

Decision of the 86th meeting of the Genetic Engineering Approval Committee held on 25.6.2008.

The 86th meeting of the Genetically Engineering Approval Committee (GEAC) was held on 25.6.2008 at 11.00 AM 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 3 to 8 are as follows:

Agenda item No. 3: Action taken report.

1.0 The Member Secretary, GEAC informed the Committee that decisions taken in the GEAC meeting held on 28.5.2008 have been communicated to the applicants, State Government agencies and others, as applicable.

2.0 It was also noted that in accordance with the decision taken in the GEAC meeting held on 2.5.2008, the following hybrids were approved for commercial release in the Central / South zones by the Chairman, GEAC based on the report received from the Chairman, MEC:

1. SP-504 B2 expressing cry 1AC & Cry 2Ab (MON 15985) gene by M/s Bayer Bioscience in the Central zone
2. KCH-707 BG II expressing cry 1AC & Cry 2Ab (MON 15985) gene by M/s Kaveri Seeds in the Central Zone
3. VICH-5 Bt (BG II) expressing cry 1AC & Cry 2Ab (MON 15985) gene by M/s Vikram Seeds Ltd. in the Central Zone
4. RCH-584 (BG II) expressing cry 1AC & Cry 2Ab (MON 15985) gene by M/s Rasi Seeds Ltd. in the Central Zone
5. 311-2 BG II and 557-2 BG II expressing cry 1AC & Cry 2Ab (MON 15985) gene by M/s Bioseeds in the Central Zone
6. PRCH 505 BGII expressing cry 1AC & Cry 2Ab (MON 15985) gene by M/s Pravardhan Seeds Ltd. in the Central Zone
7. UPLHH-2Bt expressing Cry 1 Ab-Cry 1 Ac " GFM Cry 1 A" by M/s Uniphos Enterprises Ltd. in the Central Zone
8. JK Durga Bt expressing Cry 1 Ac (event 1) by M/s J. K. Agri Genetics Ltd. in the Central Zone.

3.0 The Committee further noted that NCS 138 Bt expressing Cry 1Ac (MON 531 event) was approved by the Chairman GEAC for commercial release in the Central zone on receipt of confirmation from Member Secretary, RCGM that NCS 138 Bt has been recommended by the RCGM in its meeting held on 22.5.2007.

Agenda Item No. 4: Consideration of new proposals

A. Pharmaceuticals

It was pointed out that the title '**Pharmaceutical**' should be replaced with '**Food**' since the proposal at agenda item 4.1 pertains to food product.

4.1 Permission for manufacture and commercialization of recombinant Chymosin by M/s. Sudershan Biotech Ltd.

4.1.1 The Committee considered the request for manufacture and commercialization of r-Chymosin in India. The Committee noted that the company has conducted pre-clinical toxicology studies from Indian Institute of Chemical Technology (IICT) to evaluate the potential toxicity of r-Chymosin, if any on single and repeated doses of oral administration to mice, rats and rabbits. Intended use of the product is to increase the shelf life of cheese consumed by the human population. The use of the product is for preparation of cheese for milk clotting. The total quantity required for manufacture is 400 litres (550 IMCU/ml) per annum. The Committee noted that the RCGM has recommended the proposal in its meeting held on 25.1.2008.

4.1.2 The Committee also considered comments received from Dr. V. S. Chauhan, Director, ICGEB and noted that the data submitted by the applicant is not adequate for taking a final view on the matter. It was decided to advise the applicant to submit the additional information as sought by the expert member. Decision on the proposal was therefore deferred.

Agenda Item No 5: Consideration of applications for Commercial release of Bt cotton hybrids expressing approved gene event

B. Transgenic Crops

COMMERCIAL RELEASE IN SOUTH ZONE

Hybrids expressing *expressing* Cry 1 Ac (MON 531 event)

4.2 Permission for commercialization of NCHB 940 Bt and NCHB 945 Bt *expressing* Cry 1 Ac (MON 531 event) in the South Zone by M/s Nuziveedu Seeds Ltd.

4.2.1 The recommendations of LST/MEC/ICAR in respect of 2 Bt cotton hybrids as contained in the proposal at agenda 4.2 namely NCHB 940 Bt and NCHB 945 Bt *expressing* Cry 1Ac (MON 531 event) was considered by the GEAC.

4.2.2 The Committee noted that the above hybrids have been approved for commercial release in the South zone in the MEC Sub Committee meetings held on 31.5.2008. In the light of the recommendations made by the MEC and RCGM and taking into consideration the policy decision to adopt an event based approval mechanism for Bt cotton hybrids *expressing* approved events, the Committee approved the following hybrids for commercial release in the South Zone:

1. NCHB 940 Bt *expressing* Cry 1 Ac (MON 531 event) in the South Zone by M/s Nuziveedu Seeds Ltd.
2. NCHB 945 Bt *expressing* Cry 1 Ac (MON 531 event) in the South Zone by M/s Nuziveedu Seeds Ltd.

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

4.3 Permission for commercialization of Ankur 5642 BG II, Ankur 10122 BG II and Akka BGII *expressing* Cry 1Ac & Cry 2Ab genes (MON 15985) in the South Zone by M/s Ankur Seeds Pvt. Ltd.

&

4.4 Permission for commercialization MRC-7918 BGII and MRC 7929 BGII *expressing* Cry 1Ac & Cry 2Ab genes (MON 15985) in the South Zone by M/s Mahyco.

&

4.5 Permission for commercialization Brahma BG II *expressing* Cry 1Ac & Cry 2Ab genes (MON 15985) in the South Zone by M/s Monsanto Genetics India Pvt. Ltd.

&

4.6 Permission for commercialization of KCH-135 Bt (BGII) *expressing* Cry 1Ac & Cry 2Ab genes (MON 15985) in the South Zone by M/s Kaveri Seed Company Ltd.

- &
- 4.7 Permission for commercialization GK 217 BG II expressing Cry 1Ac & Cry 2Ab genes (MON 15985) in the South Zone by M/s Ganga Kaveri Seeds Pvt Ltd.
- &
- 4.8 Permission for commercialization KDCHH-441 BG II and KDCHH 9632 BG II expressing Cry 1AC & Cry 2Ab genes (MON 15985) in the South Zone by M/s Krishidhan Seeds Ltd.
- &
- 4.9 Permission for commercialization RCH-596 BG II expressing Cry 1AC & Cry 2Ab genes (MON 15985) in the South Zone by M/s Rasi Seeds Pvt. Ltd.
- &
- 4.10 Permission for commercialization SP-1037 B2 expressing Cry 1Ac & Cry 2Ab genes (MON 15985) in the South Zone by M/s Bayer Biosciences Ltd.
- &
- 4.11 Permission for commercialization NAMCOT 612 BG II and NAMCOT 607 BGII expressing Cry 1Ac & Cry 2Ab genes (MON 15985) in the South Zone by M/s Namdhari Seeds Pvt. Ltd.
- &
- 4.12 Permission for commercialization NSPL 999 BG II and NSPL 405 BG II expressing Cry 1Ac & Cry 2Ab genes (MON 15985) in the South Zone by M/s Nandi Seeds Pvt. Ltd.
- &
- 4.13 Permission for commercialization VBCH 1501 BGII, VBCH 1505 BG II and VBCH 1506 BG II expressing Cry 1AC & Cry 2Ab genes (MON 15985) in the South Zone by M/s Vibha Agrotech Ltd.
- &
- 4.14 Permission for commercialization PCH 2270 Bt 2 and PCH 105 Bt 2 expressing Cry 1Ac & Cry 2Ab genes (MON 15985) in the South Zone by M/s Prabhat Agri Biotech Ltd.
- &
- 4.15 Permission for commercialization ACH-155-2 BG II, ACH-177-2 BGII expressing (Cry 1Ac & Cry 2Ab genes (MON 15985) in the South Zone by M/s Ajeet Seeds Ltd
- &
- 4.16 Permission for commercialization NCS 854 Bt 2 and NCS 207 BGII expressing Cry 1AC & Cry 2Ab genes (MON 15985) in the South Zone by M/s Nuziveedu Seeds Ltd.
- &
- 4.17 Permission for commercialization ABCH 1065 Bt BG II and ABCH 1020 Bt BG II expressing Cry 1 AC & Cry 2Ab genes (MON 15985) in the South Zone by M/s Amar Biotech Ltd.
- &
- 4.18 Permission for commercialization 322-2, 113-2 and 340-2 expressing Cry 1AC & Cry 2Ab genes (MON 15985) in the South Zone by M/s Bioseed Research India Pvt. Ltd.
- &
- 4.19 Permission for commercialization PRCH 504 BG II and PRCH 505 BG II expressing Cry 1AC Cry 2Ab genes (Mon 15985) in the South Zone by M/s Pravardhan Seeds Pvt. Ltd.
- &
- 4.20 Permission for commercialization VICH 15 Bt (BG II) and VICH 5 Bt (BG II) expressing Cry 1Ac & Cry 2Ab genes (Mon 15985) in the South Zone by M/s Vikram Seeds Ltd.

1.0 The recommendations of SAU/MEC/ICAR in respect of 34 Bt cotton hybrids as contained in the proposal at agenda 4.3 to 4.20 namely Ankur 5642 BG II, Ankur 10122 BG II and Akka BGII by M/s Ankur Seeds Pvt. Ltd., MRC-7918 BGII and MRC 7929 BGII by M/s Mahyco, Brahma BG II by M/s Monsanto Genetics India Pvt. Ltd., KCH-135 Bt (BGII) by M/s Kaveri Seed Company Ltd., GK 217 BG II by M/s Ganga Kaveri Seeds Pvt Ltd., KDCHH-441 BG II and KDCHH 9632 BG II by M/s Krishidhan Seeds Ltd., RCH-596 BG II by M/s Rasi Seeds Pvt. Ltd., SP-1037 B2 by M/s Bayer Biosciences Ltd, NAMCOT 612 BG II and NAMCOT 607 BGII by M/s Namdhari Seeds Pvt. Ltd., NSPL 999 BG II and NSPL 405 BG II by M/s Nandi Seeds Pvt. Ltd., VBCH 1501 BGII, VBCH 1505 BG II and VBCH 1506 BG II by M/s Vibha Agrotech Ltd., PCH 2270 Bt 2 and PCH 105 Bt 2 by M/s Prabhat Agri Biotech Ltd., ACH-155-2 BG II and ACH-177-2 BGII by M/s Ajeet Seeds Ltd., NCS 854 Bt 2 and NCS 207 BGII by M/s Nuziveedu Seeds Ltd. ABCH 1065 Bt BG II and ABCH 1020 Bt BG II by M/s Amar Biotech Ltd., 322-2, 113-2 and 340-2 by M/s Bioseed Research India Pvt. Ltd. PRCH 504 BG II and PRCH 505 BG II by

M/s Pravardhan Seeds Pvt. Ltd., VICH 15 Bt (BG II) and VICH 5 Bt (BG II) by M/s Vikram Seeds Ltd. expressing Cry 1Ac & Cry 2Ab genes (MON 15985) were considered by the GEAC.

2.0 The Committee noted that the above hybrids have been approved for commercial release in the South zone in the MEC Sub Committee meeting held on 31.5.2008. In the light of the recommendations made by the MEC and RCGM and taking into consideration the policy decision to adopt an event based approval mechanism for Bt cotton hybrids expressing approved events, the Committee approved the following hybrids for commercial release in the South Zone:

1. Ankur 5642 BG II *expressing* Cry 1Ac & Cry 2Ab genes (MON 15985) by M/s Ankur Seeds Pvt. Ltd.
2. Ankur 10122 BG II *expressing* Cry 1Ac & Cry 2Ab genes (MON 15985) by M/s Ankur Seeds Pvt. Ltd.
3. Akka BGII *expressing* Cry 1Ac & Cry 2Ab genes (MON 15985) by M/s Ankur Seeds Pvt. Ltd.
4. MRC-7918 BGII *expressing* Cry 1Ac & Cry 2Ab genes (MON 15985) by M/s Mahyco.
5. MRC 7929 BGII *expressing* Cry 1Ac & Cry 2Ab genes (MON 15985) by M/s Mahyco.
6. Brahma BG II *expressing* Cry 1Ac & Cry 2Ab genes (MON 15985) by M/s Monsanto Genetics India Pvt. Ltd.
7. KCH-135 Bt (BGII) *expressing* Cry 1Ac & Cry 2Ab genes (MON 15985) by M/s Kaveri Seed Company Ltd.
8. GK 217 BG II *expressing* Cry 1Ac & Cry 2Ab genes (MON 15985) by M/s Ganga Kaveri Seeds Pvt Ltd.
9. KDCHH-441 BG II *expressing* Cry 1AC & Cry 2Ab genes (MON 15985) by M/s Krishidhan Seeds Ltd.
10. KDCHH 9632 BG II *expressing* Cry 1AC & Cry 2Ab genes (MON 15985) by M/s Krishidhan Seeds Ltd.
11. RCH-596 BG II *expressing* Cry 1AC & Cry 2Ab genes (MON 15985) by M/s Rasi Seeds Pvt. Ltd.
12. SP-1037 B2 *expressing* Cry 1Ac & Cry 2Ab genes (MON 15985) by M/s Bayer Biosciences Ltd.
13. NAMCOT 612 BG II *expressing* Cry 1Ac & Cry 2Ab genes (MON 15985) by M/s Namdhari Seeds Pvt. Ltd.
14. NAMCOT 607 BGII *expressing* Cry 1Ac & Cry 2Ab genes (MON 15985) by M/s Namdhari Seeds Pvt. Ltd.
15. NSPL 999 BG II *expressing* Cry 1Ac & Cry 2Ab genes (MON 15985) by M/s Nandi Seeds Pvt. Ltd.
16. NSPL 405 BG II *expressing* Cry 1Ac & Cry 2Ab genes (MON 15985) by M/s Nandi Seeds Pvt. Ltd.
17. VBCH 1501 BGII *expressing* Cry 1AC & Cry 2Ab genes (MON 15985) by M/s Vibha Agrotech Ltd.
18. VBCH 1505 BG II *expressing* Cry 1AC & Cry 2Ab genes (MON 15985) by M/s Vibha Agrotech Ltd.
19. VBCH 1506 BG II *expressing* Cry 1AC & Cry 2Ab genes (MON 15985) by M/s Vibha Agrotech Ltd.
20. PCH 2270 Bt 2 *expressing* Cry 1Ac & Cry 2Ab genes (MON 15985) by M/s Prabhat Agri Biotech Ltd.
21. PCH 105 Bt 2 *expressing* Cry 1Ac & Cry 2Ab genes (MON 15985) by M/s Prabhat Agri Biotech Ltd.
22. ACH-155-2 BG II *expressing* (Cry 1Ac & Cry 2Ab genes (MON 15985) by M/s Ajeet Seeds Ltd.
23. ACH-177-2 BGII *expressing* (Cry 1Ac & Cry 2Ab genes (MON 15985) by M/s Ajeet Seeds Ltd.
24. NCS 854 Bt 2 *expressing* Cry 1AC & Cry 2Ab genes (MON 15985) by M/s Nuziveedu Seeds Ltd.
25. NCS 207 BGII *expressing* Cry 1AC & Cry 2Ab genes (MON 15985) by M/s Nuziveedu Seeds Ltd.
26. ABCH 1065 Bt BG II *expressing* Cry 1 AC & Cry 2Ab genes (MON 15985) by M/s Amar Biotech Ltd.
27. ABCH 1020 Bt BG II *expressing* Cry 1 AC & Cry 2Ab genes (MON 15985) by M/s Amar Biotech Ltd.
28. 322-2 *expressing* Cry 1AC & Cry 2Ab genes (MON 15985) by M/s Bioseed Research India Pvt. Ltd.

29. 113-2 expressing Cry 1AC & Cry 2Ab genes (MON 15985) by M/s Bioseed Research India Pvt. Ltd.
30. 340-2 expressing Cry 1AC & Cry 2Ab genes (MON 15985) by M/s Bioseed Research India Pvt. Ltd.
31. PRCH 504 BG II expressing Cry 1AC Cry 2Ab genes (Mon 15985) by M/s Pravardhan Seeds Pvt. Ltd.
32. PRCH 505 BG II expressing Cry 1AC Cry 2Ab genes (Mon 15985) by M/s Pravardhan Seeds Pvt. Ltd.
33. VICH 15 Bt (BG II) expressing Cry 1Ac & Cry 2Ab genes (Mon 15985) by M/s Vikram Seeds Ltd.
34. VICH 5 Bt (BG II) expressing Cry 1Ac & Cry 2Ab genes (Mon 15985) by M/s Vikram Seeds Ltd.

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

- 4.21 Permission for commercialization UPLHH-12 Bt and UPLHH-5 Bt expressing (Cry 1Ab – Cry 1Ac) "GFM Cry 1A" gene in the South Zone by M/s Uniphos Enterprises Ltd.
&
- 4.22 Permission for commercialization ZCH-50072 Bt expressing (Cry 1Ab -Cry 1Ac) "GFM Cry 1A" gene in the South Zone by M/s Zuari Seeds Ltd.
&
- 4.23 Permission for commercialization NCEH 13 Bt, and NCEH 34 Bt expressing (Cry 1Ab – Cry 1Ac) "GFM Cry 1A" gene in the South Zone by M/s Nath Seeds Ltd.
&
- 4.24 Permission for commercialization SBCH-292 Bt expressing (Cry 1Ab -Cry 1Ac) "GFM Cry 1A" gene in the South Zone by M/s Safal seeds & Biotech Ltd.
&
- 4.25 Permission for commercialization Monsoon Bt expressing (Cry 1Ab -Cry 1Ac) "GFM Cry 1A" gene in the South Zone by M/s Yashoda Hybrid Seeds Pvt. Ltd.

1.0 The recommendations of SAU/MEC/RCGM/ICAR in respect of 7 Bt cotton hybrids as contained in the proposal at agenda item no. 4.21 to 4.25 namely UPLHH-12 Bt and UPLHH-5 Bt by M/s Uniphos Enterprises Ltd., ZCH-50072 Bt by M/s Zuari Seeds Ltd., NCEH 13 Bt and NCEH 34 Bt by M/s Nath Seeds Ltd., SBCH-292 Bt M/s Safal seeds & Biotech Ltd., Monsoon Bt by M/s Yashoda Hybrid Seeds Pvt. Ltd. expressing (Cry 1Ab -Cry 1Ac) "GFM Cry 1A" gene were considered by the GEAC.

2.0 The Committee noted that the above hybrids have been approved for commercial release in the South zone in the MEC Sub committee meetings held on 31.5.2008. In the light of the recommendations made by the MEC and RCGM and taking into consideration the policy decision to adopt an event based approval mechanism for Bt cotton hybrids expressing approved events, the Committee approved the following hybrids for commercial release in the South Zone:

1. UPLHH-12 Bt expressing (Cry 1Ab – Cry 1Ac) "GFM Cry 1A" gene in the South Zone by M/s Uniphos Enterprises Ltd.
2. UPLHH-5 Bt expressing (Cry 1Ab – Cry 1Ac) "GFM Cry 1A" gene in the South Zone by M/s Uniphos Enterprises Ltd.
3. ZCH-50072 Bt expressing (Cry 1Ab -Cry 1Ac) "GFM Cry 1A" gene in the South Zone by M/s Zuari Seeds Ltd.
4. NCEH 13 Bt expressing (Cry 1Ab –Cry 1Ac) "GFM Cry 1A" gene in the South Zone by M/s Nath Seeds Ltd.
5. NCEH 34 Bt expressing (Cry 1Ab –Cry 1Ac) "GFM Cry 1A" gene in the South Zone by M/s Nath Seeds Ltd.
6. SBCH-292 Bt expressing (Cry 1Ab -Cry 1Ac) "GFM Cry 1A" gene in the South Zone by M/s Safal seeds & Biotech Ltd.
7. Monsoon Bt expressing (Cry 1Ab -Cry 1Ac) "GFM Cry 1A" gene in the South Zone by M/s Yashoda Hybrid Seeds Pvt. Ltd.

Hybrids expressing Cry 1Ac event -1

4.26 Permission for commercialization of JKCH-2245 Bt, JK Indra Bt, JK Chamundi Bt and JK- Gowri Bt expressing Cry 1Ac event -1 in the South Zone by M/s JK Agri Genetics Ltd.

1.0 The recommendations of SAU/MEC /ICAR in respect of 4 Bt cotton hybrids as contained in the proposal at agenda 4.26 namely JKCH-2245 Bt, JK Indra Bt, JK Chamundi Bt and JK- Gowri Bt expressing Cry 1Ac event -1 by M/s JK Agri Genetics Ltd. were considered by the GEAC.

2.0 The Committee noted that the above hybrids have been approved for commercial release in the South zone in the MEC Sub committee meetings held on 31.5.2008. In the light of the recommendations made by the MEC and RCGM and taking into consideration the policy decision to adopt an event based approval mechanism for Bt cotton hybrids expressing approved events, the Committee approved the following hybrids for commercial release in the South Zone:

1. JKCH-2245 Bt expressing Cry 1Ac event -1 in the South Zone by M/s JK Agri Genetics Ltd.
2. JK Indra Bt expressing Cry 1Ac event -1 in the South Zone by M/s JK Agri Genetics Ltd.
3. JK Chamundi Bt expressing Cry 1Ac event -1 in the South Zone by M/s JK Agri Genetics Ltd.
4. JK- Gowri Bt expressing Cry 1Ac event -1 in the South Zone by M/s JK Agri Genetics Ltd.

Agenda Item No. 5: Consideration of Proposals for Large Scale Field Trials of Bt cotton expressing new gene/events.

5.1 Permission for Large Scale Trials and seed production of cotton hybrids 5174 Bt and 5125 Bt expressing synthetic Cry1C gene (event 9124) in Central Zone and South Zones by M/s Metahelix Life Science Pvt. Ltd.,

1.0 The application from the M/s Metahelix Life Science Pvt. Ltd seeking permission of the GEAC to conduct large scale field trials, ICAR trials and seed production with Bt cotton namely **5174 Bt** and **5125 Bt** expressing synthetic Cry1C gene (event 9124) in Central Zone and South Zones was considered by the GEAC . The following points were noted:

1. The indigenously developed Bt cotton developed by the applicant is in due compliance with the regulatory process.
2. This event expresses a truncated, synthetic cry 1C gene designed by the Company and obtained by protocols developed for cotton transformation in-house. The synthetic gene is designed based on the cry 1C protein made by *Bacillus thuringiensis*.
3. The Bt cotton hybrids 5174 Bt and 5125 Bt have completed multi locational field trials during Kharif, 2006 at seven locations in the Central and south zones.
4. The applicant has completed the following biosafety studies:
 - Acute Oral Toxicity in Rats
 - Sub chronic oral toxicity in rats (90 days)
 - Primary Skin Irritation tests in rabbits
 - Irritation of mucus membrane in rabbits
 - Skin sensitization study in guinea pigs
 - Allergenicity studies – Passive Cutaneous Anaphylaxis test.
 - Feeding studies with laying hens
 - Feeding studies with catfish
 - Feeding studies in goats
 - Feeding studies in lactating crossbred cows
 - Pollen flow studies
 - Wediness, Aggressiveness and Germination
 - Effect of Bt cotton event MLS 9124 on beneficial fauna
 - Study of soil microflora of Bt and Non Bt soils
 - Effect of Bt cotton on soil fauna
 - Estimation of Cry 1C in soils of Bt cotton fields

- Baseline susceptibility studies for *Spodoptera litura* to Bt
- Biochemical equivalence
- Limit of Detection at 0.01% and event specific PCR.

2.0 The Committee further noted that the multi locational field trials conducted in the Central and south Zones have been evaluated by the State Agriculture Universities (SAUs) in accordance with the recommendations of the Sub committee report on Bt cotton and related issues. The report of the SAUs has been considered by the MEC in its meeting held on 8-9.3.2007 and 17.4.2007. The MEC has recommended Bt cotton entries **5174 Bt and 5125 Bt** for LST in the Central and South zones. The hybrids have been recommended for large scale field trials by the RCGM based on the findings of the biosafety studies and recommendations of the MEC.

3.0 After detailed deliberations, the Committee approved the conduct of large scale trials, seed production and ICAR trials with 5174 Bt and 5125 Bt expressing synthetic Cry1C gene (event 9124) at 20 locations in the Central Zone and 10 locations in the South Zones.

Agenda Item No 6: Consideration of Applications for MLRT/Strip Trials and Experimental Seed Production of transgenic crops expressing new genes/events during Kharif, 2008 as recommended by the MEC/RCGM.

6.1 Application submitted by M/s. Dow Agro Sciences India Pvt. Ltd, Mumbai for permission to conduct experimental seed production of newly developed transgenic cotton hybrid namely WS106 expressing cry1Ac and cry 1F genes (Widestrike=Event 3006-201-23 and Event 281-24-236) in 0.5 ha area in South zone during Kharif 2008 for generating material for biosafety studies.

&

6.2 Application submitted by M/s. Dow Agro Sciences India Pvt. Ltd, Mumbai for permission to conduct pollen flow study of newly developed transgenic cotton hybrid namely WS106 expressing Cry1Ac and Cry 1F genes (Widestrike=Event 3006-201-23 and Event 281-24-236) at one location in South zone during Kharif 2008.

1.0 The Committee noted that the applicant is seeking approval of the GEAC for seed multiplication in an area of 0.5 acre area at five locations in South zone during Kharif – 2008 and conduct of pollen flow studies with transgenic cotton hybrid “WS106” expressing Cry 1AC and Cry 1F proteins (Wide Strike).

2.0 It was further noted that the GEAC has approved the conduct of biosafety studies including pollen flow studies at one location in the South Zone in its meeting held on 28.5.2008. The applicant has provided detailed protocol for conducting pollen flow trial including experiment design, treatment details, scientist in charge etc. The applicant has also provided event specific protocol at LOD of 0.01%. The RCGM has recommended the proposals in its meeting held on 27.5.2008.

3.0 After detailed deliberation and considering that the applicant will use composite seed material derived from MLRT and seed multiplication for conducting toxicology allergenicity and feeding studies, the GEAC approved the experimental seed production in an area of 0.5 acres in the South zone during Kharif, 2008. The Committee also approved the conduct of pollen flow studies at one location as per the protocol approved by the RCGM.

6.3 Application submitted by M/s. Nunhems India Pvt. Ltd., Gurgaon for permission to conduct Strip trials on 30 lines of transgenic Cabbage and Cauliflower i.e RST08-1 to RST08-30 (15 gene events for Cabbage and 15 gene events for Cauliflower containing cry 1B and cry 1C gene at 2 location Murthal (Haryana) in North and

Bangalore (Karnataka) in Central zones during July-Dec 2008 in north zone and March-July 2009 in south zone for bio-efficacy evaluation.

6.3.1 The Committee considered the request for approval for conducting strip trials for bio-efficiency evaluation of the multiple events (30 lines, 15 for transgenic cabbage and 15 for transgenic cauliflower). It was noted that all of the above lines have been tested for expression of two Bt genes using specific ELISA and Western blot assays and freeze dried samples have been tested for biological activity against different *Plutella Xylotella* (Diamond black moth) strains. The research trials would be used to investigate the performance of transgenic lines at different levels of plant development in company's own research farm. The trials will be performed as per requirements of maintaining isolation distance and will be destroyed before flowering.

6.3.2 The Committee also noted that the proposal was considered by the RCGM in its meeting held on 27.5.2008 wherein RCGM has opined that during the process of development of a GM crop, the event selection is done both in the green house and confined field trials (strip trials), following the transformation. As the strip trials or event selection trials are undertaken to select the final event, the developer may need to plant several events (could be as high as 50, -100). Therefore it may not be possible for the applicant to develop event specific protocol for 0.01% LOD at this stage. In view of the above, the RCGM recommended the conduct of strip trials for event selection under confined conditions and generating bio efficacy data at one location within the institutional research farm. Simultaneously, the company should generate SOPs for conducting field trials as well as level of detection (LOD) of the selected event at 0.01% level as per the directions of the Hon'ble Supreme Court.

6.3.3 After detailed deliberations and taking into consideration the recommendation of the RCGM, the GEAC approved the conduct of strip trial for bio-efficiency evaluation of the multiple events (30 lines, 15 for transgenic cabbage and 15 for transgenic cauliflower) at one location within the institutional research farm only.

6.4 Application submitted by M/s. Avesthagen Ltd., Bangalore for permission to conduct strip trials for male sterile rice lines (unedited NAD9) and its restorers (Antisense unedited NAD9) developed by biolistic-mediated transformation with mitochondrial targeting.

6.4.1 The request of M/s Avesthagen Ltd, Bangalore for permission to conduct strip trials for evaluation of male sterility and its restoration in transgenic rice lines expressing mitochondrial targeted unedited NAD9 and its antisense version respectively for the production of hybrids and for its transfer into elite breeding lines for the production of hybrids was considered by the GEAC. This project involves feed evaluation of sterility of unedited NAD9 rice lines and their restoration by cross-pollination of subsequent generations with rice lines expressing antisense unedited NAD9. Evaluated lines displaying male sterility will be further used purely as parents in breeding programs.

6.4.2 The Committee further noted that the RCGM in its meeting held on 27.5.2008 has recommended conduct of strip trials for event selection under confined conditions and generating bioefficacy data at one location within the company's own research farm. Simultaneously, the company should generate SOPs for conducting field trials as well as level of detection (LOD) of the selected event at 0.01% level as per the directions of the Hon'ble Supreme.

6.4.3 After detailed deliberations and taking into consideration the recommendations of the RCGM and noting that the request is only for event selection, the GEAC approved the conduct of strip trials with male sterile rice lines (unedited NAD9) and its restorers (Antisense unedited NAD9) at one location within the applicant's research farm only.

6.5 Application submitted by M/s. Avesthagen Ltd., Bangalore for permission to conduct strip trials of transgenic rice (*Oryza sativa taipae* 309) plants tolerant to oxidative stress by over expressing superoxide dismutase.

6.5.1 The Committee noted that the request is for conduct of strip trials of transgenic rice (*Oryza sativa taipae* 309) plants tolerant to oxidative stress by over expressing superoxide dismutase for event selection only and is similar to the proposals at agenda items 6.3 and 6.4. However, it was noted that the present background of the transgene is a basmati 370 line. One of the member pointed that the RCGM/ GEAC has taken a policy decision not to permit research in basmati germplasm. Views were expressed that the present background is only being taken as breeding material and would not be the final produce.

6.5.2 After detailed deliberations, the GEAC rejected the request as it is not in accordance with the policy decision taken by the RCGM and the GEAC not to permit research in basmati line.

6.6 Application submitted by M/s. Avesthagen Ltd., Bangalore for permission to conduct strip trials of transgenic tomato lines expressing unedited NAD9, for lycopene content and agronomic characters.

6.6.1 The Committee considered the request of M/s. Avesthagen Ltd., Bangalore for conduct of strip trials with transgenic tomato lines expressing unedited NAD9 for lycopene content and agronomic characters. The Committee noted that the proposal has been approved by the RCGM in its meeting held on 27.5.2008 and is similar to the proposals at agenda item no. 6.3 and 6.4.

6.6.2 After detailed deliberations, the GEAC approved the conduct of strip trials with transgenic tomato lines expressing unedited NAD9, for lycopene content and agronomic characters for event selection at one location within the institutional research farm only.

Agenda Item No. 7: Other items

7.1 Representation from Greenpeace regarding illegal GM food imports.

7.1.1 The Committee considered the following clarifications received from the M/s Greenpeace regarding the illegal imports of GM foods namely Dorito's Cool Ranch Corn chip manufactured by Frito Lays Inc. for Pepsico USA in response to queries raised by the GEAC in its meeting held on 28.5.2008 :

- a. According to the manufacturers specification listed on the rear of the packet, the ingredients seem to have contained "vegetable oil" containing one or more of the following – corn soybean or sunflower apart from partially hydrogenated soybean oil" Since a bulk of the soybean in the USA is Round Up Ready soybean, it is most possible that the unrefined oil used in the processing of "Doritos" chips might be the cause for the presence of the Round Ready Soya DNA in the testing.
- b. The process of screening had taken us three stages of qualitative testing.
 - i) Presence of any GM DNA in the sample.
 - ii) Two traces of corn and a soy ingredient in the sample.
 - iii) Two GM corn ingredients, MON 863 and NK 603 identified in the sample.
- c. These tests had been expensive and are at an accuracy of 0.01%, The detection of exact ingredient is more important in regulation as fixes the liability of the contamination on the producer of the corn, here in this case M/s Monsanto.

- d. As per the Rules for Manufacture, Use, Import, Export and Storage of Hazardous Micro Organisms/ Genetically Engineered Organisms or Cells 1989 under EPA, 1986 under Section (7) (1) that : "No person shall import, export, transport, manufacture, process, use or sell any hazardous microorganisms or genetically engineered organisms / substances or cells except with the approval of the GEAC".
- e. The assessment of percentage contamination of the GM corn as a consideration in the decision process of a regulatory authority is an unnecessary step. Guidelines regarding percentage contamination and tolerance levels are usually issued post the approval of a certain GMO in the market- to ensure segregation and labeling process are well adhered to. In this case, since neither of the GM corns in question, MON 863, NK 603 has been approved by the GEAC the question of tolerance levels does not arise.

7.1.2 After detailed deliberations, Members were of the view that there is a need to verify the allegations made by M/s Greenpeace. Accordingly, it was decided that a three member committee comprising of representatives from Ministry of Food Processing, Ministry of Health and Family Welfare and a Member of the GEAC may be deputed to collect the samples in accordance with the sampling procedure under PFA and refer the sample for analysis to a reputed laboratory in India or abroad.

7.1.3 The Committee also gave an opportunity to M/s Greenpeace for a personal hearing. However, the complainants were not available during discussion on the proposal. It was also decided to request M/s Greenpeace to provide the samples collected by them which could be used as a check.

Agenda Item No. 8: Any other matter with the permission of the Chairman

8.1 Show cause notice issued to M/s Tulasi Seeds Pvt. Ltd for illegal sale of BG II cotton hybrids in the state of Andhra Pradesh.

8.2.1 The following explanation received from M/s Tulasi Seeds Pvt. Ltd in response to the show cause notice issued by the GEAC for illegal sale of BG II cotton hybrids in the state of Andhra Pradesh was considered by the GEAC:

1. The mix up of seeds might have happened because of minor failure of man and machinery at the seed processing plant where process and packing of both Tulasi 4 Bt and Tulasi 4 BG II were carried out simultaneously as GEAC had permitted commercial release of Tulasi 4 BG II in the North and Central Zone.
2. This is an incident of identity preservation protocol failure which is an unintentional human error and not deliberate.
3. As regards, Environment (Protection), Act, 1986 is concerned it is stated that accidental and unintentional mix up does not attract the provisions of the EP Act, 1986 since both the events are declared bio-safe from environmental angle and commercialized. The issue of unintentional mix up is not at all affecting biosafety and therefore, there is no violation of EP Act, 1986.
4. On receipt of this complaint and show cause notice issued by the technology provider the seed stocks have been immediately withdrawn from the market.
5. In order to avoid such incidence in future, seeds of different hybrids are being packed in separate godowns. The applicant has also indicated that they are planning to coat the seed in different colors to avoid any mixing up of the events during packing.

8.2.2 After detailed deliberations, the GEAC concluded that the company has not behaved responsibly. However, taking into consideration the fact that the company has accepted their mistake and has taken necessary steps to rectify the same, the GEAC recommended to the Ministry to issue a stern warning to the company. It was also recommended that the Ministry may condone the lapse after verifying the legalities involved if any, and confirmation of the NOC earlier issued by the technology provider as NOC is a pre-requisite for commercial release.

8.2.3 Regarding the issue of Tulasi 9 Bt, Tulasi 45 Bt and Tulasi 118 Bt for the South Zone which was earlier deferred by the GEAC in its meeting held on 28.5.2008, the Committee was of the view that the hybrids may be approved for commercial release subject to fulfilling the regulatory procedure. On the issue of Tulasi BG II hybrids it was decided to consider the request after the applicant has resolved the issue with the technology provider.

8.3 Recommendation of RCGM in respect of applications for conduct of MLRT/SAU trials/Strip Trials/ Experimental Seed Production of Bt cotton hybrids expressing approved events.

8.3.1 The Committee considered 14 applications from 9 companies recommended by the RCGM in the 67th meeting held on 24.6.2008 for conducting MLRT/Strip trials and limited seed production of Bt cotton hybrids expressing approved events in the Central and South zones.

8.3.2 The Committee conveyed its no objection to the proposals subject to strict compliance of the new event based approval procedure adopted by the GEAC. The Committee was also of the view that the SAU trials should be conducted as per the AICCIP procedure under the ICAR system for genotype evaluation.

The next GEAC meeting is scheduled for 9.7.2008.
