**Decision taken in the 78th Meeting of the Genetic Engineering Approval Committee held on 22.6.2007**

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The 78th meeting of the Genetically Engineering Approval Committee (GEAC) was held on 22.6.2007 in the Ministry of Environment and Forests under the Chairmanship of Shri B. S. Parsheera, Additional Secretary, MoEF and Chairman, GEAC.

## 1.0 Consideration of Proposals for Large Scale Field Trials of Bt cotton expressing new gene/events.

Before initiating discussion on the agenda items, the Member-Secretary, informed the Committee that the RCGM in its meeting held on 22.5.2007 and 1.6.2007 has recommended two proposals for large scale trials with Bt cotton hybrids expressing new gene events, 14 proposals for multi locational research trials (MLRT) with GM crops expressing new gene events for generating biosafety data, 9 proposals for strip trials with GM crops expressing new gene events for generating the safety and efficacy data. RCGM has also approved 25 proposals for MLRT and 14 proposals for strip trials and 6 proposals for seed production with Bt cotton hybrids expressing approved gene events. She informed the Committee that as per the prevailing regulatory practice RCGM is authorized to approve confined multi-locational research field trials and GEAC approves large scale trials and environmental release. However, in Writ Petition (Civil) NO. 260 of 2005 by Aruna Rodrigues & Others Vs. Union of India, the Hon'ble Supreme Court vide order dated 1.5.2006 has directed that till further orders, field trials of genetically modified organisms shall be conducted only with the approval of the GEAC. It is in this context that the proposals at Agenda 5 to 9 have been forwarded for approval of the GEAC.

The Committee also deliberated on the following issues:

### 1. Compliance with the regulatory testing and evaluation procedure.

a. It was noted that in respect of GM crops expressing new gene events, completion of biosafety studies and recommendation of RCGM on the safety and efficacy of the product is a pre requisite for consideration of the proposal for large scale field trials. This procedure has been endorsed by the Sub-Committee on Bt Cotton and related issues, whose recommendations have been adopted by the GEAC in its 69th meeting, held on 30.06.2006. The Committee was of the view that no new event should be approved for large scale trials unless the complete biosafety data have been generated. The Member Secretary further informed that the new procedure also mandates that details of the locations (name of village, name of farmer, area etc), and approval of the Gram Panchayat are submitted to the GEAC prior to conduct of field trials.

b. The Committee also discussed the issue of sheep mortality at Adilabad and Warangal Districts due to grazing of Bt Cotton. The Member Secretary informed that the report received from Directorate of Animal Husbandry, Govt. of Andhra Pradesh was forwarded to Director, IVRI, Dean, College of Veterinary, Rajendranagar, Hyderabad, Joint Director, Dr. Vasantha Muthuswamy, Chief (BMS), Indian Council of Medical Research, New Delhi, Director, National Institute of Nutrition, Hyderabad, Dr. Chenga Reddy, Cotton Research Science and Dr. K. K. Tripathi, Adviser, Department of Biotechnology.

c. The report received from Joint Director, Centre for Animal Disease Research and Diagnosis, IVRI, Rae Bareilly was considered by the Committee. The report indicates that the limited studies conducted in the institute in goats and in laboratory rats fed with Bt cotton left over indicated no untoward clinical effects. However, the histopathological studies in laboratory rats are under process. Further, the Bt cotton samples tested in the toxicology laboratory of the Centre, showed absence of HCN, Nitrate/ Nitrite, Alkaloids and Glycosides. The Centre is also of the view that there is a possibility of other diseases prevailing in the area during the occurrence of mortality. The Centre has requested NGO, ANTHRA to provide suitable samples from animals

(serum, blood, and tissues from dead cases) for differential diagnosis. But the same have not yet been received. The Centre has requested to be informed about the occurrence of such kind of mortalities in future so that a team of experts can be deputed in the area. The Committee requested Member Secretary GEAC to forward the report to the State Department of Agriculture and Directorate of Animal Husbandry, Govt. of Andhra Pradesh for necessary action.

d. The Committee also considered some of the scientific reports published in international journals as well as the views of Punjab State Agriculture University, Ludhiana and Foundation for Biotechnology Awareness and Education. None of the reports or analysis concludes that Bt toxin is responsible for sheep mortality in Adilabad and Warangal in Andhra Pradesh. However, the Committee suggested that for all new events, applicants should include plant parts such as leaves/shoot/bolls in addition to seeds in the animal feeding studies for biosafety evaluation in the wake of certain reports indicating adverse effects of the leaves / shoot/bolls on animals. The Committee requested RCGM to develop protocols for conducting such studies in consultation with IVRI.

**2. Compliance with the Hon'ble Supreme Court directions dated 8.5.2007.**

a. The Hon'ble Supreme Court ruling dated 8.5.2007 in Writ Petition 260/2005 in IA No. 4/2006 filed by M/s Aruna Rodriguez vs. UoI was discussed. It was informed that the Hon'ble Supreme Court order dated 22.9.2006 directing the GEAC to stop all approvals stands amended to the extent that the GEAC may accord approval for commercial release of Bt cotton hybrids expressing approved gene events (cry 1Ac (MON 531 event), cry 1Ac and cry 2Ab (MON 15985) gene, cry 1Ac event 1 and cry 1Ab + cry 1Ac GFM. Further, the Hon'ble Supreme Court has also permitted conduct of field trials of GM crops (24 items approved by the GEAC during 1.5.2007 and 22.9.2007) expressing new gene events subject to the following conditions:

1. All trials should have a lead scientist's name with contact details who would be responsible for all aspects of the trials including regulatory requirements.
2. An isolation distance of 200 m would be maintained during field trials.
3. Prior to bringing out the GM material from the green house for conduct of open field trial the Company should submit a validated event specific test protocol at an LOD of at least 0.01% to detect and confirm that there has been no contamination.

b. The Committee was of the view that the isolation distance of 200 m for all crops is without any scientific basis. It was agreed that there is a need for crop specific isolation distance to be maintained as the nature of pollen flow and level of contamination with related species would vary depending on the biology of the crop and the host environment. The Committee also noted that the isolation distance of 200m stipulated by the Hon'ble Supreme Court is at variance with the scientifically developed minimum standards for seed certification by ICAR and prescribed under the Seed Act. The isolation distance to be maintained for various crops as per the prescribed seed certification standards was noted to be as follows:

| S.No | Crop Species | Isolation Distance (m) prescribed by ICAR |
|---|---|---|
| 1. | Rice | 200 |
| 2. | Okra | 400 |
| 3. | Brinjal | 200 |
| 4. | Groundnut | 3 |
| 5. | Castor | 300 |

| | | |
|---|---|---|
| 6. | Potato | 50 |
| 7. | Tomato | 200 |
| 8. | Cauliflower | 1600 |
| 9. | Mustard | 100 |
| 10. | Cotton | 50 |

c. The Committee was also of the view that the requirement for developing an event specific test protocol at an LOD of at least 0.01% to detect the level of contamination is not practical and is not being followed even by EU countries. This aspect also needs to be reviewed. The Committee requested Member Secretary, GEAC to convene the meeting of the Sub Committee constituted by the GEAC in its 76th meeting held on 11.5.2007 to assess the implications of the Hon'ble Supreme Court order dated 8.5.2007 on a priority basis. The Committee also requested MoEF and DBT to file applications for modification of the Hon'ble Supreme Court directions based on the sub committee recommendations.

**3. The recommendations of RCGM:**

a. The Committee noted the following recommendations/decisions taken by RCGM in the meeting held on 1.6.2007:

1. MLRT for new events should not be conducted in the farmers' field. MLRT should be undertaken by the Companies/Institutions either in their own premises, research farms or long leased land or at the SAU/ICAR institutions. In accordance with the Hon'ble Supreme Court direction an isolation distance of 200 m should be maintained.
2. Strip trials, for new events should be undertaken by the Company in their own premises/ research farms. An isolation distance of 200 m should be maintained as per the Hon'ble Supreme Court direction.
3. Applicant should generate complete biosafety data along with MLRT.
4. The applicant should submit a validated event specific test protocol before undertaking the trials.
5. For all new event applicants to include plant parts, such as leaves/shoot/bolls in addition to seeds in the animal feeding studies for biosafety evaluation in the wake of certain reports indicating adverse effects of the leaves/shoot/bolls on animals.
6. MLRT may be conducted in minimum 1 location and maximum at 2 locations in each State.

b. The GEAC endorsed the recommendations of RCGM.

**4. Approval of Gram Panchayat:**

a. The GEAC in its 72nd meeting held on 13.12.2006 had decided that applicants have to obtain approval of concerned Gram Panchayat prior to conduct of field trials. This was necessitated in view of representation received from some quarters that the farmers were not aware of the GM crop trials in their field. The Member Secretary, GEAC informed the Committee that office of the Gram Panchayat, Basantpur, Orissa and Kolathu block, Salem District, Tamil Nadu have requested GEAC to provide the following information:

1. What are the risks associated with GM crops and their field trials?
2. What are the various conditions that have been laid down by the GEAC on the applicant for each such trial including all the biosafety precautions that need to be taken?
3. What are the mechanisms that GEAC has put in place in case there are violations?

b. The Committee opined, while the above information may be forwarded to the office of the Gram Panchayat, its role would be to ensure:

- Farmers are informed about the trials
- The prescribed isolation distance is maintained.
- The transgenic material does not leave the premises of the trials.
- After the trials are over, the same is destroyed in the presence of a local authority.

c. The evaluation of field trials and risk assessment would continue to be with scientific / technical Committees notified under the rules 1989 of EPA, 1986.

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

1.1.1 The proposal of M/s Metahelix Life Science Pvt. Ltd. for large scale field trials with three Bt cotton hybrids namely 5174 Bt, 3134 Bt and 5125 Bt carrying event 9124 in the Central and South Zones was considered by the GEAC. The transgenic cotton developed by the Company expresses a truncated, synthetic cry 1C gene. The synthetic gene is designed based on the cry 1C protein made by Bacillus thuringiensis. The transgenic Bt cotton has been developed by the Company in accordance with the prescribed protocol and procedures and after obtaining the approval of RCGM/ GEAC. The three Bt cotton hybrids 5174 Bt, 3134 Bt and 5125 Bt have completed pollen flow study and strip trials during Kharif, 2005 and multi locational field trials during Kharif, 2006 at four locations in the North Zone, seven locations in the Central zone and seven locations in the South zone. As the sowing season for the North zone is over, it was decided to consider the request for LST in the Central and South Zones.

1.1.2 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.

1.1.3 The recommendations of MEC has been considered by the RCGM in its meeting held on 22.5.2007 wherein the representatives of the Company made a detailed presentation on the biosafety report highlighting toxicity, allergenicity and environmental studies conducted so far. The RCGM after detailed deliberations on the issue observed "that the applicant has not completed the biosafety studies. The feeding studies in large animals viz, cows and goats are not complete; study on soil micro-flora is ongoing; and baseline susceptibility studies of Helicoverpa to Bt cry 1C protein has not been initiated". Since the above studies are likely to be completed soon, RCGM recommended the proposal for LST.

1.1.4 The recommendations of MEC/ RCGM were considered by the GEAC. The Committee noted that as per the prevailing regulatory requirements completion of biosafety studies and recommendation of the RCGM on the safety and efficacy of the new gene is a pre-requisite before the request for LST is considered by the GEAC. This practice has been followed by the GEAC while according approval for large scale trials of Bt cotton hybrids expressing four gene events (cry 1Ac (MON 531 event), *cry 1Ab -cry 1Ac* ) "GFM Cry 1A", cry 1Ac & cry 2Ab genes (Mon 15985) gene and cry 1Ac (Event -1) which have been subsequently approved for commercialization. This

practice has also been endorsed by the Sub Committee on Bt cotton and related issues. The new procedure also mandates that details of the locations (name of village, name of farmer, area etc.) and approval of the Gram Panchayat are submitted to the GEAC along with the application for conduct of field trials. The same has not been furnished by the Company.

1.1.5 In respect of compliance with the Hon'ble Supreme Court order dated 8.5.2007 the Committee considered the following submissions made by the applicant:

1. Dr. V. Ramanathan, Head-Genomics, Metahelix Life Science and the signatory to the application has the Lead Scientist for conduct of LST during Kharif 2007.
2. The applicant has agreed to maintain the isolation of 200 m.
3. The protocol for validating event specific tests for detecting contamination at 0.01% LOD for cry 1C event MLS9124 has been submitted by the applicant.

1.1.6 The Committee gave an opportunity to the applicant for presenting their views/ clarifications. The following submissions were made by the applicant:

a. There are several difficulties in ensuring 200 m isolation for the transgenic cotton plots. However this requirement would be met in the following manner:

- Identify trial plots in the midst of other crops like maize or millets.

- Sow the seeds in polythene pouches so that we get a further lead time of one and a half months to identify appropriate plots and get the necessary consents from the farmers and the local authorities. This process can be initiated on receipt of GEAC approval. The applicant further explained, to maintain an isolation distance of 200m, a vast area has to be acquired on lease as the LST have to be conducted in 40 locations in the Central and 20 locations in the south zones. Therefore the GEAC may accord conditional approval so that the applicant can initiate acquisition of land and obtain approval of the local authorities. The applicant assured the Committee that details of location and approval of Gram Panchayat would be submitted to the GEAC before initiating the trials.

b. A blanket 200 m isolation requirement, irrespective of the crop and its pollination behaviour, is not scientifically justifiable . Further, the honourable supreme court ruling (dated 8th May 2007) that there should be 200 m isolation stems from the apprehension that there could be contamination by pollen flow to neighbouring fields. Holding up the spirit of the ruling – which is prevention of contamination by pollen flow , it should be possible to achieve the objective of the supreme court ruling, *"The GEAC shall take sufficient precautions to see that these trials are not causing any* ***contamination to the cultivation of neighbouring fields****",* with a much lesser isolation distance. Much more can be achieved with the earlier stipulation of 50 m isolation from neighbouring cotton fields. Therefore this requirement may be relaxed for crops like cotton, which are essentially self pollinated crops.

c. The Company explained the PCR protocol which would detect transgenic cotton DNA carrying the event MLS 9124 even when it is present in a mixture of non-transgenic cotton DNA at 0.01 percent level. This method works when 25 ng or more of template DNA is used in the PCR reactions. At 25 ng of template DNA and at 0.01 percent contamination by transgenic cotton DNA, the amount of transgenic cotton DNA in the reaction mix is as low as 2.5 pico gram which would correspond to only two copies of the cotton genome. The Committee requested Director ICGEB, New Delhi and Director NBRI, Lucknow to verify and validate the claim made by the applicant.

d. The applicant requested the GEAC to permit large scale field trials and ICAR trials as the data already available from the completed feeding, toxicity, allergenicity and pollen flow studies indicate that the event MLS9124 is safe. Safety of the event is demonstrated from

the ten completed studies out of a total of 14 required studies. It was noted that the schedule for completion of the biosafety studies were as follows:

- Soil micro-flora study – August 2007
- Goat feeding studies – September 2007
- Lactating cow feeding studies – October 2007
- Baseline susceptibility studies – November 2007 (and will be ongoing)

4.1.7 After detailed deliberations, it was decided to consider the request for LST and ICAR trials only after completion of the biosafety studies.

**1.2 Permission for Large Scale Trials and seed production of cotton hybrids expressing new gene even in Central and South Zones developed by Central Institute for Cotton Research, Nagpur.**

1.2.1 The proposal of Central Institute for Cotton Research, Nagpur for large scale field trials with five Bt cotton entries namely BN Bt (variety) and hybrids NHH-44, Dbt-H1, DBt-H2 and DBt-H5 in the South Zone and BN Bt and hybrids NHH 44 and DBt 1 in the Central Zone was considered by the Committee. The indigenously developed transgenic cotton expresses Bt cry 1Ac (Truncated and codon-modified) gene. The transgenic Bt cotton has been developed by CICR in accordance with the prescribed protocol and procedures and after obtaining the approval of RCGM/ GEAC. The biosafety studies conducted by the Institute include completed pollen flow study, toxicity and allergenicity, feeding studies in small laboratory animals and effect of Bt cry protein on soil micro-flora. Strip trials were conducted during Kharif, 2005 and multi locational field trials during Kharif, 2006 at four locations in the North Zone, four locations in the Central zone and four locations in the South zone. As the sowing season for the North zone is over, it was decided to consider the request for LST in the Central and South Zones.

1.2.2 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 the Bt cotton entries BN Bt (variety) and hybrids NHH-44, and DBt-H1, for LST in the Central Zone and BN Bt, NHH 44 Bt, DBt-H1, DBt-H2 and DBt-H5 (HXB) for LST in the South zone.

1.2.3 The recommendations of MEC has been considered by the RCGM in its meeting held on 22.5.2007 wherein the representatives of the CICR made a detailed presentation on the biosafety report highlighting toxicity, allergenicity and environmental studies conducted so far. The RCGM after detailed deliberations on the issue observed that the applicant has not completed the feeding studies in large animals viz, cows and goats are not complete. The committee also observed that the applicant has not complied with the Hon'ble Supreme Court directive 'Prior to bringing out the GM material from the green house for conduct of open field trials, the approved institution should submit a validated event specific test protocol at an LOD of at least 0.01% to detect and confirm that there has been no contamination".

1.2.4 The recommendations of MEC/ RCGM were considered by the GEAC. The Committee noted that as per the prevailing regulatory requirements completion of biosafety studies and recommendation of the RCGM on the safety and efficacy of the new gene is a pre-requisite before the request for LST is considered by the GEAC. This practice has been followed by the GEAC while according approval for large scale trials of Bt cotton hybrids expressing four gene events (cry 1Ac (MON 531 event), (*cry 1Ab -cry 1Ac*) "GFM Cry 1A", cry 1Ac & cry 2Ab genes (Mon 15985) gene and cry 1Ac (Event -1) which have been subsequently approved for commercialization. This practice has also been endorsed by the Sub Committee on Bt cotton and related issues. The new procedure also mandates that details of the locations (name of village, name of farmer, area etc.)

and approval of the Gram Panchayat are submitted to the GEAC along with the application for conduct of field trials. The same has not been furnished by CICR.

1.2.5 The Committee gave an opportunity to the representative of CICR to clarify on how the Institute proposes to comply with Hon'ble Supreme Court orders dated 8.5.2007. It was informed that:

a. The trials would be conducted in the research farms of the Institute under the direct supervision of the project co-coordinator. Names of the Scientists responsible for the trials would be communicated shortly.
b. A validated event specific test protocol at an LOD of at least 0.01% to detect and confirm that there has been no contamination is under preparation and would be submitted by the Institution. The Committee advised the representative of CICR to submit the above protocol to Director ICGEB, New Delhi and Director NBRI , Lucknow
c. An isolation distance of 200 m though not scientifically justifiable for fibre crops like cotton would be maintained.
d. Since the trials would not be conducted in farmers field approval of Gram Panchayat would not be applicable.

1.2.6 The representative of CICR requested the GEAC to permit large scale field trials and ICAR trials as the data already available from the completed feeding, toxicity, allergenicity and pollen flow studies confirms the safety of the event so that the material developed by a Public Institution could be made available to the farmers at a lower cost during Kharif 2008..

1.2.7 After detailed deliberations, the Committee opined that this case is similar to the proposal at agenda 1.1. Accordingly it was decided to consider the request for LST and ICAR trials only after completion of the biosafety studies.

**2.0 Consideration of Proposals for Multi Locational Research Trials (MLRT) of GM crops expressing new gene/events.**

**2.1 Permission to conduct MLRT with marker free six transgenic Bt rice hybrids namely MRP 5305 Bt, MRP 5319 Bt, MRP 5401 Bt, MRP 5445 Bt, MRP 5629 Bt and MRP 5631 Bt containing *cry*1Ac gene at twelve locations viz Thanjavur (TN), Bhandara, Raigad (Maharashtra), 24 Parganas (WB), Durg (Chhattisgarh), Gaya (Bihar), Ranchi (Jharkhand), Davangere, Mandya (KA), Anand ( Gujrat), Palakkad (Kerala) and Lucknow(UP) by M/s Maharashtra Hybrids Seeds Company Ltd., Mumbai.**

**2.2 Permission to conduct MLRT with three transgenic Bt okra hybrids namely MHOK-10 Bt, MHOK-12 Bt and MHOK-421 Bt containing stacked *cry*1Ac, cry2Ab (Event 15985) and CP 4epsps (Mon-88913) genes at twenty locations viz. Ferozepur, Muktsar, Hisar, Sirsa, Sriganganagar and Hanumangarh in North Zone, Jalna, Jalgaon, Yavatmal, Khargane, Khandwa, Rajkot, Vadodra and Surat in Central Zone and Ranga Reddy, Guntur, Haveri, Dharwad, Coimbatore and Salem in South zone by M/s M/s Maharashtra Hybrids Seeds Company Ltd., Mumbai.**

**2.3 Permission to conduct MLRT of YieldGard corn parental lines (MON810 with *cry1Ab* gene) at 2 locations i.e. Kurnool (AP) and Haveri (Karnataka) and experimental seed production at one location (Kurnul) by M/s Monsanto India Limited, Mumbai.**

**2.4 Permission to conduct MLRT of Roundup Ready corn (NK603) hybrid at various centers of Directorate of Maize Research (DMR)/State Agricultural Universities viz. PAU, Ludhiana, MPUAT, Udaipur, JNKVV, Jabalpur, SBUA&T, Meerut,**

**CCCHAU, Karnal MPKV, Rahuri, UAS, Dharwad, UAS, Bangalore, ANGRAU, Hyderabad and TNAU, Coimbatore and NRCWS, Jabalpur by M/s Monsanto India Limited, Mumbai.**

**2.5 Permission to conduct of MLRT for YieldGard corn hybrids containing *cry1Ab* gene (MON810) at 10 DMR/SAU locations viz. MPKV, Rahuri (2 locations), UAS, Dharwad, UAS, Bangalore (2 locations), ANGRAU, Hyderabad (2 locations), TNAU, Coimbatore PAU, Ludhiana, MPUAT, Udaipur, JNKVV, Jabalpur, SBUA&T, Meerut, CCCHAU, Karnal by M/s Monsanto India Limited, Mumbai**

**2.6 Permission to carry out MLRT of six hybrids of Bt brinjal (Malapur Local, Manjari Gotha, Kudachi Local, Udupi Gulla, 112-GO and Rabakavi Local) containing *cry1Ac* gene at ten locations by University of Agricultural Sciences, Dharwad.**

**2.7 Permission to conduct MLRT of two Bt brinjal hybrids namely SBJ 9Bt and SBJ 10Bt containing cry1A(c) gene at 10 locations Bhubnaeshwar, Cuttack, Puri, Kendrapara, Ranchi, Bokaro, Hazaribagh, Nadia, North 24 Paraganas, Hoogly during Kharif 2007 season by M/s Sungro seeds Research Ltd., Jammu.**

**2.8 Permission to conduct MLRT with eight cotton hybrids namely WS 102, WS103, WS 104, WS105, WS106, WS 107, WS109, WS 110 containing *cry*1Ac and *cry*1F gene (WideStrike = Event 3006-210-23 and Event 281-24-236) at six locations Waramgal, Guntur, Ranga Reddy, Dharwad, Davagere and Salem in South zone by M/s Dow Agrosciences, Mumbai**

**2.9 Permission to conduct MLRTs with five Bt cotton hybrids SCH1V1C1, SCH2V1C1, SCH3V1C1, SCH4V1C1, SCHV1C1 containing genes '*vip*3Aa'(COT102 x *cry*1Ab event at 14 locations in Central (eight) and South (six) zones by M/s Deltapine India Seed Pvt. Ltd., Hyderabad.**

**2.10 Permission for Biosafety Studies on transgenic cotton containing Vip3a gene event COT102x Cry1Ab event COT67B on Gene-flow, weediness, germination and effects on honeybees and earthworms by M/s Deltapine India Seed Pvt. Ltd., Hyderabad.**

**2.11 Permission to conduct MLRT of stacked transgenic cotton hybrids containing *Cry1EC* (Event 24) along with the commercialized *Cry1Ac* (Event1) namely JKCH 99 Bt, JK-Durga Bt, JK-Ishwar Bt, JK-Varun Bt at Central Zone and JKCH 99 Bt, JK-Durga Bt, JK-Ishwar Bt at South Zone at 14 locations viz. Jalgaon, Jalna, Aurangabad, Yeotmal, Rajkot, Himmatnagar, Vadodara, Khargone, Khandwa in Central Zone and Warangal, Guntur, Ranga reddy, Haveri, Dharwad, Davangere and Salem in South Zone and seed increase / experimental seed production by M/s J.K. Agri Genetics Ltd., Hyderabad and also.**

**2.12 Permission to conduct MLRT of BG-II Roundup Ready flex Cotton hybrids containing stacked *cry1Ac*, *cry2Ab* (Event 15985) and *CP4epsps* (MON 88913) genes at 8 locations( Jalna, Jalgaon, Yavatmal, Khargane, Khandwa, Rajkot, Vadodara and Surat in Central Zone) and 6 locations in Ranga Reddy, Guntur, Haveri, Dharwad, Coimbatore and Salem in South Zones by M/s Maharashtra Hybrid Seeds Company Ltd., Mumbai.**

**2.13 Permission to conduct MLRT of six G.hirsutum genotype Bt cotton hybrids namely DBT H3, DBT H4, DBT H6, DBT H7, DBT H8 and one G.arboretum cultivar RG 8 carrying Bt cry 1Ac gene at 4 locations Nagpur, Nanded, Khandwa, Surat in Central zone and 4 locations ARS- Dharwad, CICR-**

**Coimbatore, RARS- Guntur, RARS- Nandyal in South zone by Central Institute for Cotton Research, Nagpur.**

**2.14 Permission to conduct MLRT with transgenic hybrid mustard DMH-1 and DMH-11 expressing barnase and barstar genes developed by Delhi University.**

1.0 The Committee considered the proposals at agenda 2.1 to 2.14 in accordance with the Hon'ble Supreme Court directions dated 1.5.2006 and 8.5.2007. The Member Secretary informed that agenda 2.14 has been included as Additional agenda since it was inadvertently not included in the main agenda circulated to all Members.

2.0 The Committee noted that RCGM in its meeting held on 22.5.2007 and 1.6.2007 has recommended multi locational research trials (MLRT) with Bt rice, Bt okra, transgenic corn, transgenic brinjal and transgenic cotton developed by several companies subject to the following conditions:

a) MLRT for new events should not be conducted in the farmers' field. MLRT should be undertaken by the Companies/Institutions either in their own premises, research farms, long leased land or at the SAU/ICAR institutions. In accordance with the Hon'ble Supreme Court direction an isolation distance of 200 m should be maintained.
b) Applicant should generate complete biosafety data along with MLRT.
c) The applicant should submit a validated event specific test protocol before undertaking the trials.
d) For all new event applicants to include plant parts, such as leaves/shoot/bolls in addition to seeds in the animal feeding studies for biosafety evaluation in the wake of certain reports indicating adverse effects of the leaves/shoot/bolls on animals.
e) MLRT may be conducted in minimum 1 location and maximum at 2 locations in each State.

3.0 The Committee also noted that the Hon'ble Supreme Court directions dated 8.5.200, in respect of field trials of GM crops with new events was specific to the 24 items approved by the GEAC during 1.5.2006 to 22.9.2006. The transgenic crops approved for MLRT during this period includes rice, okra, groundnut, potato, tomato, brinjal, castor, cauliflower, mustard and cotton. During the deliberations it was noted that the proposals at agenda 2.3 to 2.5 are related to transgenic corn which is not listed in the 24 items approved by the GEAC during 1.5.2006 to 22.9.2006 and therefore the request for MLRT cannot be considered without informing the Hon'ble Supreme Court. It was pointed out that field trials of transgenic corn was initiated prior to the Hon'ble Supreme Court direction dated 1.5.2006. The Committee requested MoEF and DBT to file the UoI response in this regard. The Committee also opined that the applicant may separately file their application for relief in the Hon'ble Supreme Court.

4.0 The need for conduct of MLRT and the demand from NGOS for completion of the biosafety studies at the green house stage itself was also deliberated by the Committee. The Committee concluded sufficient quantity of material for generating food and feed safety data cannot be generated in the green house. Therefore to produces sufficient plant material for undertaking livestock feed and human food safety, MLRT is necessary. Further, the pollinators and herbivores are likely to vary regionally and therefore to assess the fitness effect of GM crop/variety MLRT are of utmost importance. The trials also generate information to conduct environment safety assessment of genetically modified plant.

5.0 The Committee also discussed in detail the implications of 200m isolation distance prescribed by the Hon'ble Supreme court and noted that the isolation distance of 200m stipulated by the Hon'ble Supreme Court is at variance with the scientifically developed minimum standards for seed certification by ICAR and prescribed under the Seed Act (refer page 2-3 para 2 (b) of

minutes). The Committee reiterated that a blanket 200 m isolation requirement, irrespective of the crop and its pollination behavior is not scientifically justifiable nor would it serve the purpose of containing the pollens. The Committee opined that this matter needs to be taken up urgently with the Hon'ble Supreme Court. Until the Hon'ble Supreme Court directions are amended, field trials shall be conducted with minimum 200 m isolation distance or standards prescribed by ICAR and Seed Act whichever is more.

6.0 After detailed deliberations, the GEAC approved the proposals at 2.1, 2.2 and 2.6 to 2.14 for MLRT subject to the following conditions:

1. The applicant should submit to the RCGM/GEAC the name of the Lead Scientist responsible for the trials before undertaking the trials.

2. The applicant should submit to the RCGM/GEAC an event specific test protocol duly validated/ verified by ICGEB, New Delhi / NBRI, Lucknow or any other accredited laboratory before undertaking the trials.

3. An isolation distance of minimum 200 m shall be maintained. In cases where the Seed Standards Certification mandates a larger isolation distance, the same shall be maintained.

4. The MLRT shall not be conducted in farmers' field. MLRT should be undertaken by the Companies/Institutions either in their own premises, research farms, long leased land (a minimum of three years lease) or at the SAU/ICAR institutions.

**3.0 Consideration of Proposals for Strip Trials of GM crops expressing new gene/events.**

**3.1 Permission to re-conduct strip trials on RB transgenic *Katahdin* lines (SP 904 & SP 951), F1 hybrids of potato obtained from crossing of transgenic *Katahdin* with Indian potato cultivars Kufri Bahar, and putative RB transgenic lines of the Indian potato cultivars Kufri Bahar and Kufri Jyoti for evaluation of late blight resistance to local races of *Phytophthora infestans* at CPRI, Shimla.**

**3.2 Permission to conduct strip trials of MXB 13 Bt cotton containing *cry 1F, cry 1Ac* genes at two locations (Vadodara and Rangareddy). The applicant has also requested for permission for pollen flow study and seed multiplication of the same hybrid by M/s Dow Agro Sciences India Pvt Ltd Mumbai.**

**3.3 Permission for conducting Strip trials on five Bt cotton hybrids DPCH1, DPCH2, DPCH3, DPCH4, DPCH5`*vip3Aa*' genes event COT 102 x *cry*1Ab Event COT 67B at two locations in Central and South zones by M/s Deltapine India Seed Pvt. Ltd., Hyderabad.**

**3.4 Permission for conducting strip trials on 96 Bt cotton hybrids namely ARCHH-101 to ARCHH-196 containing *cry1Ac* gene (MON 531) and *cry*1Ac & *cry*2Ab genes (MON 15985 ) to assess the tolerance against bollworm complex infestation and agronomic performance at two locations viz. Nagpur in Central Zone and Medak in South Zone by M/s Ankur Seeds Pvt. Ltd., Nagpur**

**3.5 Permission for conducting strip trials of 16 Bt cotton hybrids namely 511/MON531, 512/MON531, 515/MON531, 517/MON531, 521/MON531, 523/MON531, 525/MON531, 527/MON531, 511-2/MON15985, 512-2/MON15985, 515-2/MON15985, 517-2/MON15985, 521-2/MON15985, 523-2/MON15985, 525-2/MON15985, 527-2/MON15985 containing *cry1Ac* and *cryX* genes at 3 locations in Central Zone Aurangabad, Yeotmal, , Bhavnagar**

**and 2 locations Hyderabad and Guntur in South zone by M/s Bioseed research India Pvt. Ltd., Hyderabad.**

**3.6 Permission to conduct strip trials with CLCuV resistant cultivars transgenic viz., H 777, HS6, F846 carrying Antisense Coat protein, Sense Coat Protein, Antisense Replication Protein genes at CICR by Central Institute for Cotton Research, Nagpur.**

**3.7 Permission to conduct strip trials G.hirsutum Bt cotton genotype namely Anjali-Bt, LRA 5166-Bt, CPD 621 3A, CPD 621 3A, CPD 420 3A and Sahana 3A and G.aboreum genotype PA 255-Bt and PA 402-Bt carrying Bt cry 1Aa3, cry 1F and cry 1Ac genes at CICR, Nagpur in (Central) and UAS, Dharwad in (South zones) by Central Institute for Cotton Research, Nagpur.**

**3.8 Permission to conduct strip trials of Bt cotton hybrids containing stacked traits of cry 1Ac (Event 3006-210-23) and Cry 1F (event 281-24-236) genes (Widestrike ™ received from Dow Agro Sciences India Pvt. Ltd., Mumbai at one location R&D Farm, Bhadgaon, Jalgaon by M/s Nirmal seeds Pvt. Ltd.**

**3.9 Permission to conduct contained strip trials with transgenic cotton hybrids namely WS 102, WS103, WS 104, WS105, WS106, WS 107, WS109, WS 110 containing *cry*1Ac and *cry*1F gene (WideStrike - Event 3006-210-23 and Event 281-24-236) at two locations Jalgaon and Vadodara in Central and two locations Warangal and Davangere in South zone by M/s Dow Agrosciences, Mumbai.**

1.0 The Committee considered the proposals at agenda 3.1 to 3.9 in accordance with the Hon'ble Supreme Court directions dated 1.5.2006 and 8.5.2007.

2.0 The Committee noted that RCGM in its meeting held on 22.5.2007 and 1.6.2007 has recommended strip trials with transgenic potato developed by Central Potato Research Institute, Shimla and transgenic cotton developed by several companies subject to the following conditions:

a) Strip trials should be undertaken by the Companies/Institutions in their own premises/ research farms. In accordance with the Hon'ble Supreme Court direction an isolation distance of 200 m should be maintained.
b) The applicant should submit a validated event specific test protocol before undertaking the trials.

3.0 After detailed deliberations and in light of the deliberations in respect of Agenda 2.1 to 2.14 and decisions taken therein, the GEAC approved the proposals at 3.1 to 3.9 for conduct of strip trials subject to the following conditions:

1. The applicant should submit to the RCGM/GEAC the name of the Lead Scientist responsible for the trials before undertaking the trials.

2. The applicant should submit to the RCGM/GEAC an event specific test protocol duly validated/ verified by ICGEB, New Delhi / NBRI, Lucknow or any other accredited laboratory before undertaking the trials.

3. An isolation distance of minimum 200 m shall be maintained. In cases where the Seed Standards Certification mandates a larger isolation distance, the same shall be maintained.

4. The Strip trials shall not be conducted in farmers' field. Strip trials should be undertaken by the Companies/Institutions in their own premises or research farms.

**4.0 Consideration of Proposals for Multi Locational Research Trials of Bt cotton expressing approved gene/events.**

**4.1 Permission to conduct MLRT with four BG I cotton hybrids namely RCH 389 Bt, RCH 392 Bt, RCH 395 Bt, Pravin 6 Bt with *cry*1Ac gene (MON 531) at eight locations [Gujrat (Bhavnagar, Himmat nagar) Maharashtra (Nagpur, Jalgaon, Yavatmal, Aurangabad) M.P. ( Barwah, Khargaone) in Central zone. The applicant has also requested permission to conduct SAU trials in Central zone by M/s Rasi Seeds Pvt. Ltd., Tamilnadu.**

**4.2 Permission to conduct MLRT with BG I cotton hybrid RCHB 708 XL Bt with *cry*1Ac gene (MON 531) at eight locations [Gujarat (Bhavnagar, Surat/Himmatnagar) Maharashtra (Jalgaon, Yavatmal , Aurangabad ) M.P. ( Dhar, Ratlam, Jhabua) in Central zone to assess the tolerance against Bollworm complex infestation by M/s Rasi Seeds Pvt. Ltd., Tamilnadu.**

**4.3 Permission to conduct MLRT with three BG II cotton hybrids namely RCH 608 BGII, RCH 118 BGII, RCH 377 BGII with *cry*1Ac and *cry*2Ab genes (MON 15985) at eight locations [Gujarat (Bhavnagar, Himmat Nagar) Maharashtra (Akola/ Nagpur, Jalgaon, Yavatmal, Aurangabad) M.P. (Bharwa, Khargone) in Central zone by M/s Rasi Seeds Pvt. Ltd., Tamilnadu.**

**4.4 Permission to conduct MLRT with BG I cotton hybrid RCH 398 Bt containing *cry*1Ac gene (MON 531) at six locations Andhra Pradesh( Ranga Reddy, Warangal, Guntur,), Karnataka (Haveri, Hubli/ Dharwad), Tamil Nadu (Attur) in South zone by M/s Rasi Seeds Pvt. Ltd., Tamilnadu .**

**4.5 Permission to conduct MLRT with three BG II cotton hybrids namely RCH 611 BGII, RCH 614 BGII, RCH 20 BGII, containing *cry*1Ac and *cry*2Ab genes (MON 15985) at six locations Andhra Pradesh ( Ranga Reddy,Warangal, Guntur,), Karnataka (Haveri, Hubli/ Dharwad), Tamil Nadu (Attur) in South zone by M/s Rasi Seeds Pvt. Ltd., Tamilnadu.**

**4.6 Permission for conducting MLRT of four BG I cotton hybrids namely SP 503 B1, SP 671 B1, SP 700 B1, SP 1009 B1 containing *cry*1Ac genes (MON 531 event) at six locations [Andhra Pradesh (Hyderabad, Karimnagar and Guntur); Karnataka (Davangere and Haveri/Dharwad), Tamil Nadu (Salem)] in South zone by M/s Bayer Bioscience Pvt. Ltd., New Delhi.**

**4.7 Permission for conducting MLRT of two BG II cotton hybrids namely SP 904 B1 and SP 911 B1 (Minerva) containing *cry*1Ac genes (MON 531 event) at three locations [Andhra Pradesh (Hyderabad); Karnataka (Davangere/Haveri), Tamil Nadu (Salem/Krishagiri)] in South zone by M/s Bayer Bioscience Pvt. Ltd., New Delhi.**

**4.8 Permission for conducting MLRT of four BG I cotton hybrids namely SP 503 B1, SP 671 B1, SP 700 B1, SP 1037 B1 containing *cry*1Ac genes (MON 531 event) at eight locations [Maharashtra (Aurganabad, Jalna/Beed, Jalgaon, Yavatmal, Buldana/Wardha); Gujarat (Rajkot and Bhavnagar), Madhya Pradesh (Khargaon/Khandawa)] in Central zone by M/s Bayer Bioscience Pvt. Ltd., New Delhi**

**4.9 Permission for conducting MLRT of four BG II cotton hybrids namely SP 503 B2, SP 671 B2, SP 700 B2, SP 1044 B2 containing *cry*1Ac and *cry*2Ab genes (MON 15985 event) at eight locations [Maharashtra (Aurganabad, Jalna/Beed,**

**Jalgaon, Yavatmal, Buldana/Wardha); Gujarat (Rajkot and Bhavnagar), Madhya Pradesh (Khargaon/Khandawa)] in Central zone by M/s Bayer Bioscience Pvt. Ltd., New Delhi.**

**4.10 Permission for conducting MLRT four BG II cotton hybrids namely SP 503 B2, SP 671 B2, SP 700 B2, SP 1044 B2 containing *cry*1Ac and *cry*2Ab genes (MON 15985 event) at six locations [Andhra Pradesh (Hyderabad, Karimnagar and Guntur); Karnataka (Davangere and Haveri/Dharwad), Tamil Nadu (Salem)] in South zone by M/s Bayer Bioscience Pvt. Ltd., New Delhi.**

**4.11 Permission to conduct MLRT containing *cry1Ac* gene namely NAMCOT 401 BG I, NAMCOT 403 BGI, NAMCOT 404 BGI and NAMCOT 416 BGI at North Zone, NAMCOT 403 BGI, NAMCOT 405 BGI, NAMCOT 414 BGI and NAMCOT 415 BGI at Central Zone and NAMCOT 403 BGI, NAMCOT 405 BGI, NAMCOT 414 BGI and NAMCOT 417 BGI at South Zone during Kharif 2007 at 19 locations viz. Muktsar/Malot, Abohar/Bhatinda, Hissar, Sirsa, Sriganganager/Hanumangarh in North Zone, Bhavnagar, Himmatnagar, Khargone, Khandwa, Nagpur/Wardha, Amravati/Akola, Jalna/Aurangabad Dhule/Jalgaon in Central Zone and Guntur, Warangal, Nandyal, Dharwad, Haveri, Salem/Atur in South Zone by M/s Namdhari Seeds Pvt. Ltd. Bangalore has also requested approval for SAU trials in Central and Zone.**

**4.12 Permission to conduct MLRT to assess tolerance against the bollworm complex infestation for BGII cotton hybrids containing *cry1Ac* gene namely NAMCOT 603 BG II, NAMCOT 604 BGII, and NAMCOT 605 BGII at North Zone, NAMCOT 611 BGII and NAMCOT 613 BGII at Central Zone and NAMCOT 608 BGII and NAMCOT 610 BGII at South Zone during Kharif 2007 at 19 locations viz. Muktsar/Malot, Abohar/Bhatinda, Hisar, Sirsa, Sriganganager/Hanumangarh in North Zone, Bhavnagar, Himmatnagar, Khargone, Khandwa, Nagpur/Wardha, Amravati/Akola, Jalna/Aurangabad Dhule/Jalgaon in Central Zone and Guntur, Warangal, Nandyal, Dharwad, Haveri, Salem/Atur in South Zone. The application has also requested RCGM to recommend to ICAR/SAU trials in North, Central and Zone and obtain permission for half acre experimental seed production of above hybrids by M/s Namdhari Seeds Pvt. Ltd., Bangalore**

**4.13 Permission for conducting replicated MLRT of 3 intra- hirsutum hybrids namely Ankur 990 Bt, Ankur 3034 Bt, Ankur 3032 Bt containing *cry1Ac* gene (MON 531) at 8 locations viz. Gandhinagar, Rajkot, Baroda, Bharuch, Khargone, Nagpur, Aurangabad and Dhule in the Central Zone and undertake 100 ha. seed production of above hybrids by M/s Ankur Seeds Pvt. Ltd., Nagpur.**

**4.14 Permission for conducting replicated MLRT of 3 intra- hirsutum hybrids namely Ankur HB 1902 Bt, Ankur HB 1950 Bt containing *cry1Ac* gene (MON 531) at 8 locations viz. Gandhinagar, Rajkot, Baroda, Bharuch, Khargone, Nagpur, Aurangabad and Dhule in the Central Zone and undertake 100 ha. seed production of above hybrids by M/s Ankur Seeds Pvt. Ltd., Nagpur.**

**4.15 Permission for conducting replicated MLRT of 3 intra- hirsutum hybrids namely Jai BGII, Ankur 3028 BGII and Ankur 3034 BGII containing *cry1Ac & cry2Ab genes* (MON 15985) at 8 locations viz. Gandhinagar, Rajkot, Baroda, Bharuch, Khargone, Nagpur, Aurangabad and Dhule in the Central Zone and undertake half acre experimental seed production of above hybrids by M/s Ankur Seeds Pvt. Ltd., Nagpur.**

**4.16 Permission for conducting replicated MLRT of 2 inter-specific hybrids namely Ankur HB 2102 BGII, Ankur HB 2104 BGII containing *cry*1Ac & *cry*2Ab genes (MON 15985) at 8 locations viz. Gandhinagar, Rajkot, Baroda, Bharuch,**

**Khargone, Nagpur, Aurangabad and Dhule in the Central Zone during Kharif 2007 and undertake half acre experimental seed production of above hybrids by M/s Ankur Seeds Pvt. Ltd., Nagpur.**

**4.17 Permission for conducting replicated MLRT of 3 inter-specific hybrids namely Ankur 3034 Bt, Ankur 3042 Bt and Ankur 3072 Bt containing *cry1Ac* gene (MON531) at 6 locations viz. Warangal, Guntur, Belgaum, Davangere, Trichi and Villupuram in the South Zone and undertake 100 ha. seed production of above hybrids by M/s Ankur Seeds Pvt. Ltd., Nagpur.**

**4.18 Permission for conducting replicated MLRT and SAU trials of 2 inter-specific hybrids namely Ankur HB 1902 Bt and Ankur HB 1976 Bt containing *cry1Ac* gene (MON531) at 6 locations viz. Warangal, Guntur, Belgaum, Davangere, Trichi and Villupuram in the South Zone and undertake 100 ha. seed production of above hybrids by M/s Ankur Seeds Pvt. Ltd., Nagpur.**

**4.19 Permission for conducting MLRT of 5 Bt cotton hybrids Goldstar BG, Sarju BG, Shrikant BG, Solar-60 BG and Mahasangram BG, containing *cry1Ac* (MON 531) at 11 locations viz. Rajkot, Bhavnagar, Junagadh, Vadodara, Wardha, Yevotmal, Jalgaon, Aurangabad, Khargon, Dhar and Ratlam in Central Zone by M/s Solar Agrotech Pvt. Ltd., Rajkot.**

**4.20 Permission for conducting MLRT of 5 Bt cotton hybrids Goldstar BGII, Sarju BGII, Shrikant BGII, Solar-60 BGII and Mahasangram BGII, containing *cry1Ac+cry2Ab* (MON 15985) at 11 locations viz. Rajkot, Bhavnagar, Junagadh, Vadodara, Wardha, Yevotmal, Jalgaon, Aurangabad, Khargon, Dhar and Ratlam in Central Zone by M/s Solar Agrotech Pvt. Ltd., Rajkot.**

**4.21 Permission for conducting MLRT of 5 Bt cotton hybrids Goldstar BG, Sarju BG, Shrikant BG, Solar-60 BG and Mahasangram BG, containing *cry1Ac* gene (MON 531) at 7 locations viz. Warangal, Adilabad, Guntur, Khamam, Karimnagar, Haveri and Dharwad in South Zone by M/s Solar Agrotech Pvt. Ltd., Rajkot.**

**4.22 Permission for conducting MLRT of 5 Bt cotton hybrids Goldstar BGII, Sarju BGII, Shrikant BGII, Solar-60 BGII and Mahasangram BGII, containing *cry1Ac+cry2Ab* (MON 15985) at 7 locations viz. Warangal, Adilabad, Guntur, Khamam, Karimnagar, Haveri and Dharwad in South Zone by M/s Solar Agrotech Pvt. Ltd., Rajkot.**

**4.23 Permission to conduct MLRT of Bollgard cotton hybrids containing *cry1Ac* gene (MON 531) of 4 hybrids namely VBCH 1012, VBCH 1013, VBCH 1014 and VBCH 1015 at 5 locations Bhatinda, Mansa, Fatehbad, Sirsa and Sriganganagar in North Zone, 4 hybrids namely VBCH 1016, VBCH 1017, VBCH 1018 and VBCH 1019 at 8 locations Yavatmal, Nanded, Aurangabad, Jalgaon, Khargaon, Khandwa, Rajkot and Bhavnagar in Central Zone and 4 hybrids (VBCH 1016, VBCH 1017, VBCH 1018 and VBCH 1019) at 6 locations Guntur, Adilabad, Warangal, Dharwad, Davengere, Attur in South Zone by M/s Vibha Agrotech Ltd., Hyderabad,.**

**4.24 Permission to conduct MLRT of Bollgard cotton hybrids containing *cry1Ac* and *cry2Ab2* gene (MON 15985) of 4 hybrids namely VBCH 1507, VBCH 1508, VBCH 1509 and VBCHB 1510 at 5 locations Bhatinda, Mansa, Fatehbad, Sirsa and Sriganganagar in North zone, 4 hybrids namely VBCH 1511, VBCH 1512, VBCH 1513 and VBCHB 1514 at 8 locations namely Yavatmal, Nanded, Aurangabad, Jalgaon, Khargone, Khandwa, Rajkot and Bhavnagar in Central zone and 4 hybrids namely VBCH 1511, VBCH 1512, VBCH 1513 and VBCHB 11514 at 6**

**locations Guntur, Adilabad, Warangal, Dharwad, Davangere and Attur in South zone by M/s Vibha Agrotech Ltd., Hyderabad,.**

**4.25 Permission for MLRT to evaluate Bt Cotton hybrids namely SBCH- 303, SBCH-307, SBCH- 309, SBCH- 310, SBCH- 311( Central zone) SBCH- 303, SBCH- 304, SBCH- 307, SBCH- 310, SBCH- 311( South zone) at 8 locations Rajkot, Baroda, Jalna, Jalgaon, Aurangabad, Buldana, Khargone and Burahanpur in Central zone and 6 locations viz. Warangal, Guntur, Ranebennur, Dharwad, Coimbatore and Salem in South Zone during Kharif 2007 by M/s Safal Seeds & Biotech Ltd., Aurangabad.**

1.0 The Committee considered the proposals at agenda 4.1 to 4.25 in accordance with the Hon'ble Supreme Court directions dated 1.5.2006 and 8.5.2007.

2.0 The Committee noted that RCGM in its meeting held on 22.5.2007 and 1.6.2007 has recommended multi locational field trials with Bt cotton hybrids expressing approved four gene events (cry 1Ac (MON 531 event), *cry 1Ab -cry 1Ac* ) "GFM Cry 1A", cry 1Ac & cry 2Ab genes (Mon 15985) gene and cry 1Ac (Event -1) developed by several companies. The conditions stipulated by Hon'ble Supreme Court in respect of isolation distance and submission of validated event specific test protocol before undertaking the trials would not applicable in these cases. However the applicant should nominate a lead Scientist who would be responsible for the trials.

3.0 The Committee further noted that in accordance with the recommendations of the sub-Committee report on Bt cotton and related issue, RCGM has taken into consideration the following information while recommending the Bt cotton hybrids for MLRT:

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

4.0 After detailed deliberations and taking into consideration the recommendations of RCGM and directions issued by Hon'ble Supreme Court, the GEAC approved the proposals at 4.1 to 4.25 for MLRT subject to the following conditions:

1. The applicant should submit to the RCGM/GEAC the name of the Lead Scientist responsible for the trials before undertaking the trials.
2. The applicant should submit to the RCGM/GEAC approval of the Gram Panchayat before undertaking the field trials.
3. The applicant should submit to the RCGM/GEAC, the State / District wise details of locations (area, village, name of farmers etc) before undertaking the trials.

**5.0 Consideration of Proposals for Strip Trials of Bt cotton expressing approved gene/events.**

**5.1 Permission for conducting strip trials of 35 Bt cotton (BG II) hybrids at Mota Jalundra, Taluka, Dehgam, Dist. Gandhinagar (Gujarat) in Central zone by M/s Vikram seeds Ltd., Ahmedabad.**

**5.2 Permission strip trials with 115 transgenic Bt cotton hybrids containing stacked genes *cry*X (*cry*1Ac and *cry*2Ab) gene (MON 15985 event) in Central zone by M/s Vikki Agrotech Pvt. Ltd., Hyderabad.**

**5.3 Permission to conduct strip trials of 29 intra-specific (HXH) Bt cotton hybrids at Botad Research Farm (company farm) by M/s Navkar Hybrid Seeds Pvt. Ltd., Ahemdabad.**

**5.4 Permission for conducting strip trials on Rasi BGII cotton hybrids containing *cry*1Ac and *cry*2Ab genes (MON 15985) in Central and South zones by M/s Rasi Seeds Pvt. Ltd., Tamilnadu.**

**5.5 Permission to test 32 selected Bt hybrids (F1) expressing GFM *cry*1Aa gene in strip trials at Zuari Seeds Ltd. Agricultural Research Station, Aurangabad by M/s Zuari Seeds Ltd., Bangalore.**

**5.6 Permission for conducting Strip trials of 35 BGII Bt hybrids containing *cry1Ac+cry2Ab* (MON 15985) by M/s Solar Agrotech Pvt. Ltd., Rajkot**

**5.7 Permission to conduct strip trial for evaluation of 100 BGII cotton hybrids namely EGCH 17101 BG II to EGCH 17201 BG II for Central and South Zone at 4 locations at Aurangabad and Rajkot (Central Zone), Hyderabad and Dharwad (South Zone) by M/s Emergent Genetics India Pvt. Ltd., Hyderabad.**

**5.8 Permission to conduct strip trial for evaluation of 30 BGII cotton hybrids at Jalna, Akola, Rajkot and Khandwa (Central Zone) and at Hyderabad, Guntur, Dharwad and Atur (South Zone) by M/s Emergent Genetics India Pvt. Ltd., Hyderabad.**

**5.9 Permission to conduct Strip trials on 12 F1 Bt cotton hybrids containing GFM cry1A gene at research farm, Sarwadi, Jalna during Kharif 2006 by M/s Safal Seeds & Biotech Ltd., Aurangabad.**

**5.10 Permission to conduct strip trials of transgenic entries (*G.hirsutum* x *G.hirsutum*) encoding fusion gene cry 1Ab-Ac. by M/s Green Gold seeds Ltd, Aurangabad.**

**5.11 Permission to conduct strip trials of 4 Bt cotton hybrids namely KCH-999 BG II, KCH-14 K 59 BGII, KCH-15 K39 BGII AND KCH-36 BG II of Kaveri Seed Company Ltd. to assess the tolerance against Bollworm complex infection, agronomic performance and to get the protein expression report at Warangal, A.P by M/s Kaveri Seeds Company Ltd. Secunderabad.**

**5.12 Permission for strip trials of 22 BG II cotton hybrids containing *cry*1Ac and *cry*2Ab genes (MON 15985 event) at one location at Aurangabad, Maharashtra in Central zone by M/s Bayer Bioscience Pvt. Ltd., New Delhi.**

**5.13 Permission for strip trials of 22 BG II cotton hybrids containing *cry*1Ac and *cry*2Ab genes (MON 15985 event) at one location at Ranga Reddy, Andhra Pradesh in South zone by M/s Bayer Bioscience Pvt. Ltd., New Delhi.**

**5.14 Permission for strip trials of five Bt (GK 203 Bt, GK 226 Bt, GK 227 Bt, GK 228 Bt and GK 229 Bt and three BG II ( GK 223 BG II, GK 224 BG II, and GK 229BG II )cotton hybrids in Limited Green House / Contained open fields trials (strip Trial) to confirm gene event purity by molecular analysis to estimate delta endotoxin protein toxic to bollworm complex, to characterize the genotypes with DUS descriptors and to generate bio- efficacy data in laboratory / field by M/s Ganga Kaveri Seeds Pvt. Ltd., Andhra Pradesh .**

1.0 The Committee considered the proposals at agenda 5.1 to 5.14 in accordance with the Hon'ble Supreme Court directions dated 1.5.2006 and 8.5.2007.

2.0 The Committee noted that RCGM in its meeting held on 22.5.2007 and 1.6.2007 has recommended strip trials with Bt cotton hybrids expressing approved four gene events (cry 1Ac (MON 531 event), *cry 1Ab -cry 1Ac* ) "GFM Cry 1A", cry 1Ac & cry 2Ab genes (Mon 15985) gene and cry 1Ac (Event -1) developed by several companies. It was agreed that the conditions stipulated by Hon'ble Supreme Court in respect of isolation distance and submission of validated event specific test protocol before undertaking the trials would not applicable in these cases. However the applicant should nominate a lead Scientist who would be responsible for the trials.

3.0 The Committee further noted that in accordance with the recommendations of the sub-Committee report on Bt cotton and related issue, RCGM has taken into consideration the following information while recommending the hybrid for Strip Trials:

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

4.0 After detailed deliberations and taking into consideration the recommendations of RCGM and directions issued by Hon'ble Supreme Court, the GEAC approved the proposals at 5.1 to 5.14 for strip trials subject to the following conditions:

1. The applicant should submit to the RCGM/GEAC the name of the Lead Scientist responsible for the trials before undertaking the trials.
2. The applicant should submit to the RCGM/GEAC approval of the Gram Panchayat before undertaking the trials.
3. The applicant should submit to the RCGM/GEAC, the State / District wise details of locations (area, village, name of farmers etc) before undertaking the trials.

**6.0 Consideration of Proposals for Experimental Seed Production of Bt cotton expressing approved gene/events.**

**6.1 Permission for seed production of BG I seven cotton hybrids namely Shakthi 9 Bt, RCH 389 Bt, RCH 392 Bt, RCH 395 Bt, Pravin 6 Bt, RCHB 708 XL Bt and RCH 398 Bt containing *cry* 1Ac gene (MON531) for commercial purposes during Kharif 2008 by M/s Rasi Seeds Pvt. Ltd., Tamilnadu**

**6.2 Permission to conduct experimental seed production of nine BG II cotton hybrids namely RCH 602 BGII, RCH 605 BGII, RCH 134 BGII, RCH 608 BGII, RCH 118 BGII, RCH 377 BGII, RCH 611 BGII, RCH 614 BGII and RCH 20 BGII containing *cry1Ac* and *cry2Ab* genes (MON 15985) at nine locations by M/s Rasi Seeds Pvt. Ltd., Tamilnadu.**

**6.3 Permission to conduct experimental seed production of Bt cotton hybrids namely SBCH-301, SBCH-302, SBCH-303, SBCH-304, SBCH-305, SBCH-306, SBCH-307, SBCH-308, SBCH-309, SBCH-310 and SBCH-311 containing GFM cry1A gene by M/s Safal Seeds & Biotech Ltd., Aurangabad.**

**6.4 Permission for seed production of 5 Bt cotton hybrids Goldstar BG, Sarju BG, Shrikant BG, Solar-60 BG and Mahasangram BG containing *cry1Ac* gene (MON 531) by M/s Solar Agrotech Pvt. Ltd., Rajkot.**

**6.5 Permission for experimental seed production for field trials (MLT, LST, ICAR & SAU to be conducted in different zones) of 5 cotton hybrids namely GoldStar BGII, Sarju BGII, Shrikant BGII, Solar-60 BGII and Mahasangram BGII**

**containing *cry1Ac+cry2Ab* (MON 15985) event by M/s Solar Agrotech Pvt. Ltd., Rajkot.**

**6.6 Permission to carry out the parent seed multiplication of 2 Bt parent lines namely RCPF-3 and CCRI-2102 (Bt line received from Global Transgene Limited named as KI5473 and KI5476 respectively) containing *GFM cry1Aa* gene in about 0.5 acre for each line at Aurangabad by M/s Zuari Seeds Ltd., Bangalore.**

1.0 The Committee considered the proposals at agenda 6.1 to 6.6 in accordance with the Hon'ble Supreme Court directions dated 1.5.2006 and 8.5.2007 and the prevailing regulatory procedure for seed production.

2.0 The Committee was of the view that as per the prevailing regulatory procedure, experimental seed production in 0.5 acre may be permitted by RCGM during MLRT/strip trials. Subsequently, 10 ha seed production may be permitted during first year LST and 100 ha during 2nd year LST unless it is a centrally notified variety. In such cases 100 ha seed production is permitted during 1st year LST.

3.0 In case of cry 1Ac (MON 531 event) no specific approval for seed production is required. The applicant may undertake seed production subject to submission of an undertaking to RCGM that the seed produced shall not be diverted for any other purpose without the approval of RCGM. The Committee opined that in all cases, details of seed production of each hybrid and the location where it is produced should also be furnished by the applicant to the RCGM/GEAC/ State Govt/ Local Authority. Record of seed produced should be maintained by the applicant. In case of non approval for LST/commercial release, the seeds so produced shall be destroyed in the presence of a local authority.

**7.0 Proposals for commercial release in the Central Zone.**

**7.1 Permission for commercial release of ABCH-1220 Bt expressing *cry 1 Ac* gene (MON-531 event) in the central zone by M/s Amar Bio teh Ltd.**

**&**

**7.2 Permission for commercial release of NCS-950, and NCHB-991 expressing *cry 1 Ac* gene (MON-531 event) in the central zone by M/s Nuziveedu Seeds Ltd.**

**&**

**7.3 Permission for commercial release of PCH-930 Bt expressing *cry 1 Ac* gene (MON-531 event) in the central zone by M/s Prabhat Agribiotech Ltd.**

1.0 The Committee noted that the request in respect of 4 Bt cotton hybrids as contained in agenda item 7.1 to 7.3 above for commercial release and marketing of ABCH-1220 Bt by M/s Amar Biotech Ltd, NCS-950 and NCHB 991 by M/s Nuziveedu Seeds Ltd and PCH 930 by M/s Prabhat Agribiotech Limited in the Central zone was considered in the GEAC meeting held on 11.5.2007 and 29.5.2007 wherein the proposal was referred back to the MEC.

2.0 The Member Secretary GEAC informed, the MEC in its subsequent meeting held on 18.5.2007 has evaluated the above proposals based on the criteria indicated at page 17, para 3.0 of minutes. The committee noted that the MEC has recommended 4 hybrids namely ABCH-1220 Bt NCS-950 Bt, NCHB-991 Bt and PCH-930 Bt for commercial release in the Central zone.

3.0 The Committee noted that hybrids recommended by the MEC and RCGM have completed the mandatory field testing and evaluation process as outlined in the sub Committee report on Bt cotton and related issues adopted by the GEAC in its meeting held on 30.6.2006.

4.0 After detailed deliberations and taking into consideration the recommendations of MEC/RCGM/ICAR, the Committee **approved** the following hybrids for commercial release in the **Central Zone** for a period of three years subject to the usual conditions imposed.

1. ABCH-1220 Bt expressing *cry 1 Ac* gene (MON-531) by M/s Amar Bio teh Ltd.

2 NCS-950, expressing *cry 1 Ac* gene MON-531) by M/s Nuziveedu Seeds

3. NCHB-991 expressing *cry 1 Ac* gene MON-531) by M/s Nuziveedu Seeds

4. PCH-930 Bt expressing *cry 1 Ac* gene (MON-531) by M/s Prabhat Agribiotech Ltd

**7.4 Permission for commercial release of VICH-111 expressing *cry 1 Ac* gene (MON-531 event) in the South zone by M/s Vikki Agrotech Pvt. Ltd.**

**&**

**7.5 Permission for commercial release of NCS-929, and NCS-945 expressing *cry 1 Ac* gene (MON-531 event) in the south zone by M/s Nuziveedu Seeds Ltd.**

**&**

**7.6 Permission for commercial release of PCH-930 Bt expressing *cry 1 Ac* gene (MON-531 event) in the south zone by M/s Prabhat Agribiotech Ltd.**

1.0 The Member Secretary GEAC informed the Committee that decision in respect of proposals at agenda 7.4 to 7.6 have been taken in the GEAC meeting held on 22.5.2007. The proposals were inadvertently included in the agenda for this meeting. The proposals were deleted from the agenda for this meeting.

**8.0 Other Items**

**8.1 Import of Soybean oil obtained from Round up Ready soybean by M/s Solvent Extractors' Association of India.**

The Member Secretary GEAC informed the Committee that report of CFTRI has been received. After detailed deliberation and taking into consideration that quantity of DNA is far below the detection level in refined Soybean oil, the Committee accorded approval for import of GM Soybean oil derived fro Round–up-Ready Soybean for the purpose of consumption after refining.

**8.2 Renewal of GEAC permission for large scale field trials and ICAR trials with NCS-145 BT 2 in Central Zone and NCS-207 BT 2 in South Zone by M/s Nuziveedu Seeds Ltd.**

8.2.1 The Committee noted that the GEAC in its meeting held on 4.4.2006 had approved conduct of large scale field trials with NCS 145 Bt 2 and NCS 207 Bt 2 expressing cry 1Ac and cry 2Ab (MON 15985) gene in the Central and South Zones during Kharif, 2006.

8.2.2 The Committee noted that the trials could not be conducted with NCS 145 Bt 2 in Central Zone and NCS 207 Bt 2 in South Zone due to limited facilities available in ICAR. The Committee approved the request for renewal of the GEAC permission dated 17.4.2006 for conduct of LST with NCS 145 Bt 2 in Central Zone and NCS 207 Bt 2 in South Zone during Kharif 2007.

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