Decisions taken in the 100th Meeting of the Genetic Engineering Approval Committee (GEAC) held on 12.5.2010.

The 100th meeting of the GEAC was held on 12.5.2010 in the Ministry of Environment and Forests (MoEF) under the chairmanship of Shri M. F. Farooqui Additional Secretary, MoEF and Chairman, GEAC.

The deliberations/decisions taken in the GEAC meeting in respect of Agenda Items 3 to 8 are as follows:

Agenda item No. 3: **Action taken report on the decision taken in the 99th GEAC meeting.**

3.1 The Member Secretary, GEAC informed the Committee that decisions taken in the meeting held on 17.2.2010 have been communicated to the project proponents, concerned government departments and other agencies. Details of action taken were placed before the members and the following points were noted by the Committee:

(i) NBPGR has agreed to accept Bt brinjal seeds from M/s MAHYCO, TNAU, Coimbatore and UAS, Dharwad for which a separate facility has been earmarked. A meeting was convened by Director (NBPGR) with the technology providers and Member Secretary, GEAC wherein it was agreed that a tripartite MoA will be signed by NBPGR, MoEF and technology provider. The Committee was in the view that:

- Three separate MoA for M/s Mahyco, TNAU, Coimbatore and UAS, Dharwad may be signed;
- The cost of the material will be paid by the owners of the material. In case of Bt brinjal seed stock belonging to TNAU Coimbatore and UAS, Dharwad, ICAR may consider storing the seeds free of cost in the same facility in which the seed stock of M/s Mahyco will be stored.
- NBPGR must provide detailed; break-up of charges levied for storing Bt brinjal seeds and also ensure that the facility is insured; and
- The GEAC must obtain an affidavit from the Company/ Institutions confirming that all the seed stock available with them has been deposited at NBPGR storage facility.

(ii) On the issue of 'Brain Storming Session' to discuss the performance of Bt cotton, DDG (Seeds) informed that they can hold a meeting with the concerned stakeholders under All India Coordinated Programme in July 2010 at CICR, Nagpur after seeking convenience of the members.

(ii) As regards the mechanisms for creating a separate account for utilizing funds collected as processing fee, it was noted that the matter is pending consideration of the Ministry of Law and Justice. The Chairman, GEAC requested Member Secretary to expedite this matter and come out with a formal proposal by June 2010.

3.2 Dr. P M Bhargava informed that there have been newspaper reports of the development of transgenic chicken by the Hyderabad-based Project Directorate on Poultry. It was agreed that the matter will be considered in the next GEAC meeting after obtaining clarifications from RCGM.

3.3 The Committee also requested the Member Secretary, GEAC to prepare a base paper on strengthening the monitoring mechanism for GM crops field trials for further discussions in the GEAC meeting.

Agenda item No. 4 : Policy issue

4.1 Follow-up Action on Review of Bt brinjal event EE-I

4.1.1 The Member Secretary, GEAC informed that the decision document comprising of the following sections has been carefully studied:

- **Minister's decision** to impose moratorium on commercialization of Bt brinjal Event EE-1
- **Annexure -1 -** Report on proceedings of seven public consultations compiled by CEE
- **Annexure-II** - Letters from State Governments / MPs
- **Annexure-IIIA** - Submissions by scientists in India
- **Annexure III B** - Submissions by scientists from outside India
- **Annexure- IV** -Submissions by civil society groups

4.1.2 The concerns raised by various stakeholders could be broadly categorized under six categories, viz. general issues, molecular/genetic aspects, health/food and feed safety concerns, environmental concerns, market/trade issues and other issues. The report of CEE also includes views which are in favour of Bt brinjal. This has been categorized as "no concerns' Specific comments reflected in the decision document have been further sub-categorized under each category as indicated below:

A. GENERAL ISSUES

1. General opposition to GM crops
2. Need for Bt. Brinjal / use of alternative strategies
3. Inefficient regulatory frameworks/mechanisms
4. Inadequate testing of Bt brinjal/GM foods in general

B. MOLECULAR /GENETIC ASPECTS

5. Use of chimeric gene
6. Use of *Agrobacterium* based transformation system
7. Effect of transferring viral sequences to plants, viruses and other organisms
8. Antibiotic resistance

C. HEALTH/FOOD AND FEED SAFETY CONCERNS

9. Concerns about the concept of substantial equivalence
10. Potential toxins, allergens and anti-nutrients ?
11. Nutritional value of Bt brinjal/GM food

12. Transfer of novel genes to humans, animals and bacteria
13. Need for human trials
14. Need for long term food safety studies
15. Statistical differences in laboratory studies
16. Issues related to Ayurveda and Siddha

D. ENVIRONMENTAL CONCERNS

17. Potential gene transfer to related cultivated and wild species
18. Impact on biodiversity/traditional varieties
19. Impact on non-target organisms
20. Residue levels of expressed proteins in agro- ecosystem
21. Risk of becoming weedy/invasive
22. Insect resistance development

E. MARKET/ TRADE ISSUES

23. Need for post market surveillance
24. Labelling issues
25. Impact on organic farming
26. Socio -economic issues
27. Liability issues due to contamination

F. OTHER ISSUES

28. Use of company data/lack of independent studies
29. Lack of public consultation in decision making
30. Lack of public awareness
31. Technology ownerships by the MNCs
32. Other issues

G. NO CONCERNS

33. Responses in favour of introduction of Bt brinjal / GM crops

4.1.3 The Committee considered summary of issues compiled in the following documents:

1. **Matrix 1** summarises the category of concern reflected in Annexures- II, III IV of the decision document.

2. **Matrix 2** has been prepared to highlight the points raised by stakeholders during the seven consultations and documented by Centre for Environment Education (CEE).

3. **Annex 1** summarises the specific views of each stakeholder in the communication to Minister of Environment and Forests as reflected in Annexure-II to IV of the decision document.

4. **Annex 2** summarises the concerns of stakeholders into six different categories as explained in para 4.1.5 above.

4.1.4 The meeting deliberated on the future course of follow-up action to be taken by the GEAC to review the Bt brinjal event EE-1 and agreed on the following:

(i). A background paper highlighting the additional studies recommended by scientists/ experts to address the concerns that have emerged from the public consultations as well as studies that have been completed so far will be prepared within one month and circulated to scientists and experts.

(ii). A meeting with eminent scientists and experts and members of GEAC will be convened by the Chairman GEAC to deliberate on the need for additional studies to assess the safety of Bt brinjal Event EE-1 in July 2010. If additional studies are required, the protocols and procedures to be followed would also be discussed.

(iii). The review will be science based and to be completed in a time bound manner.

4.2 Report of the Sub-Committee constituted by the GEAC to examine the "Guidance document for information/data generation and documentation for safety assessment of GE Plants" during BRL-I and II trials.

4.2.1 Due to paucity of time, the agenda item was not taken up for discussion.

4.3 Development of Crop Specific Biology Documents prepared by MoEF and DBT on Cotton, Brinjal, Maize, Okra, and Rice

4.3.1 The Member Secretary, GEAC informed the Committee that MoEF and DBT had organized a series of regional consultations for strengthening the monitoring mechanism. As part of this initiative, crop specific biology documents for cotton, brinjal, okra, maize and rice for use as reference in evaluation of genetically engineered (GE) crops in India have been developed.

4.3.2 The Committee adopted the biology documents prepared by MoEF and DBT on Cotton, Brinjal, Maize, Okra, and Rice with the suggestion that various types of alkaloids present in brinjal should be indicated.

4.4 Discussion on the draft proposal for setting up a National Centre for Assessment of GMOs prepared by Dr. P. M. Bhargava.

4.4.1 Due to paucity of time, the agenda item was not taken up for discussion.

4.5 Request from DBT regarding the transfer of responsibilities of reviewing the applications for commercial release of Bt cotton hybrids expressing approved

events to the State Agriculture Departments in association with State Agriculture Universities

4.5.1 The GEAC had adopted 'event based approval mechanism (EBAM) in respect of Bt. cotton hybrids expressing approved events in its meeting held on 2.4.2008 and subsequently a new procedure under the EBAM was set up by the GEAC in its meeting held on 14.1.2009. In accordance with the decision taken therein, the Ministry vide OM No. 13/39/2007-CSII dated 20.2.2009 /17.4.2009 had constituted a 'Standing Committee' to review applications for commercial release of Bt cotton hybrids expressing approved events under the new EBAM. As per the new procedure, the 'Standing Committee' is being serviced by the DBT.

4.5.2 The issue of transfer of responsibility under the EBAM to the State Agriculture Departments in association with State Agricultural Universities as requested by DBT was discussed. The Committee did not agree to this suggestion as it would not be practical for the seed industries to obtain approval from nine different states. Also it was important to follow a uniform procedure for which an agency like ICAR may be considered.

4.5.3 After detailed deliberations, DDG-Seeds, ICAR agreed to take this responsibility from the next Kharif season. The Committee opined that till such time the responsibility is transferred to ICAR, DBT may continue reviewing the applications for commercial release of Bt cotton hybrids expressing approved events.

Agenda item No. 5: Consideration of applications for confined field trials (Event selection, BRL-I and BRL-II) of transgenic crops expressing new genes as recommended by the RCGM

5.1 Permission for confined field trials to analyze the effect of Azotobacter mutant strains on wheat in terms of yield, protein content, biomass, etc; by National Research Centre on Plant Biotechnology (NRCPB), Indian Agricultural Research Institute (IARI), New Delhi.

5.1.1 The Committee noted that the request of NRCPB is to conduct confined field trials to analyze the effect of *Azotobacter* mutant strains on wheat in terms of yield, protein content, biomass, etc. , by growing wheat inoculated with *Azotobacter* strains (both wild and mutants) generated by *in vitro* manipulations) in confined conditions by NRCPB. The trials will be conducted at one location at IARI farm, New Delhi.

5.1.2 The Committee noted that the RCGM has recommended the proposal in its 82nd meeting held on 27.10.2009.

5.1.3 The Committee conveyed 'no objection' to the proposal.

5.2 Permission to conduct event selection trials on transgenic watermelon resistant to Watermelon Bud Necrosis Virus (WBNV) by Indian Institute of Horticultural Research (IIHR), Bangalore.

5.2.1 The Committee considered the request of IIHR to conduct event selection trials on 8 transgenic watermelons events resistant to Watermelon Bud Necrosis Virus (WBNV) namely AMa112a-1, AMa412-20, AMa432-6, AMa173-5, AMa545-1, AMa546-216, AMa547-230 and AMa548-10. Transgenic watermelon in T2-T4 is proposed to be evaluated for disease

resistance and yield. The event selection trials will be conducted at Hessaraghatta, within the research farm at IIHR.

5.2.2 The Committee noted that the RCGM has recommended the proposal in its 85th meeting held on 27.1.2010.

5.2.3 The Committee conveyed 'no objection' to the proposal**.**

5.3 Permission to conduct event selection trial on transgenic tomato (*Lycopersicon esculentum L)* resistant to Tospo virus (Peanut Bud Necrosis Virus: PBNV) by IIHR, Bangalore.

5.3.1 The Committee considered the request of IIHR to conduct event selection trials on 16 transgenic tomato (*Lycopersicon esculentum L.)* events resistant to Tospo virus (Peanut Bud Necrosis Virus - PBNV) namely*;* PR 38-7, PR42-1, R55-5, AS78- 7, AS194-11, AV60-2, AV1-5, AVNv4A, AVNv4B, AM97-9, AM95-16, AM93-5, AM190-8, AM190-11, AM190-12 and AM190-14. Transgenic tomato in T2 to T4 which have been earlier evaluated for resistance to PBNV under artificial inoculation and in transgenic poly-house is proposed to be evaluated for disease resistance, yield and quality under natural conditions. The event selection trials will be conducted at Hessaraghatta, within the research farm at IIHR.

5.3.2 The Committee noted that the RCGM has recommended the proposal in its 85th meeting held on 27.1.2010.

5.3.3 The Committee conveyed 'no objection' to the proposal.

5.4 Permission to conduct event selection trials on transgenic tomato (*Lycopersicon esculentum L)* resistant to Tomato Leaf Curl Virus (TLCV) by IIHR Bangalore.

5.4.1 The Committee considered the request of IIHR to conduct event selection trials on 30 transgenic tomato (*Lycopersicon esculentum L)* events resistant to Tomato leaf Curl Virus (TLCV) namely; AM-188-4, AM188-26, AM-184-1, AM184-6, M184-31, AM171-2, AM171-9, AM171-11, AM171-12, AM171-16, AM171-17, AM190- 8, AM190-11, AM-19012, AM-190-14, AS194-5, AS194-11, AS194 -13, AS194-16, PR148-37, PR148-49, PR149-23, PR149-31, PR200-9, PR208-27, AV157-13, AV157-14, AV157-16, AV160-13, AV163-19. Transgenic tomato in T2 to T4 which have been earlier evaluated for resistance to PBNV under artificial inoculation and in transgenic poly-house is proposed to be evaluated for disease resistance, yield and quality under natural conditions. The event selection trials will be conducted at Hessaraghatta, within the research farm at IIHR.

5.4.2 The Committee noted that the RCGM has recommended the proposal in its 85th meeting held on 27.1.2010.

5.4.3 The Committee conveyed 'no objection' to the proposal.

5.5 Permission to conduct event selection trials on transgenic tomato (*Lycopersicon esculentum L.) with combined* resistant to Tomato leaf Curl Virus (TLCV) and Tospo (Peanut Bud Necrosis Virus: PBNV:PBNV) by IIHR, Bangalore

5.5.1 The Committee considered the request of IIHR to conduct event selection trials on 9 transgenic tomato (Lycopersicon esculentum L.) events which have combined resistance to Tomato Leaf Curl Virus (TLCV) and Tospo (Peanut Bud Necrosis Virus: PBNV:PBNV) namely ANMi, ANM2, ANM3, Av 225-7, ANV-9, ANV-1, PR130-13, PR 130-12, AS231-7. Transgenic tomato in T2 to T4 which have been earlier evaluated for resistance to TLCV and PBNV under artificial inoculation and in transgenic poly-house is proposed to be evaluated for disease resistance, yield and quality under natural conditions. The event selection trials will be conducted at Hessaraghatta, within the research farm at IIHR.

5.5.2 The Committee noted that the RCGM has recommended the proposal in its 85th meeting held on 27.1.2010.

5.5.3 The Committee conveyed 'no objection' to the proposal.

5.6 Permission to conduct event selection trials on transgenic papaya for evaluating disease resistance and yield by IIHR, Bangalore

5.6.1 The Committee considered the request of IIHR to conduct event selection trials on 4 transgenic Papaya (Carica papaya) events containing PRSV cp-gene resistant to PRSV, namely TSolo4R, TSolo4Y, Solo7-1 and TSolo7- 3 at IIHR during January, 2010. Transgenic papaya in T1 is proposed to be evaluated for disease resistance and yield. The event selection trials will be conducted at Hessaraghatta, within the research farm at IIHR.

5.6.2 The Committee noted that the RCGM has recommended the proposal in its 85th meeting held on 27.1.2010.

5.6.3 The Committee conveyed 'no objection' to the proposal.

5.7 Permission to conduct event selection of transgenic hybrid Rice (*Oryza sativa* L.) SPT maintainer by M/s. E. I. DuPont India Private Limited, Hyderabad

5.7.1 The Committee considered the request of M/s. E. I. DuPont India Private Limited is to conduct event selection trials on 9 transgenic hybrid rice (*Oryza sativa* L) SPT maintainer events containing *Os-Msca1* gene namely; DKC118, DKC45, JH02, JH04, JH11, JH15a, JH22, JH26b and JH34b. The events were developed by transforming M2O2 x T65 lines and then backcrossed into VIR54G9.

5.7.2 The Committee noted that the RCGM has recommended the proposal in its 85th meeting held on 27.1.2010.

5.7.3 The Committee conveyed 'no objection' to the proposal.

5.8 Permission to conduct event selection trials on transgenic Sugarcane (*Saccharum L.*) containing *cry1Ab* gene for borer resistance by Sugarcane Breeding Institute (ICAR), Coimbatore

5.8.1 The Committee considered the request of Sugarcane Breeding Institute is to conduct event selection trials on 10 transgenic sugarcane (*Saccharum L)* events containing *cry1Ab* gene for borer resistance namely; Co 86032-Bt-7 (B), Co 86032-Bt-8 (B). Co 86032-Bt-10 (B), Co 86032-Bt-17(B), Co 86032-Bt-18(B), Co 86032-Apr-Bt-2(B), Co 86032-Apr-Bt-4(B), Co

86032-Apr-Bt-3(A), Co 86032-Bt-5(A), Co 86032- Bt-6(A). The event selection trials will be conducted within the research farm of the Sugarcane Breeding Institute in Coimbatore.

5.8.2 The Committee noted that the RCGM has recommended the proposal in its 85th meeting held on 27.1.2010.

5.8.3 The Committee conveyed 'no objection' to the proposal.

5.9 Permission to conduct event selection trials on transgenic Sorghum (*Sorghum biocolor L. Moench)* containing *mtlD* gene for drought and salinity tolerance by Central Research Institute for Dryland Agriculture (ICAR) , Hyderabad

5.9.1 The Committee considered the request of Central Research Institute for Dryland Agriculture is to conduct event selection trials on transgenic sorghum (*Sorghum biocolor L. Moench)* events containing *mtlD* gene for drought and salinity tolerance namely; p^{CAMBIA} 1300: *mtlD* CRIDA 1-6-1-8-4, *mtlD* CRIDA 2-9-3-3-5, *mtlD* CRIDA 4-7-1-7-4, *mtlD* CRIDA 26-1-11-6-1, *mtlD* CRIDA 75-2-21-2-1 and Events with p^{CAMBIA} 1305.1: *mtlD* CRIDA 3-3-18-7-2 and untransformed control: SPV-462 containing *mtlD* gene. The event selection trials will be conducted with the research farm of the institute

5.9.2 The Committee noted that the RCGM has recommended the proposal in its 85th meeting held on 27.1.2010.

5.9.3 The Committee conveyed 'no objection' to the proposal.

5.10 Permission to conduct Bio-safety Research Level-1 (BRL-1) second year field trial on two transgenic corn hybrids namely Hishell and 900M Gold containing stacked events MON 89034 & NK603 at 11 SAU by M/s. Monsanto India Ltd. (MIL), New Delhi

5.10.1 The Committee considered the request of MIL to conduct second year BRL-1 field trials under confined condition on two transgenic corn hybrids namely Hishell and 900M Gold containing stacked events MON 89034 & NK603 at 12 locations (11 locations within the SAUs and 1 location within the Company's own research farm at Aurangabad.

5.10.2 The Committee noted that the GEAC in its meetings held on 12.11.2008 and 10.6.2009 had approved the conduct of BRL-I of the above mentioned two corn hybrids expressing stacked events MON 89034 and NK603 at three SAUs during Rabi 2008 and at six SAUs during Kharif 2009 for generating biosafety data respectively. The Committee further noted that both RCGM/GEAC have taken a decision to allow BRL-1 trials at only two-three locations with two to three hybrids for generation of biosafety data as a policy.

5.10.3 After detailed deliberations and based on the recommendations of the RCGM, the Committee approved the request to conduct Bio-safety Research Level-1 (BRL-1) second year field trials with two transgenic corn hybrids namely Hishell and 900M Gold containing stacked events MON 89034 & NK603 at three locations in confined conditions**.**

5.11 Extension for second year BRL-1 trials of transgenic corn hybrids to two more locations during Rabi 2010 by M/s Monsanto India Limited, Mumbai.

5.11.1 The Committee considered the present request for extension of the trials to two additional locations to focus on comparative assessment of reproductive and survival biology of transgenic corn hybrids. It was noted that the protocol has been specifically designed to understand the biology of transgenic corn line with deliberation on pollen dehiscence and flowering behaviour under confined field conditions.

5.11.2 The Committee noted that the first season BRL-I was conducted i.e. Rajendra Agricultural University, Samastipur (Bihar); Mahatma Phule Krishi Vidyapeeth, Rahuri (Maharashtra);and Tamil Nadu Agricultural University, Coimbatore (Tamil Nadu); during Rabi 2009. However during the second year Rabi in 2009, the trials at MPKV Rahuri and RAU Samastipur could not be conducted as the SAUs have not given their consent to conduct the trials within the SAU due to pressure from NGO lobby. Therefore the applicant has requested approval for extending the second season BRL-I to two districts in AP namely Kurnool and West Godavari districts.

5.11.3 The Committee conveyed it's no objection subject to the conditions that (i) the company must indicate the locations in Kurnool and West Godavari districts where the proposed trials would be conducted; and (ii) submit consent letters from the SAUs, before issuing the approval letters.

5.12 Permission to conduct event selection trials on 56 transgenic rice events containing *cry1Ab, cry1Ca and bar* genes by M/s. Bayer Biosciences Pvt. Ltd., Gurgaon.

5.12.1 The Committee considered the request of M/s. Bayer Biosciences Pvt. Ltd is to conduct event selection trials on 56 transgenic rice events containing *cry1Ab, cry1Ca and bar* genes. The event selection trials will be conducted within the research farm at Patancheru during Kharif 2010

5.12.2 The Committee noted that the company has not provided full details of variety and the genotype characters of the transgenic rice. The Committee also noted that the RCGM has recommended the proposal in its 87th meeting held on 23.3.2010.

5.12.3 The Committee conveyed 'no objection' to the proposal on receipt of the above information.

5.13 Permission to conduct event selection trials on transgenic potato resistant to Potato Virus Y by Indian Agricultural Research Institute (IARI), New Delhi.

5.13.1 The Committee noted that the request of IARI is to conduct event selection trials on transgenic potato with events namely GRPVY – 1.2, GRPVY – 2.2, GRPVY – 2.5, GRPVY – 3.3, GRPVY – 3.4 and GRPVY – 5.3 at their own experimental land to identify the transgenic event resistant to Potato Virus Y and also to multiply the mini tubers raised under the contained conditions in the previous year during November 2009 by Plant Virology Unit, Division of Plant Pathology, Indian Agricultural Research Institute (IARI), New Delhi.

5.13.2 The Committee also noted that the applicant has submitted details of nucleic acid sequence, vector description and genotype of the transgenic potato. They have also confirmed that the transgenic potato is Kufri Giriraj and accordingly the events were named as GRPVY (GR=Giriraj and PVY=Potato virus Y), as requested them by the GEAC in its 98th meeting held on 9.12.2009

5.13.3 The Committee conveyed 'no objection' to the proposal.

5.14 Permission to conduct Biosafety Research Level-1 (BRL-1) trials on two transgenic maize hybrids namely 30V92HR and 30B11HR with indigenously produced seeds containing *cry1F* & PAT and *CP4EPSPS* genes (TC1507XNK603 (DAS-01507-1) X MON-00603-6) at seven SAUs by M/s. Pioneer Overseas Corporation, Hyderabad

5.14.1 The Committee considered the request of M/s. Pioneer Overseas Corporation, Hyderabad to conduct second season BRL-1 trials on two transgenic maize hybrids namely 30V92HR and 30B11HR with indigenously produced seeds containing *cry1F* & PAT and *CP4EPSPS* genes (TC1507XNK603 (DAS-01507-1) X MON-00603-6) at seven locations within the SAUs

5.14.2 The Committee noted that the GEAC in the 98th meeting held on 9.12.2009 had conveyed its no objection to conduct confined field trials with indigenously developed transgenic maize hybrids, namely 30V92HR and 30B11HR at 4 locations within the State Agricultural Universities. The applicant has informed that the BRL-I trials in Kharif 2009 has been concluded and the report will be submitted to RCGM.

5.14.3 As per The Committee further noted that both RCGM/GEAC have taken a decision to allow BRL-1 trials at only two-three locations with two to three hybrids for generation of biosafety data a policy

5.14.4 After detailed deliberations and based on the recommendations of the RCGM, the Committee approved the request to conduct second season Bio-safety Research Level-1 (BRL-1) field trials with two transgenic maize hybrids namely 30V92HR and 30B11HR with indigenously produced seeds containing *cry1F* & PAT and *CP4EPSPS* genes (TC1507XNK603 (DAS-01507-1) X MON-00603-6) in confined conditions.

5.15 Permission to conduct Biosafety Research Level s (BRL-I) second season trials with Bt Brinjal hybrids expressing cry1Fa1 gene (event 142) by M/s. Bejo Sheetal Seeds Pvt. Ltd., Jalna

5.15.1 The Committee considered the request of M/s. Bejo Sheetal Seeds Pvt. Ltd., to conduct second season BRL-I trials with Bt Brinjal hybrids expressing cry1Fa1 gene (event 142) at three locations within their own research farms at Jalna, Guntur and Varanasi during Kharif 2010.

5.15.2 The transgenic brinjal expressing *cry 1Fa1* (event 142) was initially developed by Indian Agricultural Research Institute, New Delhi and subsequently transferred to M/s Bejo Sheetal Seeds Pvt. Ltd for introgression into the parental lines of the company and conducting biosafety studies as per the regulatory requirement. As per the MoU between IARI and the Company, M/s Bejo Sheetal would carry out all biosafety studies as required under BRL I and BRL II and would be responsible for inter-facing with the regulatory agencies for obtaining approval for environmental release.

5.15.3 The Committee noted that the RCGM has recommended the proposal in its 87th meeting held on 23.3.2010.

5.15.4 The Committee also examined whether the moratorium imposed on Bt brinjal would have any implication on the present proposal. It was noted that as per para 22 of the decision document dated 09.02.2010, the moratorium is applicable only to Bt brinjal event EE-1.

5.15.5 After detailed deliberations and taking into consideration, the recommendations of RCGM, the Committee approved the request to conduct BRL-I second season trials with Bt Brinjal hybrids expressing cry1Fa1 gene (event 142) in confined conditions.

5.16 Permission to conduct confined field trials with Bt Brinjal hybrids expressing *cry1Fa1* gene (event 142) for production of leaves and fruits of Bt Brinjal for sub-chronic feeding studies by M/s. Bejo Sheetal Seeds Pvt. Ltd., Jalna

5.16.1 The Committee considered the request of M/s. Bejo Sheetal Seeds Pvt. Ltd., Jalna to produce Bt brinjal leaves and fruits containing cry 1Fal gene (Event 142) in confined conditions within the Company's own research farm at Jalna for generating sufficient plant material for conducting sub-chronic feeding studies on mice & rats a per revised protocol developed by NIN, Hyderabad.

5.16.2 The Committee noted that the RCGM in its 87th meeting held on 23.03.10 permitted M/s Bejo Sheetal to produce the leaves and fruits in gross experimental area of 2400 sq. m and 400 sq. m respectively in confined field conditions by maintaining stipulated isolation distance of 300 m during June - November 2010

5.16.3 After detailed deliberations and taking into consideration, the recommendations of RCGM, the Committee conveyed its 'no objection' to produce Bt brinjal leaves and fruits containing cry 1Fal gene (Event 142) in confined conditions within the Company's own research farm at Jalna.

5.17 Permission to conduct Biosafety Research Trials (BRL-II) on Bollgard II X Roundup Ready Flex (BGIIRRF) cotton hybrids containing *cry1Ac &cry2Ab* and *CP4EPSPS* (events MON 15985XMON 88913 by M/s. Maharashtra Hybrid Seeds Company Ltd. (MAHYCO),

5.17.1 The Committee considered the request of MAHYCO is to conduct BRL-II with Bollgard II X Roundup Ready Flex (BGIIRRF) cotton hybrids containing *cry1Ac &cry2Ab* and *CP4EPSPS* (events MON 15985XMON 88913). The applicant has also sought approval for seed production in an area of 25 acres per hybrid. Hybrid seed production will be done within Mahyco's contracted Seed Growers Farms and/or Company's own farm.

5.17.2 The Member Secretary informed the members that the GEAC in its meetings held on 28.5.2008, 9.7.2008 and 13.8.2008 and 10.6.2009, had approved the conduct of BRL-I with two Bt cotton hybrids expressing *cry1Ac & cry2Ab and CP4EPSPS* genes (MON 15985 X MON 88913) at two locations each in the north, central and south zones, respectively, for generating biosafety data during Kharif 2008 and 2009, respectively. The hybrids tested were MRC-8017 BG-II, MRC-8031 BG-II in the north zone and MRC-8347 BG-II & MRC-8351 BG II in the central and south zones. She also informed that the applicant has submitted the following documents:

A. Application form containing the following information:

- Introduction
- Biology of the Plant System

- Molecular Biology of Plant and Transformation method
- Field Trials Plan of Bollgard II Round Up Ready Flex (BGIIRRF) Cotton
- Phenotypic characteristics of Bollgard II Round up Ready Flex (BGIIRRF) Cotton Plant.
- Consequences to the environment
- Food and Feed Safety Evaluation
- Supportive evidences to all the chapters
- Summary and Conclusion

B. Reports containing results of the following studies:

- Cotton Weed management – Case study
- Bridging studies for MON 15985 X MON 88913 cotton hybrids
- Molecular analysis of the RRF cotton Event MON 88913
- BRL-I Field Trial Report of North Zone during Kharif 2009
- BRL-I Field Trial Report of Central Zone during Kharif 2009
- BRL-I Field Trial Report of South Zone during Kharif 2009
- Protein Expression Studies from BRL-1 Trials of Kharif 2009
- Germination study during 2007
- Phenotypic evaluation and insect observations of the combined trait cotton product Round up Ready Flex (MON 88913) X Bollgard II (MON 15985) in U.S. field trials during 2004
- Weediness and Aggressiveness Study during 2008
- Soil Micro – flora Study from MLRT of Kharif 2007
- BG II RRF Compositional Study conducted in India 2010
- Comparative studies on the chemical composition of cotton seed of BGIIRRF cotton hybrids and their non-transgenic counterparts US 2004
- Bio informatics comparison with known allergens and toxins for CP4 EPSPS protein
- Bio informatics comparison with known allergens and toxins for Cry1 Ac protein
- 90 day Sub-chronic Wistar Rat Feeding study on BGII (MON 15985)
- Evaluation of cotton seed meal derived for BGII RRF as a feed ingredient for cat fish
- Safety, Compositional and Nutritional Aspects of RRF cotton (Event MON 88913)
- Bioinformatics comparison with known allergens and toxins for Cry2Ab Protein
- Bioinformatics comparison with known allergens and toxins for GUS Protein
- Bioinformatics comparison with known allergens and toxins for NPTII Protein
- Digestibility of CP4 EPSPS Protein in stimulated Gastric Fluid
- Thermal stability for CP4 EPSPS Protein
- Acute oral toxicity for CP4 EPSPS Protein
- 90 day Feeding study in Wistar Rat with BGIIRRF cotton (MON 15985 X MON 88913
- 90 day Sub-chronic Wistar Rat Feeding study on RRF (MON 88913)

5.17.3 The Committee also noted that the M/s Mahyco had made a detailed presentation to the RCGM in its 87th meeting held on 23.3.2010 on the safety and efficacy of the product. RCGM noted that the data submitted by the Company is in order and recommended to the GEAC for BRL-II trials.

5.17.4 After detailed deliberations, the Committee approved the request to conduct BRL-II trials with Bollgard II X Roundup Ready Flex (BGIIRRF) cotton hybrids containing *cry1Ac*

&cry2Ab and *CP4EPSPS* (events MON 15985XMON 88913 on the following hybrids MRC-8017 BG-II, MRC-8031 BG-II in the north zone and MRC-8347 BG-II & MRC-8351 BG II in the central and south zones at three locations in each zone in confined conditions under the direct supervision of Director, Central Institute of Cotton Research, Nagpur for two seasons. The Committee also approved the request for seed production in an area of 25 acres per hybrid in confined

Agenda item No. 6: Consideration of applications in case of Pharmaceuticals

6.1 Permission for import to conduct phase III clinical trials with Gendicine (r-adenovirus p53 (r ADp53)) in the treatment for newly diagnosed unresectable squamous cell carcinoma of head and neck from China by M/s Intas Biopharmaceuticals Ltd.

6.1.1 The Committee noted that the request from M/s Intas Biopharmaceuticals Ltd. to import r-adenovirus p53 (r-ADp53) from China to conduct phase III clinical trials for the newly diagnosed unresectable squamous cell carcinoma of head and neck was earlier discussed in the GEAC meeting wherein the proposal was referred to the RCGM. The Committee noted that the RCGM in its meeting held on 22.12.2009 had recommended the import of the gene therapy product Gendicine from China to conduct Phase-III human clinical trials in India.

6.1.2 The Committee noted that comments from ICMR and DCGI are awaited. The representative of DCGI informed that, the Company has filed its application for phase-III clinical trials to DCGI in April 2010. On prima facie examination, it is observed that there is lack of evidence on the purification of the product (3 batch data is not available), complete information on phase-I and phase II trials, pre-clinical and animal toxicity data have not been provided. The product is an unlicensed product in the country of origin (China). While the product was earlier meant for treatment of head and neck cancer, the phase-III trials is requested for a new indication (unresectable squamous cell carcinoma of head and neck). It was further informed that the applicant has been requested by DCGI to make a detailed presentation on the above issues.

6.1.3 After detailed deliberations, it was decided to await the final views of DCGI before taking a view on the matter. Decision on the proposal was therefore deferred.

6.2 Permission for Phase III clinical trials to conduct controlled study of the safety and immunologencity of Japanese Encephalitis Chimeric Virus Vaccine (JE-CV) by M/s Sanofi Pasteur India Pvt Ltd. New Delhi (former *Acambis Inc)*

6.2.1 The Committee noted that the request from M/s Sanofi Pasteur India Pvt Ltd. is to conduct Phase III clinical trials to conduct controlled study of the safety and immununogencity of Japanese Encephalitis Chimeric Virus Vaccine (JE-CV). Japanese Encephalitis (JE). The objective of the study is to asses JE-CV in phase III trials in pediatric populations in India. Subjects will be immunized with either a single dose administration of JE-CV at day 0 or with 3 doses of MBDV at day 0, day 7 and day 28, in accordance with the recommended regimen of immunization for both vaccines.

6.2.2 The Committee noted that the phase-II clinical trials were conducted with the approval of GEAC. The Committee noted that the phase II study has been completed wherein the following conclusions have been made:

- JE-CV has a satisfactory safety profile in children and infants.

- A single dose of JE-CV is as safe as inactivated MBDV in standard two dose primary immunization schedule in healthy children and infants.
- JE-CV induced a satisfactory protective immune response after a single vaccination both in terms of post-vaccination

6.2.3 Members were of the view that the safety data generated is in order and there are no new issues of environmental concerns. However, the representative of ICMR informed that ICMR had requested the applicant to submit the entire phase-II clinical trial dossier which is still awaited. It was further clarified that an Expert Committee has been earlier constituted by ICMR to evaluate the proposal at each stage of development and therefore, views of the ICMR Expert Committee should be first obtained.

6.2.4 After detailed deliberations, it was decided to await the final views of ICMR Expert Committee before taking a view on the matter. Decision on the proposal was therefore deferred.

Agenda item No. 7: Consideration of applications for export/import of GMOs / GM products.

7.1 Import of Genuity tm Roundup Ready 2 yield soybean (Event Mon-89788) oil from USA by M/s Monsanto Holdings Pvt. Ltd.

7.1.1 The Committee considered the request of M/s Monsanto Holdings Pvt Ltd. is to import crude degummed oil produced from Genuity tm Roundup Ready 2 yield (RR2Y) Soybean (MON 89788) from USA. The transgenic soybean has been developed by Monsanto by introducing CP4 EPSPS gene which is tolerant to glyphosate.

7.1.2 The Committee noted that the CP4 EPSPS/Event 89788 is approved in the following countries:

Country	Environment	Food/safety	Food	Feed
Australia		2008		
Canada	2007		2007	2007
China		2008		
European Union		2008		
Japan	2008		2007	2008
Korea			2009	2009
Mexico		2008		
Philippines		2007		
Taiwan			2007	
United States	2007	2007		

7.1.3 The Committee further noted that the GEAC in its 78th GEAC meeting held on 22.6.07 had approved import of GM Soybean oil derived from Roundup Ready Soybean for the purpose of consumption by M/s Solvent Extractors' Association of India on the grounds that (i) highly processed food like oil do not contain any detectable level of DNA or protein and (ii) oil derived from Round-up Ready soybean is being consumed in more than 40 countries and (iii) environmental release of GM Soybean oil will not have any environmental implications.

7.1.4 During the discussions, Dr P.M. Bhargava was of the view that he does not support the proposal as it should be first tested for DNA and protein, and labeling should be made mandatory. It was clarified that no country in the world imposes mandatory labeling of GM oil. Members reiterated that there is no scientific evidence to show that GM oil is harmful to health or the environment.

7.1.5 After detailed deliberations, the Committee approved the import of Genuity tm Roundup Ready 2 yield soybean (Event Mon-89788) oil.

7.2 Export of Bt cotton hybrids (4 numbers) expressing cry 1Ac (Event -1) to Pakistan by M/s JK Agri Genetics Ltd. Hyderabad.

7.2.1 The Committee considered the request from M/s JK Agri Genetics Ltd. Hyderabad to export four hybrids of *Bt* cotton hybrids JKCH-1947 Bt, JKCH-1050 Bt, JKCH-226 Bt and JKCH-1950 Bt seeds containing *cry 1 Ac* (Event -1) to M/s Ali Akbar Seeds, Lahore, Pakistan.

7.2.2 The intended purpose of the export is to study the control of cotton bollworm complex and cotton yield in different agro-climate conditions. The proposed shipment will be total 8 Kg (2kg x 4) of Bt cotton event -1 hybrids. Bt cotton hybrids expressing *cry 1Ac* (Event -1) is commercialized in India since 2006**.** The applicant has submitted the Material Transfer Agreement letter from M/s Ali Akbar Seeds, Lahore.

7.2.3 After detailed deliberations the GEAC conveyed 'no objection' for export Bt cotton hybrids (4 numbers) expressing cry 1Ac (Event -1) to Pakistan subject to the following conditions:

- Approval of the National Biosafety Committee in accordance with the Pakistan Biosafety Rule, 2005 and National Biosafety Guidelines, 2005.

- Approval from the National Biodiversity Authority, Chennai.

7.3 Export of Bollgard II Cotton variety expressing cry 1Ac and cry 2Ab (Event - MON-15985) to Pakistan by M/s Monsanto Holdings Pvt. Ltd.

7.3.1 The Committee considered the request from M/s Monsanto Holdings Pvt. Ltd. to export Bollgard II cotton variety namely S07H878 (MAxx CoT) BG II seeds containing cry 1Ac and cry 2Ab (Event -MON-15985) to M/s Monsanto Pakistan Agritech Pvt Ltd., Lahore, Pakistan.

7.3.2 The intended purpose of the export is for large scale field trials under different cotton growing areas of Pakistan. The proposed shipment will be total 200 Kg. Bt cotton hybrids expressing cry 1Ac and cry 2Ab is commercialized in India since 2006**.**

7.3.2 After detailed deliberations the GEAC conveyed 'no objection' for export Bollgard II Cotton variety expressing cry 1Ac and cry 2Ab (Event -MON-15985) to Pakistan subject to the following conditions:

- Approval of the National Biosafety Committee in accordance with the Pakistan Biosafety Rule, 2005 and National Biosafety Guidelines, 2005.

- Approval from the National Biodiversity Authority, Chennai.

7.4 Export of Bollgard II Cotton hybrids expressing cry 1Ac and cry 2Ab (Event - MON-15985) to Pakistan by M/s Monsanto Holdings Pvt. Ltd.

7.4.1 The Committee considered the request from M/s Monsanto Holdings Pvt. Ltd. is to export six hybrids of Bollgard II cotton namely PO9H028, PO9H029, PO9H030, PO9H031, PO9H032 and PO9H033 seeds containing cry 1Ac and cry 2Ab (Event -MON-15985) to M/s Monsanto Pakistan Agritech Pvt Ltd., Lahore, Pakistan.

7.4.2 The intended purpose of the export is for hybrid seed production in Pakistan. The proposed shipment will be total 6.7 kg. Bt cotton hybrids expressing cry 1Ac and cry 2Ab is commercialized in India since 2006**.**

7.4.3 After detailed deliberations the GEAC conveyed 'no objection' for export Bollgard II Cotton variety expressing cry 1Ac and cry 2Ab (Event -MON-15985) to Pakistan subject to the following conditions:

- Approval of the National Biosafety Committee in accordance with the Pakistan Biosafety Rule, 2005 and National Biosafety Guidelines, 2005.

- Approval from the National Biodiversity Authority, Chennai.

Agenda Item No 8: Information items

8.1 Renewal of GEAC permission for Bt cotton hybrids expressing approved events.

8.1.1 The Member Secretary, GEAC informed that as per the decision taken in the meeting held on 14.2.2009, routine cases of requests for renewal of GEAC approval for Bt cotton hybrids expressing approved events was granted with the approval of Chairman GEAC after seeking comments from the State Governments. List of Bt Cotton hybrids for which renewal was granted is enclosed as **Annexure A**. The Committee ratified the decision taken by the Chairman, GEAC.

8.2 Meeting with State Governments to discuss issues related to production, sale and cultivation of Illegal transgenic cotton on 19.4.2010

8.2.1 The Committee noted that a meeting with the Chief Secretaries of the State Governments of the nine cotton growing States was held on 19.4.2010 under the Chairmanship of Shri M F Farooqui, Additional Secretary and Chairman, GEAC to discuss issues related to production, sale and cultivation of illegal Bt cotton. The meeting was attended by representatives of the State Departments of Agriculture.

8.2.3 The following points were conveyed by the representatives of the State Governments

i. The Agriculture Commissioner, Govt. of Andhra Pradesh informed that based on the complaint received from M/s Monsanto, the Joint Director of Seeds was deputed to Prakasham and Guntur District. In Prakasham district, 8 samples out of 11 were tested positive for HT cotton containing Monsanto event 1445. In Guntur District 2 samples tested positive. The farmers had purchased seeds from M/s Usha Enterprises in Guntur District. On investigation, it was noted that HT Seeds were produced in Nanded District of Maharashtra. The license of M/s Usha Enterprises has been cancelled. In 2009, flying squads were deputed and in view of the strict vigil enforced by the

Government, there were no incidences of illegal Bt/Ht cotton release in Andhra Pradesh.

ii. The representative of Gujarat informed that on November 25, 2008, Directorate of Agriculture, Gujarat collected samples in response to the complaint received from MoEF and sent the samples to Central Institute for Cotton Research (CICR), Nagpur for testing. CICR Nagpur returned the samples back to the Directorate of Agriculture, Gujarat stating that they are not the designated referral laboratory for HT trait. On December 6, 2008 the Director of Agriculture, Gujarat raided the ginning mill at Mansa and seized 3-5 MT suspected illegal HT cotton seed. Due to lack of clarity on testing of material, the Director of Agriculture, Gujarat released the sealed material on April 19, 2009. The seed industries responsible for production and sale of HT cotton were M/s Parvardhan Seeds and M/s Akshay Seeds, both sub-licensees of M/s Monsanto in Bollgard -1. M/s Monsanto collected and tested the samples from the released material and found the presence of unintended event viz HT cotton containing Monsanto 1445 event. The Company shared the report with Parvardhan Seeds and as mutually agreed destroyed the released material on July 13, 2009.

iii. The representatives of Tamil Nadu, Punjab, Haryana, Karnataka and Rajasthan informed that in the initial years, there was a tendency to purchase illegal Bt cotton seeds in view of the high cost of Bt cotton but with the prices having come down, the farmers prefer to buy approved seeds as it provides a platform for redressal and compensation. The State Governments informed that all efforts are being made to prevent the illegal production sale and cultivation of spurious seeds.

8.2.4 During the deliberations, the following points also emerged:

i. The State Governments are not informed about the GEAC approval for field trials of GM crops.
ii. Due to receipt of late approval for field trials, the Companies are not sowing the seeds in the normal season. This should not be allowed and data from such trials should not be accepted.
iii. None of the farmers are growing refugia. The non-Bt seed supplied by the Companies should have the same maturity time.
iv. On the recent Monsanto report that Pink bollworms have developed resistance to Cry 1 Ac gene in four districts of Gujarat, the representative of Gujarat, informed that no farmer has reported damage or claimed any compensation because of such occurrences as reported by M/s Monsanto.
v. The representative of Haryana informed that the event based approval needs to be reconsidered as materials untested for its agronomic superiority are often released.
vi. The Ministry has received reports regarding attack on GM field trials by NGOs.

8.2.5 After detailed deliberations, the following action points were agreed upon:

i. The State Govt. should continue taking cognizance of various complaints received. Since monitoring farmer-to-farmer transfer of illegal GM cotton seeds was not found feasible, strict vigilance of the ginning units, research farms, etc; should continue as an advance action before the onset of the Kharif season. As timing is very crucial, the emphasis should be on effective action against selected parties to send right signals for enforcement of law.

ii. The State Govt. should initiate prosecution under EPA/Seeds Act against the erring companies/individuals.

iii. The State Government will submit its action taken report regularly to the GEAC. In this regard, the Chairman requested Member Secretary GEAC to prepare a proforma for submitting a annual audit report on the action taken by the State Governments to curb the illegal release of transgenic cotton seeds. In view of the recent moratorium on commercialization of Bt brinjal, he further emphasized that, the State Govt should not limit its monitoring only to Bt cotton but also to other crops in the pipeline. The annual audit report should be sent to the GEAC before the onset of the next sowing season.

iv. A scanned copy of all approval letters for field trials with GM crops will be sent to Director Agriculture / Commissioner of Agriculture by e-mail. As per the conditions imposed in the approval letter, the applicants are required to inform the State Govts about the field trials within 15 days of sowing. In case this is not complied, the State Govts through the SBCC/DLC may take punitive action as deemed fit and also inform the GEAC.

v. Issues regarding refugia and event based approvals system will be considered by the GEAC.

vi. As security of the GM crop field trials is of utmost importance, the State Governments may issue strict instructions and put in place appropriate mechanisms to prevent attack at GM field trials.

vii. Ministry of Agriculture may be requested to take expeditious action in notifying CICR and other referral laboratories for testing and verification of GM crop expressing different events.

8.3 Meeting with the technology providers and concerned departments to discuss the development of insect resistance to Bt cotton in Gujarat — Monsanto Report in HT dated 6.3.2010.

8.3.1 The Committee noted that a meeting with the representatives of the five technology providers was held on 20.4.2010 under the chairmanship of Shri M F Farooqui, Additional Secretary and Chairman, GEAC to discuss Monsanto report regarding development of resistance to cry 1 Ac gene in pink bollworms and mechanisms to strengthen post release surveillance wherein the representatives of Monsanto and Dr. Kranti, Director CICR, Nagpur made a presentation on the Monsanto findings. The following points emerged during the meeting:

8.3.2 Dr. Kranthi informed that, the methodology followed by Monsanto was unscientific and therefore unacceptable on the following grounds:

- The unusual survival of the pink bollworm in Saurashtra region of Gujarat was due to weather conditions that favoured the pest survival and not because of resistance as stated by Monsanto.
- The CICR data (www.cicr.org.in AICCIP, All India Coordinated Cotton Improvement Project reports 2009-10) showed that during 2009, there were indeed unusually high level of pink bollworm moth catches in the pheromone traps installed in Junagarh of Saurashtra region (more than 1100 moths per week per trap) at an average of about 700 moths per week all through mid-November until the end of January. This happened only in Saurashtra this year. At all other 12 centres where monitoring was carried out, the pest incidence in the trap catches were low at less

than 100 moths per trap per week. Therefore the unusually high level of pink bollworm survival in Saurashtra was not at all surprising.

- The fact that India is the only country in the world that cultivates hybrids and also that the bolls on F1 hybrid plants possess 25% non-Bt seeds, enables the survival of pink bollworm larvae that feed mainly on the developing seed, was also responsible for the high infestation levels on Bt-cotton.
- The Monsanto bioassay data were derived from 33 pink bollworm larval population samples collected from Bt cotton fields in all the four districts of Saurashtra, instead of collecting on conventional cotton as per the standard methodology. Therefore, their inferences on resistance were not correct.
- Further, thus far there has been no scientific evidence anywhere in the world including India to indicate that the pink bollworms had developed resistance to Cry1Ac under field conditions.

8.3.3 There was also discussion on non-compliance of refuge and how to get farmers plant the refuge. Dr. Kranthi suggested that insect resistance management strategies, such as supplemental insecticidal spray, stubble destruction, pheromone traps and deep ploughing would delay the development of insect resistance to cry 1 Ac gene. He also mentioned that desi cotton and late planted Bhendi may be recommended as refuge.

8.3.4 Dr. Kranti has been requested to form a network of technology providers and lead the resistance monitoring efforts in this country, involving SAUs specifically. The proposed network should be actively involved in developing strategies to increase refuge compliance and come out with a firm proposal which can then be considered by the GEAC within one month.

8.4 Bt cotton seeds encoding fusion-gene protein (Cry1Ac-1Ac) show enhanced tolerance to armyworm (spodoptera litura) – reg.

8.4.1 Bt cotton hybrids encoding fusion gene (Cry 1Ab-Cry 1Ac) developed by M/s Nath Seeds (P) Ltd. (now known as M/s Global Transgene Ltd.) was approved by the GEAC in 2006. Bt cotton hybrids encoding fusion gene (Cry 1Ab-Cry 1Ac) was tested for its efficacy in controlling bollworms (lepidopteron pests) and safety prior to environmental release.

8.4.2 During the commercial cultivation, the Company has observed that the Bt cotton hybrids encoding fusion genes is also providing protection to armyworms (Spodoptera) in addition to bollworms. To validate the field observations, the Company has conducted insect bioassays in the laboratory which has also confirmed that the fusion gene has a distinct value addition in controlling armyworms. Subsequent to these findings, the Company has validated the observations through the Plant Protection Centres of the Tamil Nadu Agricultural University, Coimbatore and University of Agriculture Sciences, Dharwad who have also confirmed the findings of the Company.

8.4.3 The Company now proposes to incorporate the additional advantage depicted by fusion gene technology to the product related literature and marketing campaigns. During Kharif 2009, the Company had approached the Government of Maharashtra to accord approval for the above. The State Government requested Mahatma Phule Krishi Vidyapeeth, Rahuri (MPKV). The bioassays studies by MPVK are also in conformity with the findings of the studies conducted by the Company, TNAU, Coimbatore and UAS, Dharwad.

8.4.4 The Maharashtra State Govt has advised the Company to obtain 'No Objection' from the GEAC. The Company has been informed that approval for information to be provided in

the product related literature and marketing campaigns do not fall under the purview of the GEAC on the following grounds:

i. The mandate of the GEAC under Rules, 1989 is to accord approval for environmental release of GMOs based on the bio-safety data generated during field testing and in the laboratory.
ii. The GEAC has also adopted an event based approval mechanism for Bt cotton hybrids expressing approved events. The fusion gene of M/s Nath Genes falls in this category.
iii. Presently, Bt cotton seeds are being sold as 'truthfully labeled seeds' as per the Seed Act. Therefore, the applicant will be liable for any false claim made by them during the marketing campaigns.
iv. Agriculture being a state subject and marketing license are being issued by the State Dept of Agriculture, the State Govt may take decision as deem fit on the matter based on information submitted by the applicant / findings of the State Agricultural University.

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Annexure - A

List of Bt cotton hybrids approved by GEAC for renewal for commercial release.

A. North Zone

Name of the Hybrid	Name of the Company	Event
Ole Bt	M/s Vibha Agrotech Ltd	*cry 1 AC gene* Event (Mon-531)
Sigma Bt	M/s Vibha Agrotech Ltd	*cry 1 AC gene* Event (Mon-531)
Navkar 5 Bt.	M/s Navkar hybrid Seeds Pvt. Ltd	*cry 1 Ab-cry 1Ac "GFM cry 1A"*
RCH 134 Bt	M/s Rasi Seeds	*cry 1 AC gene* Event (Mon
RCH 317 Bt	M/s Rasi Seeds	*cry 1 AC gene* Event (Mon
NAMCOT 402 Bt	M/s Namdhari seeds Pvt Ltd	*cry 1 AC gene* Event (Mon-531)
PCH-406	M/s Parbhat Seeds Pvt Ltd	*cry 1 AC gene* Event (Mon-531)
KDCHH 9810 Bt	M/s Krishidhan Seed Ltd	*cry 1 AC gene* Event (Mon-531)
JKCH 1050 Bt	M/s JK Agrigenetics Ltd	*cry 1 AC gene* Event-1
JKCH 99 Bt	M/s JK Agrigenetics Ltd	*cry 1 AC gene* Event-1
ACH-33-2	M/s Ajeet seeds Ltd	*cry 1AC & cry 2Ab* Event(Mon-15985)
NCS 145 Bt 2	M/s Nuziveedu seeds Pvt Ltd	*cry 1AC & cry 2Ab* Event(Mon-15985)
NCS 950 Bt 2	M/s Nuziveedu seeds Pvt Ltd	*cry 1AC & cry 2Ab* Event(Mon-15985)
IT 905 BGI	M/s Bayers bio Sciences	*cry 1 AC gene* Event-1
6317 Bt	M/s Bioseed Research India Pvt Ltd	*cry 1 AC gene* Event (Mon-531)
6488 Bt	M/s Bioseed Research India Pvt Ltd	*cry 1 AC gene* Event (Mon-531)
SDS-27 BT	M/s Nandi Seeds Pvt Ltd.	*cry 1 Ac gene* (Mon-531)
SDS-9 BT	M/s Nandi Seeds Pvt Ltd.	*cry 1 Ac gene* (Mon-531)
SDS-234 BT	M/s Nandi Seeds Pvt Ltd.	*cry 1 Ac gene* (Mon-531)
GK 206 Bt	M/s Ganga Kaveri Seeds Pvt Ltd.	*cry 1 Ac gene* (Mon-531)
SDS-1368 Bt	M/s Amar Bio-Tech Ltd	*cry 1 Ac gene* (Mon-531)

B. Central zone

Name of the Hybrid	Name of the Company	Event
Sigma Bt	M/s Vibha Agrotech Ltd	*cry 1 AC gene* Event (Mon-531)
Dyna Bt	M/s Vibha Agrotech Ltd	*cry 1 AC gene* Event (Mon-531)

VBCH 1009 Bt (Hero Bt)	M/s Vibha Agrotech Ltd	*cry 1 AC gene* Event (Mon-531)
VBCH 1010 Bt	M/s Vibha Agrotech Ltd	*cry 1 AC gene* Event (Mon-531)
RCH2 BGII	M/s Rasi Seeds	*cry 1AC & cry 2Ab* Event(Mon-15985)
RCH 386 Bt	M/s Rasi Seeds	*cry 1AC & cry 2Ab* Event(Mon-15985)
RCH 515 BGII	M/s Rasi Seeds	*cry 1AC & cry 2Ab* Event(Mon-15985)
RCH 2 Bt	M/s Rasi Seeds	*cry 1AC & cry 2Ab* Event(Mon-15985)
KCH 135 Bt	M/s Kaveri seeds company Ltd	*cry 1 AC gene* Event (Mon-531)
KCH 707 Bt	M/s Kaveri seeds company Ltd	*cry 1 AC gene* Event (Mon-531)
PRCH 31 Bt	M/s Pravardhan Seeds Pvt Ltd	*cry 1 AC gene* Event (Mon-531)
Rudra Bt	M/s Pravardhan Seeds Pvt Ltd	*cry 1 AC gene* Event (Mon-531)
ABCH 1165 Bt	M/s Amar Bio-Tech Ltd	*cry 1 AC gene* Event (Mon-531)
ABCH 1220 Bt	M/s Amar Bio-Tech Ltd	*cry 1 AC gene* Event (Mon-531)
Dhruv Bt (ZCH-50064)	M/s Zuari seeds Ltd	*cry 1 Ab-cry 1Ac "GFM cry 1A"*
KDCHH 786 Bt	M/s Krishidhan Seeds Ltd	*cry 1 AC gene* Event (Mon-531)
JKCH 226 Bt	M/s J.K.Agrigenetics Ltd	*cry 1 AC gene* Event- 1
JKCH-666 Bt	M/s J.K.Agrigenetics Ltd	*cry 1 AC gene* Event- 1
ACH-155-2BG-II	M/s Ajeet Seeds	*cry 1AC & cry 2Ab* Event(Mon-15985)
ACH-21-1	M/s Ajeet Seeds	*cry 1 AC gene* Event (Mon-531)
NCS-955 Bt	M/s Nuziveedu seeds Pvt Ltd	*cry 1 AC gene* Event (Mon-531)
NCS-207 Bt2	M/s Nuziveedu seeds Pvt Ltd	*cry 1AC & cry 2Ab* Event(Mon-15985)
NCHB 991 Bt	M/s Nuziveedu seeds Pvt Ltd	*cry 1 AC gene* Event (Mon-531)
KDCHH -621 BGII	M/s Krishidhan Seed Ltd	*cry 1AC & cry 2Ab* Event(Mon-15985)
NCS-954 Bt	M/s Nuziveedu seeds Pvt Ltd	*cry 1 AC gene* Event (Mon-531)
NCS-950 Bt	M/s Nuziveedu seeds Pvt Ltd	*cry 1 AC gene* Event (Mon-531)
SP-504 BI Dhanno)	M/s Bayers bio Sciences	*cry 1 AC gene* Event-1
SP-923Bt (IT-923 Bt) (Dhanno)	M/s Bayers bio Sciences	*cry 1 AC gene* Event (Mon-531)
622 Bt	M/s Bioseed Research India Pvt Ltd	*cry 1 AC gene* Event (Mon-

		531)
110 Bt	M/s Bioseed Research India Pvt Ltd	*cry 1 AC gene* Event (Mon-531)
6188 Bt	M/s Bioseed Research India Pvt Ltd	*cry 1 AC gene* Event (Mon-531)
563 Bt	M/s Bioseed Research India Pvt Ltd	*cry 1 AC gene* Event (Mon-531)
NSPL-405 Bt	M/s Nandi Seeds Pvt Ltd	*cry 1 Ac gene* (Mon-531)
NSPL-36 Bt	M/s Nandi Seeds Pvt Ltd	*cry 1 Ac gene* (Mon-531)
NSPL-45 Bt	M/s Nandi Seeds Pvt Ltd	*cry 1 Ac gene* (Mon-531)
NSPL-99 Bt	M/s Nandi Seeds Pvt Ltd	*cry 1 Ac gene* (Mon-531)
NSPL-9 Bt	M/s Nandi Seeds Pvt Ltd	*cry 1 Ac gene* (Mon-531)
NSPL-207 Bt	M/s Nandi Seeds Pvt Ltd	*cry 1 Ac gene* (Mon-531)
NCEH-3R Bt	M/s Global Transgenes Ltd (Nath seeds Ltd)	(*cry 1Ab-cry 1Ac) "GFM" Cry 1A" gene*
NCS-950	M/s Nuziveedu Seeds	*cry 1 Ac gene* (Mon-531)
Kashinath Bt	M/s Global Transgenes Ltd (Nath seeds Ltd)	(*cry 1Ab-cry 1Ac)"GFM" Cry 1A" gene*
Navkar 5 Bt	M/s Navkar Hybrid Seeds Pvt Ltd	(*cry 1Ab-cry 1Ac) "GFM" Cry 1A" gene*
VICH -15 Bt	Vikram Seeds Pvt Ltd,	*cry 1 Ac gene* (Mon-531)

C. South Zone

Name of the Hybrid	**Name of the Company**	**Event**
NSPL-405 Bt	M/s Nandi Seeds Pvt Ltd.	*cry 1 Ac gene* (Mon-531)
NSPL-36 Bt	M/s Nandi Seeds Pvt Ltd.	*cry 1 Ac gene* (Mon-531)
NSPL-45 Bt	M/s Nandi Seeds Pvt Ltd.	*cry 1 Ac gene* (Mon-531)
NSPL-99 Bt	M/s Nandi Seeds Pvt Ltd.	*cry 1 Ac gene* (Mon-531)
NSPL-9 Bt	M/s Nandi Seeds Pvt Ltd.	*cry 1 Ac gene* (Mon-531)
NSPL-207 Bt	M/s Nandi Seeds Pvt Ltd.	*cry 1 Ac gene* (Mon-531)
NCS-950	M/s Nuziveedu Seeds	*cry 1 Ac gene* (Mon-531)
NCEH-3R Bt	M/s Global Transgenes Ltd (Nath seeds Ltd)	*(cry 1Ab-cry 1Ac)"GFM" Cry 1A" gene*
Kashinath Bt	M/s Global Transgenes Ltd (Nath seeds Ltd)	(*cry 1Ab-cry 1Ac) "GFM" Cry 1A" gene*
Ole Bt	M/s Vibha Agrotech Ltd	*cry 1 AC gene* Event (Mon-531)
Sigma Bt	M/s Vibha Agrotech Ltd	*cry 1 AC gene* Event (Mon-531)
Dyna Bt	M/s Vibha Agrotech Ltd	*cry 1 AC gene* Event (Mon-531)
RCH2 BGII	M/s Rasi Seeds	*cry 1AC & cry 2Ab* Event(Mon-15985)
RCH 530 BGII	M/s Rasi Seeds	*cry 1AC & cry 2Ab* Event(Mon-15985)
RCH 533 BGII	M/s Rasi Seeds	*cry 1AC & cry 2Ab* Event(Mon-15985)
RCH 2 Bt	M/s Rasi Seeds	*cry 1AC & cry 2Ab* Event(Mon-

		15985)
RCH 368 Bt	M/s Rasi Seeds	*cry 1AC & cry 2Ab* Event(Mon-15985)
RCH 371 Bt	M/s Rasi Seeds	*cry 1 AC gene* Event (Mon-531)
KDCHB -407 Bt	M/s Krishidhan Seed Ltd	*cry 1 AC gene* Event (Mon-531)
KDCHH -621 Bt	M/s Krishidhan Seed Ltd	*cry 1AC & cry 2Ab* Event(Mon-15985)
JKCH-634 Bt	M/s JK Agrigenetics	*cry 1 AC gene* Event -1
ACH-33-2	M/s Ajeet Seeds	*cry 1AC & cry 2Ab* Event(Mon-15985)
ACH-22-1	M/s Ajeet Seeds	*cry 1 AC gene* Event (Mon-531
NCHB-990	M/s Nuziveedu seeds Pvt Ltd	*cry 1 AC gene* Event (Mon-531)
NCS-954 Bt	M/s Nuziveedu seeds Pvt Ltd	*cry 1 AC gene* Event (Mon-531)
NCS-929 Bt	M/s Nuziveedu seeds Pvt Ltd	*cry 1 AC gene* Event (Mon-531)
NCHB-992	M/s Nuziveedu seeds Pvt Ltd	*cry 1 AC gene* Event (Mon-531)
NCS-145 Bt 2	M/s Nuziveedu seeds Pvt Ltd	*cry 1AC & cry 2Ab* Event(Mon-15985)
SP 504B1 (Dhanno)	M/s Bayers bio Sciences	*cry 1 AC gene* Event (Mon-531)
KCH 135 Bt	M/s Kaveri seeds company Ltd	*cry 1 AC gene* Event (Mon-531)
KCH 707 Bt	M/s Kaveri seeds company Ltd	*cry 1 AC gene* Event (Mon-531)
PRCH 31 Bt	M/s Pravardhan Seeds Pvt Ltd	*cry 1 AC gene* Event (Mon-531)
Rudra Bt	M/s Pravardhan Seeds Pvt Ltd	*cry 1 AC gene* Event (Mon-531)
ABCH 1165 Bt	M/s Amar Bio-Tech Ltd	*cry 1 AC gene* Event (Mon-531)
ABCH 1220 Bt	M/s Amar Bio-Tech Ltd	*cry 1 AC gene* Event (Mon-531)
Dhruv Bt (ZCH-50064)	M/s Zuari seeds Ltd	*cry 1 Ab-cry 1Ac "GFM cry 1A"*
340 Bt	M/s Bioseed Research India Pvt Ltd	*cry 1 AC gene* Event (Mon-531)
6188 Bt	M/s Bioseed Research India Pvt Ltd	*cry 1 AC gene* Event (Mon-531)
302 Bt	M/s Bioseed Research India Pvt Ltd	*cry 1 AC gene* Event (Mon-531)
563 Bt	M/s Bioseed Research India Pvt Ltd	*cry 1 AC gene* Event (Mon-531)

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