 10.11.1997 to MAHYCO to conduct limited field trials the Chairman of the DLC was kept informed. In compliance with conditions in the letter of approval of the GEAC, Respondent No.2 has identified the CICR for monitoring the susceptibility of bollworm to the Bt gene and has also submitted the report *for* the year 2002-2003. It has been stated that SBCC's and DLC's have been set up in 15 and 13 States respectively. Respondent No.1 has stated that subsequent to approval by the GEAC, eight awareness workshops were organized on 'Biosafety Issues Relating to Genetically Modified Organisms' in Delhi, Pune, Bhopal, Kolkatta, Hyderabad, Guwahati, Bangalore and Lucknow. A kit for verification of the Bt gene at the field level has been developed by the CICR. It is noted that the GEAC is empowered under The Rules 1989 to give approvals for a maximum period of four years at a time, renewable two years at a time. In the present matter, the GEAC has given permission for a period of three years in the first instance. The GEAC is empowered to revoke approvals if there is any new information of the harmful effects of the

genetically engineered organisms or if they cause such damage to the environment, nature or health, which could not be envisaged at the time of giving approval. The GEAC can also revoke such permission for non compliance of any condition stipulated by it. The GEAC or any persons authorized by it have the powers to take punitive actions under The Environment (Protection) Act, 1986. It is noted that compliance reporting to the conditions of approval of the GEAC order dated 5.4.2002 is satisfactory.

9.2. In view of these reasons, this authority is of the view that the existing safety guidelines, procedures and monitoring mechanisms presently appear adequate to ensure compliance with the conditions of approval.

RESULT: On consideration of all the matters as above, this appeal is liable to be dismissed and is accordingly dismissed. However, the parties are to bear their own costs of appeal.

(Vishwanath Anand)
Appellate Authority