Decisions taken in the 83rd Meeting of the Genetic Engineering Approval Committee held on 2.4.2008

The 83rd meeting of the Genetically Engineering Approval Committee (GEAC) was held on 2.4. 2008 in Room No. 623 in the Ministry of Environment and Forests under the Chairmanship of Shri B. S. Parsheera, Additional Secretary, MoEF and Chairman, GEAC.

The deliberations of the GEAC in respect of Agenda Item 4 to 9 are as follows:

Agenda Item No. 4 : Policy issues.

4.1 Recommendations of the Sub committee constituted by the Ministry to review the need for case by case regulation of Bt cotton hybrids expressing approved gene events.

4.1.1 The Member Secretary, GEAC informed, during the period 2002-2007 the GEAC has approved about 135 Bt cotton hybrids expressing four events namely (*Cry 1Ac* (MON 531 event), *Cry 1Ac* and *Cry 2Ab* genes (MON 15985 event), *Cry 1Ab-Cry 1*A "GFM" *Cry 1A* and *Cry 1Ac* (event 1). The Cry 1Ac (MON 531 event) was first released in 2002 and subsequently in 2006 the remaining three events were approved for commercial cultivation after evaluation of the biosafety data. Since the release of Bt cotton in India, several measures have been initiated for streamlining the Bt cotton approval process in India. The first such initiative was the setting up of the Task Force on Agriculture Biotechnology under the Chairmanship of Prof. M. S. Swaminathan. The report of the Task Force recommended, (i) an event based approval system (ii) once an event has been declared as 'bio-safe', its derivatives need not be subjected to extensive biosafety testing and (iii) a fast track approval process may be considered for notified varieties expressing the approved events.

4.1.2 While the GEAC adopted the recommendations that Bt cotton hybrids expressing approved events need not repeat the biosafety studies and a fast track system for centrally notified varieties was introduced, decision on 'event based approval system' was deferred until more experience is gained.

4.1.3 On the basis of six years experience in commercial cultivation of Bt cotton, there has been a demand for consideration of an event based approval system in Bt cotton. Accordingly, the GEAC in its meeting held on 8.8.2007 decided to set up a Sub-committee under the Chairmanship of Dr. B. M. Khadi, Director, CICR, Nagpur with the following terms of reference:

a) To review the need for continued case by case regulation of Bt cotton expressing *cry 1Ac* (MON 531 event) and implication of de regulation if any.
b) Rationalization of the Zones based on the agro climatic conditions
c) Recommendation regarding the suitability for release of Bt cotton in other cotton growing states.

4.1.4 The following recommendations of the Sub Committee were placed for consideration of the GEAC. Dr Khadi, Chairman of the Sub committee explained the new procedure that could be followed on adopting the recommendations of the Sub Committee. The Committee noted, in respect of Bt cotton hybrids expressing approved events, a decentralized system involving the SAU and State Department of Agriculture may be followed. The steps involved would be as follows:

a) Transfer of GM material to be approved by the RCGM through the IBSC.
b) The strip trials to be conducted with the approval of IBSC under intimation to RCGM.
c) Transformation and backcrossing under the mandate of IBSC.
d) In house trials / farmers field trials to be conducted by the Company.
e) Request for SAU trials along with an affidavit confirming the following:

- Confirmation of gene event through molecular characterization
- Level of protein expression in green house and field trials
- Morphological characters using DUS descriptors
- Bio-efficacy data generated in laboratory conditions
- Authorization/NOC from technology provider in case of sub-licensee.

f) Based on the SAU trial data and company data, the SAU and State Governments to identify the genotype suitable for commercial cultivation.

g) In case the company likes to identify certain genotypes, as centrally notified varieties they should follow the prevailing AICCIP procedure under the ICAR system.

4.1.5 The Chairman then invited the expert members to give their views on the recommendations of the Sub Committee regarding the need for case by case approval of Bt cotton hybrids expressing approved events.

4.1.6 Dr Bhargava, in his opening statement informed, he would not be able to support release of GM crops for commercialization or field trials without examining the biosafety data and other available alternatives. He further opined, enhanced cotton productivity in India cannot be attributed to Bt technology alone. As a case in example, he referred to the sheep death in Warangal and Adilabad districts of Andhra Pradesh and farmers' suicide in Vidharbha region. As an analogy to the argument given by Dr. Bhargava one of the members opined that sheep death and farmers suicide cannot be attributed to Bt technology as these incidents have been prevailing in the region even prior to release of Bt cotton. It was also informed that the GEAC had given an opportunity to NGOs to present their view/ evidence regarding sheep death in Andhra Pradesh. The matter has also been examined by the State Government and report received from Directorate of Animal Husbandry, Hyderabad, Indian Veterinary Research Institute, Izatnagar, U.P indicate that the sheep deaths might be due to high content of Nitrates/Nitrites, residues of hydrocyanide (HCN) and organophosphates which are common constituents of pesticides used during cotton cultivation and not that of Bt toxin. It was further informed that data on toxicity of Bt protein to higher mammals is extensively available as Bt cotton was released globally about a decade ago. Further, prior to release of Bt cotton in India a battery of studies to assess the safety of Bt toxin to the environment and animals have been conducted.

4.1.7 On the issue of an 'event based approval' process, Dr Bhargava opined, he was not in favour of a blanket approval for Bt cotton for the following reasons:

a. With the information available with him, he feels there is a case for review of the Bt cotton approval in India

b. Every event needs to be tested and reviewed for biosafety. The list of biosafety studies conducted prior to Bt cotton approval may be made available to him. He was of the view that he cannot comment on the matter until he has examined the data and other available alternatives.

c. He further suggested that proteomics study and DNA finger printing should form an important component of the biosafety evaluation.

d. There is a need for an independent testing laboratory. Member Secretary RCGM informed, the decision to set up a National Biotechnology Regulatory Authority has already been taken. The proposal would include setting up an independent testing facility.

4.1.8 Member Secretary GEAC clarified that the GEAC is not considering a blanket approval for all transgenic cotton. The deregulation policy would be applicable to only Bt cotton expressing four events (*Cry 1Ac* (MON 531 event), *Cry 1Ac* and *Cry 2Ab* genes (MON 15985 event), *Cry 1Ab-Cry 1*A "GFM *Cry 1A* and *Cry 1Ac* event 1) which are under commercial cultivation. She further informed, as per the prevailing regulatory process the GEAC is following a case by case approval of each hybrid even after the event has been declared bio-safe and approved for environment release. The present system provides for only agronomic evaluation and selection of the genotypes suitable for a particular zone. She further explained the step by step evaluation process and the role of IBSC, RCGM, MEC and the State Agricultural University in the evaluation of Bt cotton field trials. Dr. Bhargava thanked

the Members Secretary for the clarification and putting the matter in proper perspective. After a brief discussion on the matter, he reiterated his earlier stated concern and requested the Chairman, GEAC to place his views on record which would be applicable for all proposals relating to commercial release and field trials of GM crops until he has examined the data. He further suggested that proteomics study should be done for each hybrid developed through backcrossing.

4.1.9 The recommendations of the Sub Committee and view of Dr. Bhargava was extensively discussed and following views were expressed by members of the GEAC:

1. There is no scientific rationale in adopting a case by case regulation of approved events as the biosafety assessment in respect of the event has been completed before the product has been approved for environmental release and commercialization.

2. The biosafety profile of an event does not change when it is transferred to other genetic backgrounds of the same crop through back-crossing to develop new hybrids/parents.

3. Studies on proteomics analysis of the Bt cotton hybrids is not necessary as the structural and functional integrity of the proteome as manifested by the original event expressing the Bt gene has been found to be safe as tested by a battery of tests and procedures to ascertain the toxicity and allergenicity in various animal systems.

4. Use of Bt cotton has enhanced cotton productivity substantially and facilitating the availability of genotype suited for the region is urgently required to optimize benefits to the farmers. The new procedure would empower State Government to take a view on the genotype best suited for their region.

5. The Central Institute of Cotton Research (CICR), the nodal agency for 'Monitoring the susceptibility of bollworms to Bt gene and development of insect resistance" has reported, there is no development of insect resistance as of now based on the six year study conducted by the institute during 2002-2007.

6. Streamlining of the regulatory process is a continuous process which require policy changes /review of decision as and when new evidence positive or negative emerge. Stopping the regulatory mechanism is not a solution to address all problems / issues.

4.1.10 In due compliance with the Hon'ble Supreme Court direction dated 13.2.2008 the Committee took note of Dr. Bhargava's views. It was also noted that as per the above directions the GEAC is permitted to consider any application presented to it in accordance with law and take appropriate decisions after considering all aspects before the final decision is taken including bio-safety aspects.

4.1.11 After detailed deliberations, the GEAC adopted the event based approval mechanism recommended by the Sub Committee. However, the present system would continue until the new procedure is formally notified. The Committee requested the Chairman, GEAC to constitute a small committee for (i) drafting a notification empowering the State Department of Agriculture and SAUs to monitor and evaluate Bt cotton hybrids expressing approved events in cotton crop. (ii) drafting the guidelines to be followed by the State Agriculture Departments and SAUs and (iii) drafting the contents of the Affidavit including legal implication in case of non compliance / submission of wrong information.

4.1.12 The GEAC further agreed with the revised zoning pattern for cotton recommended by the Sub committee based on agro-climatic zone. It was also agreed that Orissa State may be included in the Central zone for commercialization of Bt cotton after completion of appropriate testing and evaluation procedures.

4.2 Presentation by Central Institute of Cotton Research on the 'Monitoring the susceptibility of bollworms to Bt gene and development of insect resistance" and outcome of the National Consultation on IRM Strategy organized by MoEF on 21-22 January, 2008.

4.2.1 Dr K. R. Kranthi, Head, Crop Protection Division, CICR, Nagpur presented the results of resistance monitoring work carried out with Cry1Ac and Cry2Ab2 on the cotton bollworm *Helicoverpa armigera* collected from 49 cotton growing districts of the country during 2007-08. Changes in the geographical variability in *H. armigera* susceptibility levels to Cry1Ac toxin from *Bacillus thuringiensis* were monitored through log dose probit assays conducted on populations collected from 10 cotton-growing districts of North India, 26 districts of Central India and 13 districts of South India. The LC_{50} values derived from 17,330 larvae tested, ranged from 0.057 to 1.146 μg Cry1Ac/ml of diet with 8.5-fold, 16.61- fold and 14.88 –fold variability in susceptibility across the North, Central and South Indian strains of *H. armigera*. The IC_{50} values ranged from 0.009- 0.201 μg Cry 1Ac/ml of diet with 22.33 fold variability across the country. Dr Kranthi also presented the baseline data derived from *H. armigera* field populations collected from 10 locations in India, during 1999, prior to the introduction of Bt-cotton. He summarized the entire data sets of monitoring results from 2002-2008 to state that there was no development of resistance thus far in any part of the country. However, he felt that there was an imminent need to initiate robust pro-active resistance management strategies all over the country, with special focus in parts of Gujarat, AP and Maharashtra, in view of the subtle disturbances observed in the baseline in these regions. He suggested that based on the Indian data, the resistance management group had devised 'insect resistance management (IRM) strategies' that could be of immense use in the Indian context. Some of the strategies were listed as A). Adherence to a minimum hybrid seed rate of 700-750 gm seed per acre, with at least one border row of any early maturing pigeon-pea varieties. B). Use of one application of an insecticide such as thiodicarb or quinalphos or chlorpyriphos, during 100-140 days after sowing (DAS), which would effectively reduce the population of larvae (also possibly heterozygous for the resistant allele) that survive on Bt-cotton due to the decline in the transgene toxin levels. The spray would control incidental populations of pests such as *Spodoptera litura*, mealy bugs, mirid bugs, dusky cotton bugs and the pink bollworms that have been reported to increase and cause economic damage in the absence of any insecticide application during the 100-140 DAS window. C). Optimize INM & nutrient management for macro and micronutrients. Foliar spray of MgSO4, 2% Urea followed by 2% DAP, to ensure proper Cry1Ac expression and also to reduce problems of leaf reddening. D). Hand-picking of surviving larvae from Bt-cotton fields during peak bollworm infestation, wherever possible and destruction of residual pupae by deep ploughing in Bt-cotton fields immediately after final harvest. Apart from the above suggestions he felt that baseline toxicity data must be made mandatory for all new genes/events and also that there was a need to continue work on resistance monitoring as a net-working programme involving State Agricultural Universities with CICR as the nodal agency.

4.2.2. Dr. Bhargava appreciated the efforts of CICR. He said that refinements in protocols should be made as much as possible to simulate naturally occurring conditions in India. He felt that it would be important to ensure that the resistance monitoring bioassays reflected the actual field conditions in which the pest interacts with the pest resistant GM crop. He suggested that the actual toxin along with the host matrix in a fresh condition would be the most appropriate to assess changes in adaptability of the pest to the GM crop. Dr Bhargava also suggested that it was important to track the relative occurrence of bollworm populations on Bt-cotton in comparison with the corresponding non-Bt version of the genotype, continuously over the years, so that it would represent the actual field situation in terms of bollworm adaptation to Bt-cotton. Dr Kranthi agreed with the observation and said that exactly such efforts were being carried out in a project funded by the ICAR. On clarifications on the methodology followed in resistance monitoring protocols, Dr Kranthi replied that the assays being carried out by CICR along with the net-work group partners follow a set of 'standard operating procedures' which were published in the manual 'Insecticide Resistance' and circulated to all concerned including the networking laboratories. He added that all the project partners had extensive interactive workshops and training programmes before initiating the resistance monitoring programme using the same toxin batches and identical procedures. He said that the assays represented the best possible standard conditions with scope for lowest possible error and that the results of standardization itself were published in 'Current Science', 'Crop Protection' and 'International Journal

of Pest Management'. He said that the relevant papers would be sent to Prof. Bhargava. Dr Bhargava highlighted the need for gene stacking especially as an Indian effort to ensure that the crop has least problems from insect pests. He also said that at some stage it would be necessary to move towards a more natural farming condition with least dependence on insecticides, or if possible none at all.

4.2.3 Dr. Bhargava applauded CICR for the excellent and meticulous work carried out by Dr. Kranthi and his team. He requested the Chairman, GEAC to organize a separate meeting of the concerned scientists as there are several issues which he would like to discuss and understand. He was of the view that some of the innovative suggestions recommended for delaying the development of insect resistance to Bt gene can also be integrated as part of the IPM strategy in organic farming. The Chairman requested Dr. P. L. Gautam, DDG (CS), ICAR to organize the meeting requested by Dr. Bhargava and make available the recommendation to the GEAC for further consideration.

Agenda Item No 5: Consideration of applications for commercial release of Bt cotton expressing approved gene events.

5.1 Application for commercialization of VBCH-1006 and VBCH-1008 BG *expressing Cry 1 Ac* gene in the North Zone by M/s Vibha Agrotech Ltd.

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5.2 Application for commercialization of VICH-11 BG *expressing* Cry 1 Ac gene in the North Zone by M/s Vikram seeds (P) Ltd.

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5.2 Application for commercialization 6488- 2 *expressing* Cry 1Ac & Cry 2Ab genes (Mon 15985 event) in the North Zone by M/s Bioseeds.

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5.4 Application for commercialization of VBCH-1501 and VBCH-1504 *expressing* (Cry 1Ac & Cry 2Ab (Mon-15985 event) in the North Zone by M/s Vibha Agrotech Ltd.

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5.5 Application for commercialization MRC-7041 BGII and MRC-7045 *expressing* (Cry *1Ac & Cry 2Ab* genes (Mon 15985 event) in the North Zone by M/s Mahyco.

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5.6 Application for commercialization Jassi BGII *expressing* (Cry 1AC & Cry 2Ab genes (Mon 15985 event) in the North Zone by M/s Ankur Seeds.

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5.7 Application for commercialization of RCH-134 BGII *expressing* (Cry 1AC & Cry 2Ab genes (Mon-15985 event) in the North Zone by M/s Rasi Seeds (P) Ltd.

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5.8 Application for commercialization KDCHH-441 BGII expressing (Cry 1AC & Cry 2Ab genes (Mon 15985 event) in the North Zone by M/s Krishidhan Seeds (P) Ltd.

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5.9 Application for commercialization of VICH-11 BGII and VICH-9 *expressing* (Cry 1AC & Cry 2Ab genes (Mon 15985 event) in the North Zone by M/s Vikram seeds (P) Ltd.

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5.10 Application for commercialization of UPLHH-1 *expressing* (Cry 1Ab –Cry 1Ac) "GFM Cry 1A" in the North Zone by M/s Uniphos Enterprises.

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5.11 Application for commercialization of Navkar-5 Bt *expressing* (Cry 1Ab –Cry 1Ac) "GFM Cry 1A" in the North Zone by M/s Navkar Hybrid seeds Pvt. Ltd.

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5.12 Application for commercialization of JKCH-1945 Bt and JKCH-226 Bt containing Cry 1Ac event -1 in North Zone by M/s J. K. Agri Genetics Ltd.

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5.13 Application for commercialization GK-212 BGII *expressing* Cry 1AC & Cry 2Ab genes (Mon 15985 event) in the North Zone by M/s Ganga Kaveri Seeds Pvt Ltd.

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5.14 Application for commercialization KCH-707 Bt (BG II) *expressing* Cry 1AC & Cry 2Ab genes (Mon 15985 event) in the North Zone by M/s Kaveri seeds.

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5.15 Application for commercialization Tulasi-4 BGII and Tulasi- 45 BG II *expressing* Cry 1AC & Cry 2Ab genes (Mon 15985 event) in the North Zone by M/s Tulasi seeds Pvt Ltd.

1.0 The recommendations of SAU/ MEC/RCGM/ICAR in respect of 21 Bt cotton hybrids as contained in the proposals at agenda 5.1 to 5.15 namely VBCH-1006 BG, VBCH 1008 BG and VICH-11 BG expressing Cry 1Ac (MON 531 event), 6488-2, VBCH 1501 BG II, VBCH 1504 BG II, MRC 7041 BG II, MRC 7045 BG II, Jassi BG II, RCH 134 BG II, KDCHH 441 BG II, VICH 11 BG II, VICH 9 BG II, GK 212 BG II, KCH 707 BG II, Tulasi-4 BG II and Tulasi 45 BG II expressing Cry 1Ac and Cry 2Ab genes (MON 15985 event), UPLHH-1 and Navkar-5 Bt expressing Cry 1Ab-Cry 1A "GFM Cry 1A and JKCH-226 Bt and JKCH-1945 Bt expressing Cry 1Ac event 1 were considered by the GEAC.

2.0 The Committee noted that the above hybrids have been approved for commercial release in the North Zone by MEC and RCGM in its meetings held on 26.2.2008 and 25.1.2008 & 7.3.2008 respectively. It was also noted that in respect of Bt cotton hybrids namely 6488-2 developed by M/s Bioseeds, VBCH-1501 BG II and VBCH-1504 BG II developed by M/s Vibha Seeds (P) Ltd., MRC 7041 BG II and MRC 7045 BG II by M/s Mahyco, VICH 11 BG II by M/s Vikram Seeds Pvt. Ltd. UPLHH-1 by M/s Uniphos Enterprises and JKCH 226 Bt by M/s J. K. Agri Genetics Ltd., the hybrids have completed only one year of LST and one year of ICAR trials instead of the two year requirement earlier stipulated by the GEAC. The Committee considered these cases in light of the policy decision to deregulate Bt cotton hybrids expressing approved events from biosafety angle at Agenda Item 4.1.

3.0 Dr Bhargava, reiterating his earlier concerns and informed that he would not be able to support release of additional Bt cotton hybrids for commercialization without examining the biosafety data and other available alternatives. Member Secretary GEAC further clarified that the Bt cotton hybrids listed in Agenda 5.1 to 5.15 contain approved events which are already under commercialization. Dr. Bhargava opined that proteomics study and DNA finger printing should be conducted for each hybrid. The expert members of the GEAC opined that the biosafety profile of an event does not change when it is transferred to other genetic backgrounds of the same crop through back-crossing to develop new hybrids/parents and therefore proteomics study for each hybrid may not be necessary. After a brief discussion on the matter, Dr. Bhargava requested the Chairman, GEAC to place his views on record which would be applicable for all proposals relating to commercial release and field trials of GM crops until he has examined the data.

4.0 In due compliance with the Hon'ble Supreme Court direction dated 13.2.2008 the Committee took note of Dr. Bhargava's views. It was also noted that as per the above directions the GEAC is permitted to consider any application presented to it in accordance with law and take appropriate decisions after considering all aspects before the final decision is taken including bio-safety aspects.

5.0 The Member Secretary, GEAC informed the Committee that M/s Uniphos Enterprises is a sub licensee of Global Transgenes Limited, Aurangabad (GTL) a Nath Group Company who have obtained exclusive rights for use of the Chinese patented Transgenic Fusion Gene Bt cotton Technology in India. In respect of Agenda item No. 5.10 pertaining to Bt cotton hybrid UPLHH-1 expressing (Cry 1Ab –Cry 1Ac) "GFM Cry 1A" by M/s Uniphos Enterprises, Dr. S. K. Raina representative of M/s Nath Seeds Pvt. Ltd. has informed telephonically that the applicant has not obtained NOC from the Licenser for UPLHH-1. On verification of the records, it is observed that GTL has authorized M/s Uniphos Enterprises to seek the approval of the GEAC for large scale trials of seven Bt cotton hybrids which include UPLHH-1 hybrid. Since no written complaint has been registered, the Committee approved UPLHH-1 Bt hybrid for commercial release.

6.0 After detailed deliberations and taking into consideration the recommendations of MEC/RCGM/ICAR, the Committee recommended the following hybrids for commercial release in the North Zone.

1. VBCH-1006 BG expressing *cry 1Ac (MON 531 Event).* by M/s Vibha Agrotech Ltd.
2. VBCH-1008 BG expressing *cry 1Ac (MON 531 Event) by M/s Vibha Agrotech Ltd.*
3. VICH-11 BG expressing *cry 1Ac (MON 531 Event)* by M/s Vikram seeds (P) Ltd.
4. 6488- 2 *expressing* Cry 1AC & Cry 2Ab genes (Mon 15985 event) by M/s Bioseeds.
5. VBCH-1501 *expressing* Cry 1AC & Cry 2Ab genes (Mon 15985 event) by M/s Vibha Agrotech Ltd.
6. VBCH-1504 *expressing* (Cry 1AC & Cry 2Ab genes (Mon-15985 event) by M/s Vibha Agrotech Ltd.
7. MRC-7041 BGII *expressing* Cry 1AC & Cry 2Ab genes (Mon 15985 event) by M/s Mahyco
8. MRC-7045 BG II *expressing* (Cry*1Ac & Cry 2Ab* genes (Mon 15985 event) by M/s Mahyco.
9. Jassi BGII *expressing* (Cry 1AC & Cry 2Ab genes (Mon 15985 event) by M/s Ankur Seeds.
10. RCH-134 BGII *expressing* (Cry 1AC & Cry 2Ab genes (Mon-15985 event) by M/s Rasi Seeds (P) Ltd.
11. KDCHH-441 BGII expressing (Cry 1AC & Cry 2Ab genes (Mon 15985 event) by M/s Krishidhan Seeds Ltd.
12. VICH-11 BGII *expressing* Cry 1AC & Cry 2Ab genes (Mon 15985 event) by M/s Vikram Seeds (P) Ltd.
13. VICH-9 *expressing* (Cry 1AC & Cry 2Ab genes (Mon 15985 event) by M/s Vikram seeds (P) Ltd.
14. GK-212 BGII *expressing* Cry 1AC & Cry 2Ab genes (Mon 15985 event) by M/s Ganga Kaveri Seeds Pvt Ltd
15. KCH-707 Bt (BG II) *expressing* Cry 1AC & Cry 2Ab genes (Mon 15985 event) by M/s Kaveri seeds.
16. Tulasi-4 BGII *expressing* Cry 1AC & Cry 2Ab genes (Mon 15985 event) by M/s Tulasi seeds Pvt Ltd.
17. Tulasi- 45 BG II *expressing* Cry 1AC & Cry 2Ab genes (Mon 15985 event) by M/s Tulasi seeds Pvt Ltd.
18. UPLHH-1 *expressing* (Cry 1Ab –Cry 1Ac) "GFM Cry 1A" by M/s Uniphos Enterprises.
19. Navkar-5 Bt *expressing* (Cry 1Ab –Cry 1Ac) "GFM Cry 1A" by M/s Navkar Hybrid seeds Pvt. Ltd.
20. JKCH-1945 Bt expressing Cry 1Ac event -1 by M/s J. K. Agri Genetics Ltd.
21. JKCH-226 Bt expressing Cry 1Ac event -1 by M/s J. K. Agri Genetics Ltd.

Agenda Item No 6: Consideration of Applications for field trials (MLRT and Strip Trials) of Bt cotton expressing approved gene events in the North Zone during Kharif, 2008 as recommended by the MEC/RCGM

Hybrids expressing Cry 1 Ac gene (MON 531 event)

6.1 Application submitted by M/s. Seeds Works India Pvt. Ltd., Hyderabad for permission to conduct Multi Location Research Trials (MLRT) trials on five Bt. cotton hybrids BG-I (HXH) namely SWCH-4314, SWCH-4322, SWCH-4324, SWCH-4428 & SWCH-4531 containing *cry1Ac gene* (MON 531 event) in North Zone.

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6.2 Application submitted by M/s. Seeds Works India Pvt. Ltd., Hyderabad for permission to conduct SAU trials on five Bt. cotton hybrids BG-I (HXH) namely SWCH- 4314, SWCH-4322, SWCH-4324, SWCH-4428 & SWCH-4531 containing *cry1Ac* gene (MON 531 event) in North zone.

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6.3 Application submitted by M/s. Seeds Works India Pvt. Ltd., Hyderabad for permission to conduct Strip trials of 30 Bollgard cotton hybrids (HxH) namely SWCH 4362 to SWCH 4391 Bt containing *cry1Ac* gene (Event MON 531) at their own research farm located at Ghaziabad, UP in North Zone.

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6.4 Application submitted by M/s. Amar Bio-tech Ltd., Hyderabad for permission to conduct Multi Location research trials MLRT/SAU/ICAR trials on three BG-I cotton hybrids namely ABCH-3083Bt, ABCH-3483Bt & ABCH-1857 Bt containing *cry1Ac* (Event MON 531) in North zone.

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6.5 Application submitted by M/s. Rasi Seeds Pvt. Ltd., Tamil Nadu for permission to conduct Multi Location research Trials MLRT/SAU trials on one Bt cotton hybrid namely Shakti 9 Bt cotton hybrid (BG-1) expressing *cry1Ac* gene (MON 531) in North Zone.

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6.6 Application submitted by M/s. Super Seeds Pvt. Ltd., Hissar for permission to conduct limited field trials (Strip trials) for 94 new transgenic Bt cotton hybrids containing *cry1Ac* gene, MON 531 event at one location Hisar, Haryana in North zone.

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6.7 Application submitted by M/s. Nuziveedu Seeds Ltd., Hyderabad for permission to conduct Multi Location Research Trial of five Bt cotton hybrids namely NCS-901 Bt, NCS-902 Bt, NCS-903 Bt, NCS-904 Bt and NCS-905 Bt containing *cry1Ac gene* (Event MON 531) in North zone.

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6.8 Application submitted by M/s. Ankur Seeds Pvt. Ltd., Nagpur for permission to conduct limited Research Field Trials (strip tests) of 40 Bt cotton hybrids namely ARCHH-101 to ARCHH-140 containing *cry1Ac* gene (MON 531) in 20 hybrids & *cry1Ac* & *cry2Ab* genes (MON 15985) in 20 hybrids in North zone.

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6.9 Application submitted by M/s. Ankur Seeds Pvt. Ltd., Nagpur for permission to conduct Replicated Multi Location Research Trials (MLRT)/SAU Trials/ Seed production of three intra-hirsutum Bt cotton hybrids namely Jai Bt, Ankur 3028 Bt and Ankur 8120 Bt containing *cry1Ac* gene (MON 531) in North zone.

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6.10 Application submitted by M/s. Bayer Bioscience Pvt. Ltd., Hyderabad for permission to conduct SAU Trials and Seed production of Bt cotton hybrids namely SP 499 B1 (Goldmine) containing *cry1Ac* gene (MON 531) in North zone.

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6.11 Application submitted by M/s. Prabhat Agri Biotech Ltd., Hyderabad for permission to conduct Multi Location Research Trial (MLRT) of three Bt cotton hybrids namely PCH-401 Bt, PCH-402 Bt and PCH-403 Bt containing *cry1Ac* genes (Event MON 531) in North zone.

Hybrids expressing stacked genes Cry 1AC & Cry 2Ab (Mon 15985 event)

6.12 Application submitted by M/s. Nandi Seeds Pvt. Ltd., Mahabubnagar for permission to conduct MLRT/ SAU & ICAR trials on three Bt. cotton hybrids BG-II (HXH) namely SDS 6003, SDS 27 & SDS 234 containing *cry1Ac* (MON 531 event) during Kharif 2008 in North zone

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6.13 Application submitted by M/s. Pravardhan Seed (P) Ltd., Hyderabad for permission to conduct Multi Location Research Trials (MLRT) on five Bt. cotton hybrids (HXH) BG II namely PRCH-301 BGII, PRCH-302 BGII, PRCH-331 BGII, PRCH-333 BGII, PRCH-343 BGII containing *cry1Ac* & *cry2Ab* (MON 15985) in North zone.

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6.14 Application submitted by M/s. Seeds Works India Pvt. Ltd., Hyderabad for permission to conduct Multi Location Research Trials (MLRT) of five Bollgard II Bt cotton hybrids (HxH) namely SWCH 2 Bt, SWCH 4704 Bt, SWCH 4707 Bt, SWCH 4711 Bt and SWCH 4713 Bt containing *cry1Ac* and *cry2Ab* genes (Event MON 15985) in North Zone.

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6.15 Application submitted by M/s. Seeds Works India Pvt. Ltd., Hyderabad for permission to conduct Strip trials of 40 Bollgard II cotton hybrids (HxH) namely SWCH 4731 to SWCH 4770 Bt containing *cry1Ac and cry2Ab* genes (Event MON 15985) at their own research farm located at Ghaziabad, UP in North Zone.

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6.16 Application submitted by M/s. Amar Bio-tech Ltd., Hyderabad for permission to conduct Multi Location research Trials MLRT/SAU/ICAR trials on four BG-II cotton hybrids namely ABCH-1299Bt, ABCH-2099Bt & ABCH-4899 Bt and ABCH-7399 Bt containing *cry x (cry1Ac + cry2Ab)* (Event MON 15985) in North zone.

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6.17 Application submitted by M/s. Rasi Seeds Pvt. Ltd., Tamil Nadu for permission to conduct Multi Location research Trials MLRT/ICAR trial on three Bt cotton hybrids namely RCH-602 BG II, RCH-605 BG II and RCH-314 BG II expressing *cryX (cry1Ac and cry2Ab)* gene (MON 15985) in North zone.

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6.18 Application submitted by M/s.Super Seeds Pvt. Ltd., Hissar for permission to conduct limited field trials (Strip trials) for 10 new transgenic BGII Bt cotton hybrids containing (*cry1Ac & cry2Ab* gene event, MON 15985) in their own farm Hisar, Haryana in North zone.

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6.19 Application submitted by M/s. Kaveri Seeds Pvt. Ltd., Secunderabad for permission to conduct Multi Location research Trials (MLRT) on four Bt cotton hybrids namely KCH-36, 999, 14K59, 15K39 BG II) containing *cry1Ac* & *cry2Ab* gene MON 15985 in North zone.

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6.20 Application submitted by M/s. Kaveri Seeds Pvt. Ltd., Secunderabad for permission to conduct Strip Trials on seven Bt cotton hybrids namely KCH-100, KCH-172, KCH-189, KCH-211, KCH-311, KCH-411 and KCH-611 BG II containing *cry1Ac* & *cry2Ab* gene MON 15985 in North zone.

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6.21 Application submitted by M/s. Bayer Bioscience Pvt. Ltd., New Delhi for permission to conduct contained limited research trial (Strip trials) of 20 Bt cotton hybrids namely SP7101 B2 to SP7120 B2 BGII containing *cry1Ac* & *cry2Ab* gene MON 15985 in North zone.

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6.22 Application submitted by M/s. Bayer Bioscience Pvt. Ltd., New Delhi permission for Multi location research trials (MLRT)/SAU trial/Seeds production of four Bt cotton hybrids namely SP139 B1, SP1169 B1, SP7007 B1, SP1056 B1 containing *cry1Ac* gene MON 531 in North zone.

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6.23 Application submitted by M/s. Bayer Bioscience Pvt. Ltd., New Delhi permission for Multi location research trials (MLRT)/ SAU trial/ ICAR/ Seed production of five Bt cotton hybrids namely SP1169 B2, SP7017 B2, SP1036 B2, SP7001 B2, SP7010 B2 containing *cry1Ac* & *cry2Ab* gene MON 15985 in North zone.

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6.24 Application submitted by M/s. Monsanto Genetics India Pvt. Ltd., Mumbai for permission to conduct Multi location research trials (MLRT) on six (HXH) BG II cotton hybrids namely EGCH-1426 B2, EGCH 5 B2, EGCH 73 B2, SO7H846, SO7H866, S07H878 containing *cry1Ac & cry2Ab* gene in North zone.

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6.25 Application submitted by M/s. Vibha Agrotech Ltd., Hyderabad for permission to conduct Multi location research trials (MLRT)/SAU/Seed production on four Bt cotton hybrids namely VBCH-1515, VBCH-1516, VBCH-1517 , and VBCH-1518 containing *cry1Ac & cry2Ab* gene in North zone.

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6.26 Application submitted by M/s. Prabhat Agri Biotech Ltd., Hyderabad for permission to conduct Multi Location Research Trial (MLRT) of four Bt cotton hybrids namely PCH-876 Bt2, PCH-877 Bt2, PCH-878 Bt2 and PCH-879 Bt2 containing *cry1Ac* & *cry2Ab* gene (Event MON 15985) in North zone.

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6.27 Application submitted by M/s. Prabhat Agri Biotech Ltd., Hyderabad for permission to conduct limited seed production of four Bt cotton hybrids namely PCH-876 Bt2, PCH-877 Bt2, PCH-878 Bt2 and PCH-879 Bt2 containing *cry1Ac* & *cry2Ab* gene (Event MON 15985) in North zone.

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6.28 Application submitted by M/s. Nuziveedu Seeds Ltd., Hyderabad for permission to conduct Multi Location Research Trial (MLRT) of four Bt cotton hybrids namely NCS-855 Bt2, NCS-856 Bt2, NCS-857 Bt2 and NCS-858 Bt2 containing *cry1Ac* & *cry2Ab* genes (Event MON 15985) in North zone.

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6.29 Application submitted by M/s. Nuziveedu Seeds Ltd., Hyderabad for permission to conduct limited seed production of four Bt cotton hybrids namely NCS-855 Bt2, NCS-856 Bt2, NCS-857 Bt2 and NCS-858 Bt2 containing *cry1Ac* & *cry2Ab* gene (Event MON 15985) in North zone.

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6.30 Application submitted by M/s. Vikram Seeds Limited, Ahmedabad for permission to conduct Multi Location Research Trials (MLRT) of four cotton hybrids (HXH) namely VICH-303 Bt (BG-II), VICH-304 Bt (BG-II), VICH-305 Bt (BG-II) and VICH-306 Bt (BG-II) containing *cry1Ac* & *cry2Ab* genes (MON 15985) in North zone.

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6.31 Application submitted by M/s. Ankur Seeds Pvt. Ltd., Nagpur for permission to conduct Multi Location Research Trials (MLRT) of three intra-hirsutum Bt cotton hybrids namely Jai BG-II, Ankur 3028 BG-II and Ankur 2420 BG-II containing *cry1Ac* & *cry2Ab* genes (MON 15985) in North zone and seed production of the same hybrids in half acre each.

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6.32 Application submitted by M/s. Maharashtra Hybrid Seeds Co. Ltd., Maharashtra for permission to conduct Multi Location Research Trials (MLRT) of four transgenic stack cotton hybrids namely MRC 7361 BG-II, MRC 7365 BG-II, MRC 7373 BG-II & MRC 7083 BG-II containing staked *cry1Ac & cry2Ab* genes (MON 15985) in North zone.

Hybrids expressing genes (Cry 1Ab -Cry 1Ac) "GFM Cry 1A"

6.33 Application submitted by M/s. Safal Seeds & Biotech Ltd., Jalna for permission to conduct Multi Location Research Trial/ (MLRT) and Seed production of three Bt cotton hybrids namely SBCH-278 Bt, SBCH-286 Bt and SBCH-290 Bt containing *GFM cry1Ac* gene in North zone.

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6.34 Application submitted by M/s. Navkar Hybrid Seeds Pvt. Ltd., Ahmedabad for permission to conduct Multi Location Research Trials (MLRT) of three (HXH) Bt-cotton hybrids viz. ACH-1085 Bt, ACH-1163 Bt and ACH-1177 Bt containing *'GFM cry1A'* gene in North zone.

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6.35 Application submitted by M/s. Uniphos Seeds & Bio-Genetics, Secunderabad for permission to conduct Multi Location Research Trials (MLRT)/ SAU trials and Experimental Seed Production of four transgenic Bt cotton hybrids namely UPLHH-168 Bt, UPLHH-264 Bt, UPLHH-342 Bt and UPLHH-350 Bt containing GFM *cry1A* fusion gene in North zone.

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6.36 Application submitted by M/s. Uniphos Enterprises Ltd., Mumbai for permission to conduct Multi Location Research Trials (MLRT)/ SAU trials and Experimental Seed Production of four transgenic Bt cotton hybrids namely UPLHH-360 Bt, UPLHH-338 Bt, UPLHH-10 Bt and UPLHH-12 Bt containing GFM *cry1A* fusion gene in North zone.

Hybrids expressing Cry 1Ac event -1

6.37 Application submitted by M/s. JK Agri Genetics Ltd., Hyderabad for permission to conduct Multi Location Research Trials (MLRT) of four newly developed JKAL-Bt cotton hybrids namely JKCH-1950 Bt, JKCH-1953 Bt, JKCH-1974 Bt and JKCH-2021 Bt containing *cry1Ac* gene (Event-1) in North zone.

1.0 The Committee noted that the applications for MLRT/SAU/STRIP trials and seed production of Bt cotton hybrids expressing approved events at agenda items 6.31 to 6.37 was recommended by the RCGM in its meetings held on 7.3.2008. The GEAC considered the 37 applications received from 20 Companies for conducting MLRT/SAU and Strip trials and seed production of Bt cotton hybrids expressing approved events in the North zone in light of the policy decision to deregulate Bt cotton hybrids expressing approved events from biosafety angle at Agenda Item 4.1 and the recommendations of the RCGM. The Committee took note of Dr. Bhargava views that he would not be able to give his views on the matter unless he has examined the available biosafety data.

2.0 The Committee taking into consideration that the Bt cotton hybrids at Agenda item 6.1 to 6.37 contain events which has been approved for commercial release, conveyed its no objection to the proposals subject to strict compliance of the new procedure adopted by the GEAC at agenda item 4.1. The Committee further directed the applicants to submit details of the locations of MLRT/STRIP/SAU trials along with the name of the lead Scientist to the GEAC/RCGM/SAU/ State Agriculture Departments.

Agenda Item No 7: Consideration of Applications for field trials of Bt cotton expressing new gene events in the North Zone during Kharif, 2008 as recommended by the MEC/RCGM

7.1 Application submitted by M/s. Maharashtra Hybrid Seeds Co. Ltd., Maharashtra for permission to conduct MLRT of four transgenic stack cotton hybrids namely MRC 7017 BG-II RRF, MRC 7031 BG-II RRF, MRC 7041 BG-II RRF & MRC 7045 BG-II RRF containing staked *cry1Ac & cry2Ab* genes (MON 15985) & *CP4 EPSPS* Event (MON 88913) in North zone.

7.1.1 The Committee noted that the present request of the applicant is for permission to conduct MLRT of four transgenic BG II RRF cotton hybrids namely MRC 7017 BG-II RRF, MRC 7031 BG-II RRF, MRC 7041 BG-II RRF & MRC 7045 BG-II RRF containing staked *cry1Ac & cry2Ab* genes (MON 15985) & *CP4 EPSPS* Event (MON 88913) in North zone. The RCGM in its meeting held on 7.3.2008 has recommended MLRT with the above mentioned Bt cotton hybrids at five locations i.e. Punjab (Bhatinda, Muktsar), Haryana (Hisar and Sirsa) & Rajasthan (Sriganganagar) in North Zone during Kharif, 2008.

7.1.2 The Member secretary GEAC further informed that the GEAC had accorded permission for conducting MLRT in the South zones after the applicant had complied with the requirement of 200 m isolation distance, submission of a validated event specific protocol at an LOD of 0.01% and name of a lead scientist as directed in the Hon'ble Supreme Court directions dated 8.5.2007. Accordingly the applicant has conducted MLRT at 6 locations (Guntur, Ranga Reddy, Haveri, Dharwad, Coimbatore and Salem) in the South zone during Kharif 2007. The MLRT has been evaluated by the MEC. Report of the MEC is awaited.

7.1.3 Dr Bhargava, reiterating his earlier concerns informed that he would be able to give his views only after review of the biosafety data. It was informed that MLRT is being conducted to generate biosafety data and therefore only limited data would be available at this stage. It was agreed that the available information may be forwarded to him. The Committee requested Dr Bhargava to give his views within two weeks time. The Committee also opined that data generated during MLRT in the South zone should also be made available to all the Members.

7.1.4 Decision on the proposal was deferred.

7.2 Permission for large scale trials, ICAR trials and seed production of Bt cotton expressing cry 1Ac protein in the North zone by Central Institute for Cotton Research, Nagpur.

7.2.1 The application from the Central Institute for Cotton Research (CICR), Nagpur seeking permission of the GEAC to conduct large scale field trials, ICAR trials and seed production with Bt cotton namely BN Bt (variety) expressing Bt Cry 1Ac protein in the North Zone was considered by the GEAC. The following points were noted:

1. The indigenously developed Bt cotton developed by CICR in due compliance with the regulatory process is the first public sector GM crop in India.
2. The transgenic cotton expresses Bt cry 1Ac (Truncated and codon-modified) gene which is very similar to the Cry 1Ac toxin expressed by MON 531 event developed by M/s Monsanto as well as event 1 of IIT, Kharagpur both of which are already under commercial cultivation.
3. Bt technology has been deployed in a known varietal background.
4. The applicant has completed the following biosafety studies:

i) Evaluation Report of Bt cotton hybrids / variety under RCGM Trial conducted at four locations in North Zone during the year 2006-07.
ii) Estimation of Bt – Cry 1Ac protein expression at various stages of plant growth in the transgenic cotton plants.
iii) Event specific flanking region sequence analysis.
iv) Pollen flow studies with Bt transgenic Cotton to find out the percentage of out cross pollination with compatible Crops cultivated in and around the area.
v) Transgenic Cotton expressing Bt Cry 1Ac protein and its effects on soil microflora.
vi) Transgenic Cotton expressing Bt Cry 1Ac protein and its effects on soil fauna (earthworms)
vii) Biosafety of Bt Cry 1Ac protein on laboratory animals such as Rabbit, Rat and Guinea Pigs.

i. Primary skin irritation test on Rabbit.
ii. Irritation to mucous membrane in Rabbits
iii. Acute Oral Toxicity study in Rats.
iv. Skin sensitization study in Guinea pigs.

viii) Biosafety of Bt Cry 1Ac protein on fish
ix) Biosafety of Bt Cry 1Ac protein on broiler chicken.
x) Biosafety of Bt Cry 1Ac protein on large animals like cow/buffalo and Goat/sheep.

7.2.2 In compliance with the Hon'ble Supreme Court directions, the applicant has also developed the standard operating procedure and validated event specific testing protocol at an LOD of at least 0.01%.

7.2.3 The merits of the proposal were extensively discussed wherein the following views were expressed by the Members:

7.2.4 During the deliberations the following points in favour of the proposal emerged:

1. Bt technology has been for the first time introduced in a varietal background whereby the farmers can save the seeds.
2. Bt technology has been introduced in a popular and well established agronomic background.
3. No cost to the trait value which would provide cheaper options to the farmers.
4. Adequate data on Cry 1Ac protein is available.

7.2.5 Dr Bhargava opined, given his earlier reservation on the Bt technology policy in India, he would have liked to review the biosafety data and the competence of the institute who have generated the data. However, given the background of ICAR and recognizing that Bt crops expressing cry1 Ac toxin is already under commercial cultivation, he extended his full support to the proposal subject to the condition that additional data if required would be generated by the applicant. Further

in the national interest, he suggested that as an exceptional and unique situation, the GEAC may consider commercial release at this stage.

7.2.6 The Committee was of the view, a step by step review of the biosafety data is mandatory and any deviation from the regulatory procedure is not advisable taking into consideration that public sector institutions are developing several GM crops and also to avoid any litigation from other stakeholders. The representatives of CICR and ICAR also opined that seeds available with the institute are adequate only for conduct of large scale trials and ICAR trials. However, the seeds generated during the trials would be made available to the farmers free of trait value.

7.2.7 In light of the above discussions the GEAC approved the large scale trials, ICAR trials, and large scale seed production in an area of 100 ha with BN Bt (variety) expressing Bt Cry 1Ac protein in the North Zone during Kharif, 2008. The Committee requested CICR to submit the biosafety dossier to Dr. Bhargava for his comments. The Committee requested Dr. Bhargava to give his comments within two weeks' time.

Agenda item No 8: Other item

8.1 Revalidation of GEAC Permission for Large Scale trials and seed production with SP 499 (Cry 1Ac & Cry 2Ab) (Mon -15985) gene in the North Zone by M/s Bayer Biosciences.

8.1.1 In light of the policy decision to deregulate Bt cotton hybrids expressing approved events from biosafety angle the Committee opined, large scale trials under GEAC would no longer be applicable and accordingly advised the applicant to follow the new procedure at Agenda Item 4.1.

8.2 Application for permission for conducting Experimental seed production of Bt Brinjal by M/s Mahyco.

8.2.1 The GEAC in its meeting held on 8.8.2007 based on the recommendations of Expert Committee on Bt Brinjal had approved large scale trials and seed production of Bt Brinjal containing cry 1 Ac gene in various agro-climatic zones under the direct supervision of Director, Indian Institute of Vegetable Research (IIVR) Varanasi with certain conditions. One of the conditions was that the seed production shall be undertaken in the Institutions/ research farms of IIVR/ICAR/SAU as per the protocol prescribed by Director IIVR. In this regard Dr. Mathura Rai, Director IIVR, Varanasi has informed vide his letter dated 13.9.2007 that the seed production of Bt brinjal may be assigned to the applicant.

8.2.2 The Committee noted that the request of the applicant is for conduct of experimental seed production at Jalna district, Maharashtra within their institutional research farm as per the protocol approved by IIVR. Views were expressed, that feasibility of seed production in other institutional farms falling under the jurisdiction of State Agricultural University or other ICAR institutions may be considered. It was also opined that seed production being the propriety of the applicant, experimental seed production at Jalna under the supervision of Director Horticulture Research or Director Research of the State Agriculture University located in proximity to Jalna may be considered to facilitate the monitoring and supervision mechanism.

8.2.3 Dr Bhargava, reiterating his earlier concerns informed he would be able to give his views only after review of the biosafety data. It was explained that experimental seed production is necessary to enable the applicant to generate biosafety data and therefore only limited data would be available at this stage. It was agreed that the available information may be forwarded to him. The Committee requested Dr Bhargava to give his views within two weeks time.

8.2.4 Decision on the proposal was deferred.

8.3 Representations regarding conduct of MLRT with Bt okra hybrid at Nadia District, West Bengal by M/s. Maharashtra Hybrid Seeds Co. Ltd.

8.3.1 The Committee considered the representation from Prof. T. K. Bose, Member West Bengal State Agriculture Commission stating that Bt okra field trials at Nadia District, West Bengal is illegal on the following grounds:

1. The Statutory bodies namely State Biotechnology Coordination Committee (SBCC) and District Level Committees (DLCs) empowered under Rules, 1989 of EPA, 1986 to monitor/ inspect/ investigate and take punitive actions have not been informed about the Bt okra trials.
2. As per the communication dated 9.7.2007 sent to various State Government Agencies, the GEAC had approved only Bt rice and Bt brinjal in West Bengal.
3. In the 78th GEAC meeting held on 22.6.2007 there is no mention of Bt okra trials in farmers field in West Bengal.
4. The applicant is conducting Bt okra trials in farmers field in violation to the decision taken by the GEAC and RCGM that GM crop field trials expressing new gene event will not be conducted in farmers field.
5. The Panchayat is not authorized to approve the proposal of conducting GM crop field trials without the knowledge and instructions of DLC.

8.3.2 The following facts of the case were placed before the Committee:

1. The DBT vide communication dated 14.11.2007 has informed the Chief Secretary, Director Research and Commissioner of Agriculture, Govt. of West Bengal regarding the Bt okra field trials at Nadia District of West Bengal.
2. The Ministry has also informed the Chief Environmental Officer vide communication dated 14.11.2007 regarding the GM crops field trials in West Bengal which include Bt rice, Bt okra and Bt brinjal. The matter was also recently discussed with the State Government during the visit of the Nodal Officer of this Ministry to the state of West Bengal wherein the State Government has suggested that, in future, field trials may be carried out in agricultural farms of the Government instead of leased land from farmers. They have indicated that the State Government has a large number of agricultural farms in almost all the district and agro climatic zone and therefore it would not be difficult to find suitable Government agricultural farms for the trials.
3. The complaint that the GEAC had not approved Bt okra trials in Nadia district is based on the title of the agenda item 5.2 and the subsequent minutes posted on the GEAC website prior to the meeting. While preparing the agenda there was an inadvertent computer error whereby the locations submitted by the applicant and recommended by RCGM did not match with the title of the agenda placed before the GEAC. In fact the 20 locations indicated in the agenda item 5.2 against Bt okra pertains to cotton growing areas. This was brought to the notice of the regulatory authority by the applicant. On verification of the application and the recommendations of the RCGM it was confirmed that the applicant had requested for field trials at only 12 locations which include Nadia district in West Bengal. Notwithstanding the above, in view of the Hon'ble Supreme Court directions, the GEAC in its meeting held on 22.6.2007 did not approve any location unless confirmation on availability of land for maintaining the required isolation distance was received. Accordingly, no locations have been specified in the approval letter dated 23.7.2007 issued by RCGM at the direction of the GEAC. Only after the applicants have confirmed the availability of land,, permission of Panchayat and submitted the validated event specific protocol of 0.01% LOD, they were allowed to conduct the field trials at specified locations. The locations where the field trials are being conducted is available in the public domain (www.envfor.nic.in, www.igmoris.nic.in).
4. While the GEAC has not approved MLRT in farmers' field, it may be noted that MLRT has been permitted in long leased land (minimum of three years). There is no restriction for acquiring the lease from farmers. The applicant has acquired the land by signing an agreement with the owner of the land Mr. Anil Ghosh and the Company will be responsible for all aspects of the trials.

5. The GEAC is the apex body for permitting GM crop field trials and approval of SBCC / DLC is not required. The need for informing the Panchayat was introduced to keep the villagers informed about the need to conduct the trials in a safe manner and increase awareness on biosafety issues.
6. The field trials of Bt okra have also been monitored by BCKV Agriculture Scientist on 22.1.2008. The GEAC has not received any report of non-compliance from the SAU monitoring teams.

8.3.3 The Member Secretary, GEAC also informed, the above clarifications have been provided by the Ministry under RTI. DBT has also clarified some of the issues to Prof T. K. Bose. Since the above facts have not been reflected in the minutes of the GEAC, the apprehension that Bt okra trials at Nadia district are illegal seems to linger on.

8.3.4 After detailed deliberation on the matter, the Committee concluded that the Bt okra being conducted in West Bengal is legal and ratified the locations where Bt okra trials have been undertaken by the applicant during 2007. The Committee advised Member Secretary, GEAC to send a formal communication in this regard to Dr. T. K. Bose, Member, State Agriculture Commission, Govt. of West Bengal.

8.4 Guidelines for the Conduct of Confined Field Trials of Regulated, Genetically Engineered Plants In India and Standard Operating Procedures (SOPs)

8.4.1 The Member Secretary, GEAC informed in accordance with the decision taken in the GEAC meeting on 22.11.2007, the following documents prepared by DBT and MoEF through a joint project implemented by BCIL were placed on the website for public comments for 45 days:

1. Draft guidelines for the conduct of confined field trials of regulated genetically engineered plants in India including the application form.
2. Draft Standard operating procedures (SOPs) for confined field trials of genetically engineered cotton.
3. Recording formats
4. Draft guidelines for monitoring of confined field trials of regulated, genetically engineered plants in India including proforma for monitoring report.

8.4.2 The draft guidelines and SOPs were also circulated to MEC/RCGM/GEAC members. Three regional consultations were held with the State Agricultural University and State Department of Agriculture at Chandhigarh for the Northern region, Nagpur for the Western Region and at Hyderabad for the Southern and Eastern region. The consultations were attended by 150 participants from 15 states. The comments/concerns raised by various stakeholders have been addressed and suitable modifications have been made in the guidelines and SOPs. RCGM has accepted the guidelines and SOPs in its meeting held on 7.3.2008 and has forwarded the same for consideration of the GEAC.

8.4.3 It was decided that the draft guidelines and SOPs would be forwarded to the members by e-mail and a presentation could be made to the Committee in the next GEAC meeting for taking a final view on the matter. A hard copy of the guidelines and SOPs were handed over to Dr. Bhargava with a request that his comments may be made available to the GEAC within two weeks' time.

8.5. ICMR Guidelines Draft Protocols for Safety Assessment for the Safety Assessment of Foods Derived from Genetically Engineered Plants in India.

8.5.1 The Member Secretary, GEAC informed that in the GEAC meeting held on 22.11.2007, ICMR was requested to post the guidelines on ICMR website. The stakeholder comments have been suitably incorporated and the final draft has been forwarded by Dr. Vasantha Muthuswamy, Head (BMS) ICMR for consideration and adoption by the GEAC.

8.5.2 It was decided that the draft guidelines and protocols would be forwarded to the members by e-mail and a presentation could be made to the Committee in the next GEAC meeting for taking a final view on the matter. A hard copy of the guidelines and SOPs were handed over to Dr. Bhargava with a request that his comments may be made available to the GEAC within two weeks' time.

Agenda Item No. 9: Any other matter with the permission of the Chair.

1.0 Dr. Bhargava requested for some time to detail out his concerns related to release of GM crops in the environment. He opined that agriculture security of India is utmost important and therefore, it is necessary to consider alternatives before taking a decision on a need for GM crop**.** He indicated that the risk associated with GM crop include gene flow issues, marker gene, experimental errors, impact on useful insect micro-flora, change in surface properties of soil, reproductive interference, question of second side change and its mapping, selective transcription/ translation, change in nature of protein itself, change in metabolic balance, development of resistance, increased requirement of refugia, emergence of super weeds, phenotypic changes, toxicity of GM crops especially in human gut, pliotropic effect, tolerance to physical factors and transfer of organisms to another country. He suggested that in addition to molecular characterization of the flanking sequence, proteomics study and DNA finger printing should be conducted. The other studies suggested include changes in glycosylation changes to assess the allergenicity, information on the technology including plasmids mapping and transposons properties of the product, impact on the human and animal gut, toxicity studies using real protein and not surrogate protein, stability of gene, reproductive interference and impact on local pest. Dr. Bhargava informed the Committee that he would forward a detailed note on his concerns for consideration of the Committee.

2.0 It was noted by the Committee that the studies enumerated by Dr Bhargava are being carried out. However the Committee would be happy to receive his comments. Dr Bhargava further stated that generation of data is one issue but it is also important to consider who is conducting the study. It was informed that institutions such as ICAR and SAUs are involved in the monitoring and evaluation of field trials of Bt cotton. Feed studies are being conducted in institutions such as Indian Veterinary Research Institute, Izatnagar, National Dairy Research Institute, Karnal, Indian Toxicological Research Institute, Lucknow, Avian Research Institute, Rae Bareilly, Central Fish Institute and Education, Mumbai, Rallies India Limited, Bangalore and other NABL accredited laboratories. He requested the Member Secretary to provide him with the list of biosafety studies posted on the website and list of NABL accredited laboratories. He expressed his constraints in reviewing the information electronically and suggested that he would take some time to review the data in the Ministry during his visits to Delhi. The Chairman GEAC expressed that Dr. Bhargava is always welcome to the Ministry and can have access to any document which he requires. Thanking the Chairman and Members, Dr Bhargava expressed that he was happy to be associated with the GEAC and interact with technical members of very high caliber. He commended CICR for the outstanding nature of the study on 'Monitoring the susceptibility of bollworms to Bt gene and development of insect resistance'.

Date of the next GEAC meeting: It was decided, the next GEAC meeting would be held on 2.5.2008. In view of the sowing season it was also suggested that GEAC meeting may be convened during the last week of May, 2008. It was agreed tentatively to hold the meeting on 28.5.2008.

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