

Decisions taken in the 73rd Meeting of the Genetic Engineering Approval Committee held on 10.1.2007.

The 73rd Meeting of the Genetic Engineering Approval Committee (GEAC) was held on 10.1.2007 at 12.00 noon in Room No. 624 in the Ministry of Environment and Forests under the Chairmanship of Shri B. S. Parsheera, Additional Secretary, MoEF and Chairman GEAC.

1.0 Action taken report on the decision taken in the 72nd meeting.

Details of action taken were placed before and noted by the Committee. During the deliberation Member Secretary, RCGM briefed the Committee on the action taken and views of RCGM on the following matter.

a) Investigation Report on alleged irregularities in GM Okra field trials at Gulbarga and Guntur Districts – Centre for Sustainable Agriculture.

The RCGM in its meeting held on 8.1.2007 expressed serious concern over the issues raised by the NGOs regarding inadequacy of the monitoring and reporting mechanism and was of the view that the revised guidelines for alternate monitoring mechanism through the SAU should be followed. The Member-Secretary, RCGM informed that the new guidelines were adopted in July, 2006 and therefore, there was a delay in constitution of the monitoring teams and processing of papers relating to these activities. However, the new guidelines would be made effective in the forthcoming years as the new mechanism has been put in place. Further, there is no need for any investigation at this stage on the alleged irregularities of GM Okra since the crop has already been uprooted as informed by the applicant.

To strengthen the monitoring mechanism with a view to make it transparent and effective the Committee noted and endorsed the following recommendations of RCGM with certain amendments:

- i. The state level and district level committees should be constituted in all the states which can oversee more closely the approved GMO field trials in different places and, therefore, GEAC may be requested to ensure that the constitution of SBCCs and DLCs are in place in all relevant states.
- ii. RCGM desired that while conducting multilocation field trials, the applicants should submit full details of the crops, sites, coordinator of the field trials etc. to the concerned authorities well in advance. It should also be available in their websites. As per the present system, DBT/ MoEF sends a copy of permission letters on field trials to concerned State Agriculture Secretaries and Directors of Research for information. The Member Secretary, GEAC clarified that in the previous GEAC meeting held on 13.12.2006, it has been decided that in future, the applicants may be directed to obtain prior approval of the concerned Panchayats for conducting field trials and also submit details of locations where they intend to undertake the activity before approval is accorded by the GEAC/RCGM for conducting the field trials of GM crops.
- iii. RCGM/ GEAC nominee of the SAU Monitoring Team can nominate experts of the university or near by institutions as his representative to different Monitoring Teams of the SAU with intimation to RCGM/GEAC secretariat. The GEAC nominee would be involved only in the monitoring of large scale field trials approved by the GEAC.
- iv. The schedule of visits to field trials should be communicated to the members especially to the RCGM/GEAC nominee at least one month in advance.

- v. On the suggestion that MEC constituted by RCGM should not do monitoring and evaluation of large scale field trials, it was agreed that in respect of Bt cotton hybrids expressing **Cry 1Ac MON 531 event**, the new procedure recommended by the sub committee on Bt cotton and related issues under the Chairmanship of Dr. C. D. Mayee, Chairman, ASRB and Co-Chair, GEAC would apply. As per the new procedure large scale field trials is optional and, therefore, evaluation by MEC is not required. In case of new events the mechanism for monitoring and evaluating large scale field trials would be reviewed based on the experience gained during Kharif 2006. For the coming Kharif season, until an alternate mechanism for evaluating the large scale field trials is put in place, the present system of MEC evaluating the same would continue.

The Committee requested Member-Secretaries, RCGM and GEAC to communicate the revised guidelines to the SAUs and seed industries on a priority basis.

b) Report of the Independent Expert Committee on Bt brinjal which was set up by Centre for Sustainable Agriculture (Hyderabad) and Thanal (Trivendrum).

The Member Secretary, RCGM informed that the above report was considered by the RCGM in its meeting held on 8.1.2007 wherein the Committee noted that comments and observations of the expert member on toxicology and allergenicity data submitted by the Company on Bt brinjal has already been communicated to the MoEF. On comments in respect of agronomy, it was informed that views of the experts would be communicated in due course.

The Member Secretary, GEAC further informed that the report received from the NGOs and comments from RCGM would also be considered by the Expert Committee on Bt brinjal constituted by MoEF under the Chairmanship of Dr. Deepak Pental, VC, Delhi University to review the feedback received on the Bt brinjal developed by M/s Mahyco.

c) Burning / uprooting of contained GM field trials in some States.

The Member Secretary, GEAC informed that a press release from Chairman, GEAC clarifying that there is no ban imposed by the Hon'ble Supreme Court on the ongoing field trials of GM crops has been issued by the Ministry on 14.12.2006.

Member Secretary, RCGM informed that All India Rice Exporters Association have been pursuing with DBT to stop the present GM rice field trials so as not to put exports of Basmati rice in jeopardy. The background of this request arises from the fact that the fear of GM contamination has disrupted the US supply to the EU market. APEDA is exploring the possibility of business opportunity with EU for exporting long grained Indian rice as an alternative to the US long grained rice. However, to capture the EU market there is a need for a clear official statement that the Indian non GM rice is uncontaminated.

The RCGM in its meeting held on 8.1.2007 has taken a view that "field trials on GM rice should be away from Basmati rice growing area especially in the state of Haryana, Punjab and Uttaranchal. Views were expressed that from the above statement it was not clear whether GM rice field trials can be permitted in the vicinity of Basmati growing areas and if so at what distance needs to be specified. After detailed deliberation it was agreed that contained field trials within the green house and multi locational field trials within the institutional farms can continue. The restriction would be applicable only to multi locational field trials in farmers' field.

It was also noted that in view of the business opportunities and economic benefit arising from non GM Basmati rice, there may be a need to evolve a strategy for testing and issuance of GM free certificate. The Committee was of the view that the request of the Rice Growers' Association for notification of referral laboratories / agencies for issuance of GM free rice certificates merits consideration. It was

agreed that in addition to notification of public institution laboratories as referral laboratories; private laboratories that have the requisite facilities and necessary accreditation may also be considered for this purpose. It was further suggested by some of the Members, the system of accreditation followed by National Accreditation Board for Testing and Calibration Laboratories (NABL) under Department of Science and Technology may be adopted. After detailed deliberation the Committee requested MoEF to initiate necessary action in this matter on a priority basis.

2.0 Consideration of Proposals.

2.1 Development of transgenic hybrid mustard developed by Delhi University.

2.1.1. The Member Secretary, GEAC briefed the Committee on the directions issued by the Hon'ble Supreme Court (SC) vide order dated 15.12.2006. The Committee noted that the mandate accorded by the SC was to examine the above proposal and clarify whether GURT has been deployed in transgenic mustard developed by Delhi University as stated by the three international experts in the IA No. 5/2006 in WP 260/2005.

2.1.2. The Committee invited Dr. Deepak Pental, Vice Chancellor, Delhi University and Dr. V. Pradhan, Scientist, Delhi University to make a presentation on the development of transgenic mustard developed by Delhi University. The following points were noted by the Committee:

A. Development of Transgenic Mustard

- i) The proposal on "Transgenics in Mustard (*Brassica juncea*) for heterosis breeding" with main objectives of (a) development of male sterile lines in *B. juncea* by fusing barnase gene and (b) restoration of male sterility by barstar containing *B. juncea* transgenic lines was funded by the Department of Biotechnology in 1994.
- ii) DMH-11 uses transgenic (genetic engineering technologies) for pollination control. A ribonuclease gene, barnase, under the control of an anther, more precisely, tapetum tissue of another specific promoter was used to obtain a male sterile plant. Similarly, barstar gene was introduced in another line for fertility restoration in the hybrids. The two plants, one male sterile with the barnase gene and the other fertile and containing barstar gene, are crossed to obtain F1 hybrid, i.e. DMH-11. The F1 hybrid is fertile and sets seeds.
- iii) In studies on development of male sterile lines in *B. juncea* using the barnase gene, it was found that tissue specific expression of the barnase gene was deregulated under the influence of a strong constitutive promoter (CaMV35S) used for expression of the marker gene bar which confers resistance to the herbicide Phosphinothricin. This not only reduced the recovery of transgenic shoots in transformation experiments but also affected several agronomically important traits (viz. vegetative morphology, female fertility, seed germination frequencies and inheritance of male sterility) of male sterile lines, rendering them unsuitable for agronomic applications.
- iv) To circumvent this problem, a strategy of using a Spacer DNA fragment as an effective insulator to protect tissue specific expression of the barnase gene was adopted. This construct was mobilized into disarmed *Agrobacterium tumefaciens* which was used for the genetic transformation of *B. juncea* var. RLM-198. The use of insulator fragment significantly enhanced recovery of agronomically viable male sterile lines in *B. juncea*. The use of a spacer fragment, therefore, will control any leaky expression due to strong constitutive promoters lying nearby the barnase gene thus assuring complete safety of such transgenics.
- v) Similarly, constructs containing a codon modified barstar gene were developed. These constructs were also mobilized into *Agrobacterium tumefaciens* and transgenic plants were developed. These plants served as pollen donor (restorer) male plants. Plants with single

copy barstar gene were used as pollen donors and crossed with single copy male sterile barnase lines (female parent) to obtain F1 progeny (hybrid seed).

- vi) The F1 progeny was fertile and contained both barnase and barstar genes. The barstar barnase genes are expressed only in the tapetum, tissue that surrounds developing micropores/pollen. In the hybrid the effect of the barnase gene is negated by barstar by formation of a barstar barnase complex. As a consequence hybrids are fertile and set seed. The pollen produced by the hybrids is also fertile. Hybrid DMH-11 has no leaky expression of the barnase gene as any such expression will lead to abnormalities and lethality. The hybrid cannot yield 30% more than the best parental variety if there is any leaky expression of the barnase gene.
- vii) The results of this work has been peer reviewed and published in the International Journal "Molecular Breeding" in 2001 and "Current Science" in 2002.

B. Status of field trials

- i) The hybrid has been tested in limited field trials with the approval of RCGM as follows:
 - At one location at Jaunti village during Rabi 2002-03
 - At one location at Jaunti village during Rabi 2003-04
 - At multi locations during Rabi 2005-06
 - The sowing of the seeds for the season 2006-07 was permitted by the Hon'ble Supreme Court vide order dated 13.10.2006.
- ii) In all the field trials conducted during 2002-06 in respect of DMH 11, the yield was found to be around 30% higher than the national check variety Varuna. The multi location trials are being conducted under the aegis of Indian Council of Agricultural Research and are being funded by the Department of Biotechnology vide letter No. BT/PR2130/AGR/106/2005 dated 29.9.2005.
- iii) The trial being conducted in 2006-07 growing season by NRC on Rapeseed/Mustard (ICAR) is a contained field trial and is being conducted under the following conditions:
 - a) The trial is in a limited plot of 200 m², solely for experimental purposes
 - b) A 50 meter buffer zone is being maintained on all sides of the plot as per the guidelines of the Govt. of India
 - c) The trial is being conducted only to estimate the yield of the crop. After conclusion of the trial in March-April, 2007, the entire crop would be burnt.
 - d) Only researchers involved in the process would handle the crop in the field and no other person is authorized to contact the plants.
 - e) The oil extracted from the seeds of DMH-11 shall not be sold in the market for any purpose.
 - f) No part of DMH 11 shall be sold to the farmers or provided to the cattle for feeding.
- iv) The multi-locational trials are being conducted within the research farms of the ICAR institutions and not in farmers' field.

C. Technology deployed in transgenic mustard DMH-11

- i) The issue of whether DMH-11 is GURT which are of two types namely V-GURT and T-GURT was discussed as follows:
 - a) V-GURT: This type of GURT plant produces sterile seeds; hence, the farmer cannot save the seeds and must purchase the same for every season. The technology is

restricted at the variety level; hence called 'V-GURT'. **The DMH-11 produces fertile seeds and does not use V-GURT system.**

- b) T-GURT: This type of GURT plant is so modified that the genes therein are switched on only if the plant is treated with a certain chemical. Farmers can save seeds, but would get desired results only if the activator compound is used. Since the technology is restricted at the trait level, this is called "T-GURT". **The DMH-11 does not use this technology either; it naturally produces fertile seeds.**
- ii) The DMH-11 type of system (using the barnase/barstar genes) has been used for pollination control to develop rapeseed hybrids in Canada. This is called MS8/RF3 system and uses barnase / barstar genes for pollination control to develop hybrids.
- iii) MS8/RF3 system in rapeseed was first given safety clearance for commercial planting in Canada in 1997. GURT patent was granted in 2000. So the use of barnase/barstar for hybrid seed production precedes GURT technologies.

D. Safety and salient features of mustard hybrid DMH-11

- i) Effect of barstar barnase system is found only in the tapetum. The barstar barnase genes are expressed exclusively in the tapetum and no other part of the plant.
- ii) If the yield of DMH-11 is found to be high as observed so far, the oil will be examined for toxicity and allergenicity and other similar studies will be taken up as per the rules and regulations of Government of India. Reasonable amount of oil meal is required for the desired test on toxicology, allergenicity and nutrition.
- iii) The system MS8/RF3 expressing barstar barnase system has been thoroughly tested, certified as safe and approved for use in U.K., USA, China, Japan, Korea, Canada, Australia, Europe and few other countries. The barstar barnase system in *B. juncea* has also been tested in Australia and the Australian Government (Department of Health and Aging, Office of Gene Technology Regulator) on June 2, 2005 has issued a license for controlled release of transgenic Indian mustard (*B. juncea*) at four sites (area of 4 hectares per site) in each of winter and summer growing seasons of 2005-08.
- iv) India is not a centre of origin for *B. juncea* and there is no wild relatives found in India.

2.1.3 After detailed deliberation, the expert members were unanimous in their view that the technology deployed in transgenic mustard by Delhi University is not GURTs. Further, views were also expressed that the transgenic mustard supported by the Government and developed through a public institution merits consideration subject to fulfilling the requisite biosafety assessment for which field trials and limited seed production is necessary. The Committee, therefore, proposed to request the Hon'ble Supreme Court, to permit the ongoing field trials of transgenic mustard.

2.1.4 The Committee, however, decided to obtain considered opinion of the following experts before filing its response to the directions issued by the Hon'ble Supreme Court:

1. Dr. V. S. Chauhan, Director, ICGEB, New Delhi.
1. Dr. Rakesh Tuli, Director, NBRI
2. Dr. P. Anand Kumar, Scientist, NRCPB, Pune
3. Dr. M. Uday Kumar, Deptt. of Crop Physiology
4. Dr. K. K. Tripathi, Adviser, DBT, New Delhi.

2.2 Renewal of GEAC permission for Bt cotton hybrids approved by the GEAC for commercialization in 2004 and 2005.

2.2.1 The Member Secretary informed the committee, as per Rule 13 (2) of Rules 1989, all approvals of the Genetic Engineering Approval Committee shall be for a specified period not exceeding four years at the first instance renewable for 2 years at a time. In the case of transgenic crops the validity of the approval in most of the cases is initially only for a period of three years. However in case of 6 Bt cotton approved for the first time in the North zone during Kharif 2005, the approval was granted only for a period of two years in view of the concern regarding susceptibility to CLCUv. In accordance with the approvals granted by the GEAC during 2004 and 2005, the validity of approvals granted by the GEAC for the following Bt cotton hybrids expires in February – April, 2007:

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| 1. RCH 2 Bt by M/s Rasi Seeds Ltd: | approved for Central & South Zone in 2004 |
| 2. RCH 134 Bt by M/s Rasi Seeds Ltd: | approved for North Zone in 2005 |
| 3. RCH 317 Bt by M/s Rasi Seeds Ltd: | approved for North Zone in 2005 |
| 4. MRC-6301 Bt by M/s Mahyco: | approved for North Zone in 2005 |
| 5. MRC 6304 Bt by M/s Mahyco: | approved for North Zone in 2005 |
| 6. Ankur 651 Bt by M/s Ankur Seeds Ltd.: | approved for North Zone in 2005 |
| 7. Ankur 2534 Bt by M/s Ankur Seeds Ltd: | approved for North Zone in 2005 |

2.2.2 The Committee considered the views of Prof. Govindraj Hegde, National Law School, Bangalore and Expert Member, GEAC on the implication of the Court order dated 22.09.2006 in WP 260/2005 in IA No 4/2006 and noted that the directions issued in no way prevent GEAC from undertaking its other functions provided they do not overlap with approval for field trails. Accordingly, the Committee was of the view that the cases for renewal may be considered by the GEAC in the subsequent meetings.

2.2.3 After a brief deliberation the Committee decided that the following information may be obtained to decide the merits of the case:

- i) Detailed compliance report on the status of compliance of conditions stipulated by the GEAC in its clearance order for commercial release.
- ii) Information on the susceptibility of the hybrids to CLCUv.
- iii) Declaration that the non Bt hybrids seeds provided by the Company for planting the refugia is of the same species, similar duration and similar fibre quality in cases where the same non Bt counter-part is not being used as refugia.
- iv) NOC from the licensor in case of sub licensees.
- v) Views of the State Department of Agriculture on the performance of the hybrids in the respective states.

2.2.4 It was also decided to request the Secretary, State Department of Agriculture of the respective State to nominate a suitable representative of the Department to attend the GEAC meeting and provide the necessary inputs to the GEAC for taking a final view on the matter.
