Decisions taken in the 98th Meeting of the Genetic Engineering Approval Committee (GEAC) held on 9.12.2009.

The 98th meeting of the GEAC was held on 9.12.2009 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 7 are as follows:

Agenda item No. 3: Action taken report on the decision taken in the 97th GEAC meeting.

3.1 The Member Secretary, GEAC informed the Committee that decisions taken in the meeting held on 13.5.2009 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:

1. The Ministry is in the process of constituting a sub-committee under the chairmanship of Shri A K Goyal, Joint Secretary, MoEF comprising of a legal expert and the Controller of Accounts from DBT and MoEF to examine the feasibility of creating a separate account for utilization of funds collected as processing fee for meeting the expenses incurred in giving the approvals, monitoring, etc;

2. Subsequent to the decisions taken in the GEAC meeting held on 14.10.2009, the report of the Expert Committee (EC-II) has been posted on the MoEF's website. As the Ministry has received views both in favour and against commercialization of Bt brinjal in India from various stakeholders including farmers, civil societies, NGOs and scientists, the Minister of Environment and Forests has invited comments from all stakeholders up to 31.12.2009 on the report of EC-II. This will be followed by national consultations during January - February 2010 before a final view on the environmental release of Bt brinjal is taken by the Ministry. Tentatively, the consultations are proposed to be held at Ahmedabad, Bangalore, Bhubaneswar, Chandhigarh, Hyderabad, Nagpur and Kolkata. Details of the national consultations will be posted on the MoEF website as and when finalized.

3. In accordance with the decision taken in the GEAC meeting held on 9.9.2009, the meeting of the Technology Provider (IARI/NRCPB) and Licensees/Technology Partners of Bt brinjal Event 142 to bring clarity on the modalities for generating biosafety data and sharing of responsibilities in getting biosafety clearance was held on 27.10.2009 under the chairmanship of Mr A. K. Goyal, Joint Secretary, MoEF. Dr Ranjini Warrier, Member Secretary, GEAC, Dr P. Ananda Kumar, Project Director, NRC on Plant Biotechnology (Technology Provider) and representatives of the seed companies (licensees/ technology partners) attended the meeting. The following consensus emerged:

- 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. In case the company is unable to do so at any given point of time, the Technology Provider (IARI/NRCPB) will continue the studies.

- All the licensees enjoy equal status and parity and therefore will have equal rights over all the studies conducted by M/S Bejo Sheetal, the first licensee, including on LOD, flanking sequence analysis, biosafety, etc. The cost of generating biosafety data and getting the regulatory approval will be shared by all the licensees.

- Dr P. Ananda Kumar would arrange a meeting at of all licensees of Event 142 to address the issue of resource sharing at an appropriate time.

- As the GEAC has adopted an event based approval mechanism, any GM event in any crop species needs to be tested for biosafety only once and therefore the data generated by M/s Bejo Sheetal on the safety of Event 142 would be applicable to Bt brinjal hybrids / varieties developed by other licensees.

4. During the discussions, Dr P M Bhargava, special invitee, pointed out that GEAC had requested ICAR to organize a brainstorming session to discuss the performance of Bt cotton. However, this has not happened till date. It was agreed that MoEF would follow it up with to DG, ICAR.

5. On the draft proposal for setting up a "National Centre for Assessment of GMOs" prepared by Dr. P. M. Bhargava, the Member Secretary, GEAC informed that the Hon'ble Supreme Court in WP (Civil) 260/2005 had directed the UOI to submit its response. The response prepared in consultations with several institutes involved in GMO research, development and testing has been submitted to the Hon'ble Supreme Court. It was agreed to compile the comments received from various institutes and discuss the same in the next GEAC meeting.

Agenda item No. 4: Policy issue

4.1 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.

As the above agenda would involve extensive deliberations, it was agreed initially to take up the matter after completing all other agenda items. However, due to paucity of time the matter was deferred for the next GEAC meeting in January 2010. It was agreed that meeting will be primarily devoted to discuss the draft guidance document. The Committee suggested that a presentation on the document would facilitate discussion and its finalization.

4.2 Stocktaking assessment of GM crops which are under various stages of field testing.

4.2.1 In accordance with the decision taken in the GEAC meeting held on 8.7.2009, information on the status of GM cereals under field trials was placed before the Committee. The Committee noted that the status of field trials of GM cereals is as under:

A. M/s Bayer Bioscience Pvt Ltd.

Development of transgenic rice expressing Oryza sativa (*cry 1 Ab, cry 1Ca & bar* genes)

1. The source of genetic material (*cry 1 Ab, cry 1Ca & bar* genes), was received from M/s Bayer BioScience N.V Belgium and transformation was done at Bayer BioScience CropDevelopment Centre at Patrancheru.

2. The applicant has so far conducted only event selection trials under net house conditions as per the RCGM approval given below:

Sl. No.	RCGM permit No. & date	Permission
1.	BT/BS/17/06/95-PID dt. 15.07.2008	Conduct Greenhouse trials of 44 Bt rice lines.
2.	BT/BS/17/06/95-PID dt. 01.09.2008	Conduct confined field trials for event selection of 28 Bt rice lines during kharif 2008.
3.	BT/BS/17/06/95-PID dt. 09.02.2009	Conduct confined field trials for event selection of 41 Bt rice lines during Rabi 2008-09.
4.	BT/BS/17/06/95-PID dt. 19.06.2009	Conduct Greenhouse trials of 47 Bt rice lines.
5.	BT/BS/17/06/95-PID dt. 19.06.2009	Conduct confined field trials for event selection of 88 Bt rice lines during kharif 2009.

3. Based on the event selection trials, the applicant has short-listed 4-5 events for further event selection trials under net house conditions. No confined trials under BRL-I have been initiated. The request for additional event selection trials during 2009-10 has also been received (refer Agenda 5.1)

B. Avesthagen Ltd.

Development of transgenic rice expressing *Oryza sativa taipae 309*

1. Rice plants transgenic for *Nicotiana plumbaginifolia* MnSOD targeted to the chloroplast via chloroplast targeting peptide have been developed. The rice line used for transformation via biolistic is TP309.

2. The chronological sequence of crop development (year-wise) is as follows:

1998 - Transformation and generation of T0 plants.
1999 - Generation of T1 plants and analysis.
2000 - Generation of T2 Plants and analysis.
2001 - Identification of promising events
2001 – 2002 - Laboratory studies for molecular and biochemical analysis.
2006 - Generation of T3 Plants and analysis.
2007 - Generation of T4 Plants and analysis.
2008 - Application for Strip trials.
2009 - Bio-efficacy and Bio-safety studies.

3. RCGM in its meeting held on 27.05.2008 (Letter No.BT/BS/17/14/2000-PID), had requested to furnish information on bio-efficacy data generated in laboratory condition, pepsin digestibility, heat, thermal stability, acute oral toxicity data generated on the purified protein and other safety assessment study on the purified protein as per the new protocols being adopted by the RCGM/ GEAC. Only after the requested studies are completed the proposed confined field trials for event selection will be initiated. No field trials have been initiated so far.

C. Mahyco

Development of transgenic rice expressing *cry 1Ac gene*

1. The *cry1Ac* gene, source *Bacillus thuringiensis* was received from Monsanto and transformation was done at Mahyco. Pollen flow / Weediness and aggressiveness studies were conducted at Anand Nagar, Nizamabad, AP in July 2003.

2. Applicant has been permitted to conduct multi-location field trials at:

- Two locations during Kharif 2005
- Seven locations during Rabi 2005
- Ten locations during Kharif 2006
- Ten locations during Rabi 2007
- A trial was planted at Shamshabad, Rangareddy, A.P. to generate material for biosafety studies during Kharif 2009

3. The applicant has completed 4 seasons (3 years) of multi-location field trials. The studies conducted during the trails include:

a) Evaluation of performance of Bt rice against target pest.
b) Pollen flow
c) Effect of germination, aggressiveness and weediness.
d) Soil rhizospheric studies.
e) Monitoring of occurrence of beneficial and non target insects
f) Estimation of level of expression of Bt proteins at regular intervals
g) Generation of baseline susceptibility data

Details of the field trials are enclosed as **Annexure-6.** A biosafety package is being generated.

D. Metahelix Life Science Ltd.

Development of transgenic rice expressing *cry 1C.*

1. The applicant has informed that they could not proceed with the conduct of event selection trials with rice expressing as they have not received the necessary approval from RCGM. RCGM in its meeting held on 29.07.2008, had requested the applicant to furnish information on bio-efficacy data generated in laboratory condition, pepsin digestibility, heat, thermal stability, acute oral toxicity data generated on the purified protein and other safety assessment study on the purified protein as per the new protocols adopted by the RCGM/ GEAC. Only after the requested studies are completed the proposed confined field trials for event selection will be initiated. No field trials have been initiated so far.

E. Monsanto India Ltd.

Development of transgenic corn expressing *cry 2Ab2* and *cry 1A*.105 genes, (event MON 89034 and CP4EPSPS genes)

1. The source of genetic material *cry 2Ab2* and *cry 1A*.105 genes, (event MON 89034 and CP4EPSPS genes) was received from M/s Monsanto USA and transformation was done

at Monsanto India Ltd. The chronological sequence of crop development (year-wise) is as follows:

Sl. No.	RCGM permit No. & date	Permission to
1.	BT/BS/17/44/97-PID dated 31.3.2003	To conduct pollen flow study in herbicide tolerant corn (RR Corn)
2.	BT/BS/17/44/97-PID dated 21.07.2004	To carry out efficacy & pollen flow study in herbicide tolerant corn (RR Corn)
3.	BT/BS/17/44/97-PID dated 07.07.2006	Import of NK603 inbred line
4.	BT/BS/17/44/97-PID dated 19.12.2007	Import of MON89034 inbred lines
5.	BT/BS/17/44/97-PID dated 19.5.2008	Imported 500g of transgenic stacked corn hybrid for developing LOD and for insect bioassay study in green house
6.	BT/BS/17/44/97-PID dated 8.12.2008	Permission to conduct BRL-1 trials at three locations during Rabi season 2008-09
7.	BT/BS/17/44/97-PID dated 19.06.2009	Permission to conduct BRL-1 trials at six location during Kharif season 2009

2. The BRL -1 trial for conduct to hybrid namely Hishell and 900M Gold expressing *cry 2Ab2* and *cry 1A*.105 genes, (event MON 89034 and CP4EPSPS genes). The studies conducted during the trails include:

1. Evaluation of bio-efficacy and residue study of glyphosate in transgenic (GM Corn) (MON89034 X NK603)
2. Biosafety Research Level-1 for transgenic stack corn hybrids (MON89034 X NK603) in India
3. BRL-1 Rabi trial report of MPVK Kolhapur, Maharashtra on Biosafety Research Level -1 for transgenic stack corn hybrids (MON89034 X NK603) in India
4. Baselines susceptibility of various geographical populations of Chilo partellus and Helicoverpa armigera to Bt insecticidal protein Cry1A.105 and Cry2Ab2 Kharif 2008.
5. Quantification of transgenic proteins CryaA.105, Cry2Ab2 and CP4-EPSPS in tissues to transgenic stacked corn hybrids (MON89034 X NK603)field tested in the 2008 Rabi Season in India
6. Bio Efficacy of tissues to transgenic stack corn (MON89034 X NK603)hybrids against major lepidopteron pests of corn
7. Insect bio-efficacy studies with tissue of transgenic corn lines (Event MON89034) against maize stem borer Chilo partellus (Swinhoe).
8. Expression analysis of Bt proteins , Cry1A.105, and Cry2Ab2 in tissues of transgenic corn lines (Events MON89034).
9. Pollen flow study in herbicide tolerant corn (Roundup Ready corn) 2003-2004
10. Pollen containment and bio-efficacy trials for herbicide tolerant corn expressing CP4EPSPS gene (NK 603 Corn) 2004-2005.
11. Validation of protocols for limit of detection (0.01 %) for transgenic corn events Mon 89034 & NK 603.

F. Pioneer Overseas Corporation

Development of transgenic corn expressing *cry 2Ab2* and *cry 1A*.105 genes, (event MON 89034 and CP4EPSPS genes)

1. M/s. Pioneer Overseas Corporation, Hyderabad, has initiated bio-safety research trials (BRL-1) on two transgenic corn hybrids namely 30V92HR and 30B11HR containing *cry1F* and *CP4EPSPS* genes (stacked event of TC1507 X NK603) at four State Agricultural Universities (SAUs) during Kharif 2009 for generation of bio-safety data.

2. M/s Dow Agro Sciences (DAS), USA and Pioneer Hi- Bred International, USA have jointly developed TC-1507 event in corn and holds equal rights on the said event. A declaration has been signed whereby DAS has authorized M/s Pioneer Overseas Corporation, Hyderabad to file a joint application before the regulatory authorities for obtaining regulatory approvals for transgenic corn expressing TC-1507+NK 603 event in India.

3. The transgenic corn hybrid seeds were imported from Pioneer Hi-Bred International, Johnstone USA in February 2009 with the approval of RCGM.

4. The BRL-I trials at four locations with two transgenic corn hybrids namely 30V92HR and 30B11HR Bt are presently on going and date of planting is as follows :

1) UAS Bangalore	:	01.08.09
2) UAS Dharwad	:	07.08.09
3) Angrau, Karimnagar	:	04.08.09
4) MPUAT Udaipur	:	07.08.09

5. In collaboration with Dow Agro Sciences, the applicant has developed LOD of 0.01%, which has been validated by SGS India Private Limited.

G. Dow AgroSciences

Development of transgenic corn expressing *Cry 1F (event TC 1507)*

1. The source of genetic material *Cry 1F (event TC 1507) was* received from M/s Dow AgroSciences LLC USA and transformation was done at Dow AgroSciences India Pvt. Ltd. The chronological sequence of crop development (year-wise) is as follows:

Sl. No.	RCGM permit No. & date	Permission
1.	BT/BS/17/56/2002-PID dated 4.8.2008	Import
2.	02.09.2008	NBPGR gave import
3.	03.11.2008	DAS received 500g each of TC1, TC2, TC3, TC4 and TC5 seeds
4.	Feb.2009	Validation of Event specific protocol at LoD 0.01% for Cry 1F gene expressed in maize by SGS Ahmedabad

5.	Feb. 2009	Evaluation of TC1507 maize for resistance to spotted stem borer Chilo partellus Swin. Under containment greenhouse conditions
6.	8.5.2009	DAS submitted application to RCGM for BRL-1 trials at three location in SAUs
7.	BT/BS/17/56/2002-PID dated 15.07.2009	RCGM approved TC 1507 BRL-1 trials in three location
8.	July to August -2009	All three locations were planted

2. The BRL-I trials at three locations with two transgenic corn hybrids namely TC-1 and TC-2 expressing Cry *1F (event TC 1507)* are presently on going and date of planting is as follows:

1) Baljigapade, UAS Bangalore : 12.08.09
2) Kathalgere, UAS Bangalore : 14.08.09
3) TNAU, Coimbatore : 29.08.09

3. The applicant has developed LOD of 0.01%, for *Cry 1F (event TC 1507) which* has been validated by Eurofins GenScan, Germany.

H. National Research Centre for Sorghum

Development of transgenic sorghum expressing *Cry1B gene NRCSCRY1B event 4 and NRCSCRY 1B event 19*

1. Sorghum Bt transgenic plants were developed through *Agrobacterium*-mediated genetic transformation by infecting the shoot tip explants of the genotype M35-1 using binary vector pCAMBIA 3300 carrying synthetic *cry1B* gene under the control of maize ubiquitin promoter at Directorate of Sorghum Research (formerly National Research Center for Sorghum).

2. Synthetic *cry1B* gene was cloned under the control of entire 5' untranslated region of the maize polyubiquitin gene *Ubi-1* (promoter, exon-1 and intron-1) and the polyadenylation sequence from the *Agrobacterium tumefaciens Nos* gene into the *Hind III* site of the pCAMBIA3300 plasmid constructed by Dr. Monique Royer from CIRAD, FRANCE (MTA on 25th June, 2002). The plasmid pCAMBIA3300 contains the *Bar* gene from Streptomyces hygroscopicus under control of *CaMV35S* promoter for plant selection marker and the nos terminator, this plasmid also contains kanamycin gene amplified from pIG121Hm.

3. The Chronological sequence of Bt sorghum development (year-wise):

2004-05 - Sorghum transformation (*Agrobacterium*-mediated) started.

2005-06 - Evaluation of T1 sorghum *Bt* transgenics in both laboratory and glasshouse (Insect bioassay studies).

2006-07 - Evaluation of T2 sorghum *Bt* transgenics in both laboratory and glasshouse (Insect bioassay studies).

2007-08 - Evaluation of T3 sorghum *Bt* transgenics in both laboratory and glasshouse (Insect bioassay studies).

2008-09 - Evaluation of T4 sorghum *Bt* transgenics in both laboratory and glasshouse (Insect bioassay studies).

2009-10 - RCGM - Biosafety Research Trial-1 (BRL-1) in one location (NRCSCRY 1B event 19).

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The BRL-I trials were initiated in July 2009 and would be completed by December 2009.

4. The institute has also been directed by the RCGM to generate the following information simultaneously with the BRL-I trials:

- Bio-efficacy data, protein digestibility, thermal stability, oral toxicity study using purified protein;
- SOPs for conducting field trials; and
- Validated event specific protocol of 0.01% LOD of the selected event.

4.2.2 The Committee noted that only Bt rice developed by M/s Mahyco and transgenic corn developed by M/s Monsanto, M/ Pioneer Overseas Corporation and M/s Dow AgroSciences respectively have progressed from the laboratory stage to the confined field trial (BRL-I) phase for generation of biosafety data.

4.2.3 During the deliberations, one of the experts pointed out *Oryza sativa taipae 309* used by M/s Avesthagen in the development of transgenic rice is good material for transformation but is highly susceptibility to all kinds plant diseases and pathogens. As this material is not cultivated in India, the susceptibility to plant diseases and pathogens needs to be studied and monitored for at least three years in the lines expressing the gene of interest before it goes for BRL-I trials.

4.2.4 The Committee noted that the information provided by the applicant in respect of the transgenic hybrids/ varieties is limited to only giving numbers which is not adequate. The Committee was of the view that all the applicants should provide information on the geneotype, pedigree, original source, single or double hybrid and commercial name, etc. It was clarified that the new guidelines and SOPs for confined field trials require applicants to provide these details. As these guidelines were adopted only recently, the Committee opined that the above information needs to be obtained from all applicants who were granted approvals prior to the adoption of the new guidelines.

4.2.5 The Committee further desired that the mechanism for monitoring the GM crop field trials may be presented by one of the monitoring teams in any of the GEAC meetings. The Committee further recommended that setting up a monitoring cell in a public institution such as ICAR would be advantages in many ways. The Committee requested Member Secretary, GEAC to examine the feasibility of setting up a monitoring mechanism under the ICAR system in consultation with DDG-ICAR.

4.2.6 The Committee also sought clarification on whether M/s SGS India Private Limited is a NABL accredited laboratory and if so for what purpose? It was agreed that the requisite information would be obtained for perusal of the Committee.

Agenda item No. 5: Consideration of applications confined field trials of transgenic crops expressing new genes/events for event selection /BRL-I /BRL-II as recommended by the RCGM.

5.1. Permission to conduct Bio-safety Research level-1 (BRL-1) Trial under confined conditions on two transgenic maize hybrids namely 30V92HR and 30B11HR with indigenously produced seeds containing *cry1F & PAT* and *CP4EPSPS* genes (TC1507 x NK603 (DAS-01507-1 x MON-00603-6) at 4 SAUs by M/s. Pioneer Overseas Corporation, Hyderabad.

5.1.1 The Committee noted that the GEAC in its meeting held on 9.9.2009 had taken a decision not to permit BRL-I trials with direct imported GM seeds without carrying out R and D work in the country. However, in respect of the recent approval given to M/s Pioneer the Committee agreed that the company may be advised to repeat the BRL-I trials with GM seed developed in the country.

5.1.2 The Committee considered the request for conducting BRL-I trials with two transgenic maize hybrids namely 30V92HR and 30B11HR containing *cry1F & PAT* and *CP4EPSPS* genes (TC1507 x NK603 (DAS-01507-1 x MON-00603-6) at 4 locations namely Rajendera Agricultural University, Bihar; Birsa Agricultural University (BAU), Jharkhand; Tamil Nadu Agricultural University (TNAU), Coimbatore and Acharya N.G. Ranga Agricultural University (ANGRAU*),* Hyderabad during Rabi season 2009-10 in light of the recommendations made by the RCGM in its meetings held on 27.10.2009 and 24.11.2009.

5.1.3 The Committee noted that RCGM has recommended "all plant transgenic material (parental lines, hybrids and varieties developed abroad) can be imported through the existing process of approval to promote technology access, up-gradation and/or germplasm enhancement irrespective of whether the host material is already cultivated or adopted under Indian conditions. However, in all such cases in order to ensure safety, the imported material should be essentially grown first under contained conditions as prescribed. Observations on growth, reproduction, phenotype, etc; in contained conditions along with required biosafety information as already prescribed and unintended effects if any may be recorded. These observations may be submitted along with the requests for conduct of confined field trials including event selection trials and Biosafety Research Level-I (BRL-I) trials in the prescribed format and procedure." After detailed deliberations, the Committee accepted the above recommendations.

5.1.4 The Committee also considered the clarifications provided by the company and noted that imported transgenic corn hybrids namely 30V92HR and 30B11HR have been fully converted into propriety parental lines in June 2009 and the company has planted parental lines for hybrid make up in August 2009 and is going to harvest the hybrid seeds in November-December 2009. The company has also informed that the imported parental lines are fully converted with cry1F & PAT and CP4EPSPS genes and are being used for further multiplication of parental lines and hybrid make up in green house conditions at their research station at Bangalore. Research activities like assessment of presence of genes and the level of protein expression have been undertaken and the parent are selected for production of hybrid seeds based on presence of genes with high protein expression levels. It was also noted that the company does not have any plan to introgress into any other varieties/lines in India. The company has proposed to use indigenously produced seed for BRL-I trials.

5.1.5 In view of the above stated facts, the GEAC conveyed its no objection to conduct BRL-1 trials under confined conditions on two transgenic maize hybrids namely 30V92HR and 30B11HR with indigenously produced seeds containing *cry1F & PAT* and *CP4EPSPS* genes (TC1507 x NK603 (DAS-01507-1 x MON-00603-6) at 4 SAUs by M/s. Pioneer Overseas Corporation, Hyderabad.

5.2. Permission for conducting second year BRL-1 trials of transgenic corn hybrids at two more locations by M/s Monsanto India Limited, Mumbai

5.2.1 The Committee noted that the GEAC in its meeting held on 14.10.2009, had approved the request for conduct of second year Biosafety Research Level-I (BRL-I) trials on corn hybrids namely Hishell and 900 M Gold containing stacked *cry2ab2* and *cry1A.105 (Event MON-89034) & CP4EPSPS genes (NK603*) under confined conditions within the three SAUs where first season BRL-I was conducted. The Company has now informed that due to pressure put on by the anti-GM lobby, the two SAUs namely MPKV Rahuri and RAU Samastipur have not given their consent to conduct the trials within the SAU for the second season. Therefore the applicant has requested approval of the GEAC for conducting BRL-1 trials at alternate sites namely ANGRAU Regional Research Station, Karimnagar and BHU Institute of Agricultural Sciences.

5.2.2 The Committee considered the request in light of the recommendations made by the RCGM in its meeting held on 27.10.2009. It was noted that the request of the company and recommendations of the RCGM regarding the locations for conducting BRL-I trials during Rabi 2009 are at variance. The Committee decided that the discrepancy needs to be first resolved and the applicant would be requested to provide the reasons along with proof as to why the two SAUs refused consent to conduct trials. The decision on the proposal was deferred.

5.3 Permission 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 – at their own experimental land to identify the transgenic event resistant to Potato Virus Y and also to multiply the mini tubers raised under contained conditions in the previous year during November 2009 by Plant Virology Unit, Division of Plant Pathology, Indian Agricultural Research Institute (IARI), New Delhi.

5.3.1 The Committee noted that the applicant has not provided full details of the genotype of the transgenic potato. Decision on the proposal was therefore deferred. It was decided that these details should invariably be obtained in all such cases in future before placing them before the Committee.

5.4 Permission to conduct event selection trials on transgenic lines of Bt chickpea (T-2) expressing cry2Aa gene at their own research farm to test the efficacy of transgenic lines during November 2009 by National Research Centre on Plant Biotechnology (NRCPB), New Delhi.

5.4.1 The Committee noted that the request of the NRCPB is to conduct "event selection trials" on transgenic lines of Bt chickpea(T-2) expressing *cry2Aa* to test the efficacy transgenic lines of Bt chickpea(T-2) expressing *cry2Aa* toxin during November 2009 by National Research Centre on Plant Biotechnology (NRCPB), Indian Agricultural Research Institute (IARI), New Delhi, at their Research farm.

5.4.2 The Committee also noted that RCGM has recommended the proposal in its meeting held on 27.10.2009.

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

Agenda item No. 6: Other items:

6.1 Export of *G. hirsutum* cotton lines containing *Vip3Agene* (Event COT 102) (5 numbers, 100 gm each) to Monsanto USA by M/s Monsanto Holdings Pvt Ltd. New Delhi.

6.1.1 The request was not considered as M/s Monsanto Holdings Pvt Ltd has informed vide letter No. SK/09/096 dated 25.11.2009 that they wish to withdraw their application for Export of *G. hirsutum* cotton lines containing *Vip3Agene* (Event COT 102) (5 numbers, 100 gm each) to Monsanto USA as they were able to arrange the seed directly from other sources. However, the Committee has sought clarifications from the company on the source and origin of the seeds exported to USA.

6.2 Export of BGII RRF cotton hybrids (15 numbers) to Pakistan from India by M/s Monsanto Holdings Pvt Ltd. New Delhi.

6.2.1 The Committee considered the request from M/s Monsanto to export Bt cotton BGII RRF cotton expressing *Cry 1Ac, cry 2Ab* and *CP4Epsps* (Events Mon-15985x Mon 88913) (15 numbers) to M/s Monsanto Pakistan Agritech Pvt. Ltd; Lahore. The proposed shipment will contain a total 4.5 Kg. (300 g x 15) of BG II x RRF cotton hybrid seeds. Mon 15985 has been commercialized in India since 2006 and stacked traits of Mon 15985 and Mon 88913 are undergoing second year of BRL-I trials in India.

6.2.2 The intended purpose of the export is to conduct multi locational field trials in different agro-climatic zone in Pakistan. The applicant has submitted a copy of the license agreement with M/s Monsanto and import permit from the Ministry of Food, Agriculture and Livestock, Department of Plant Protection (Plant Quarantine Division), Government of Pakistan to import Bollgard II (R) X Roundup Ready Flex ® cotton Hybrid Seed for field trials.

6.2.3 After detailed deliberations, the Committee conveyed its 'no objection' for export of Bt cotton BGII RRF cotton expressing *Cry 1Ac, cry 2Ab* and *CP4Epsps* (Events Mon-15985x Mon 88913) to Pakistan subject to obtaining:

- Approval of the Pakistan National Biosafety Committee in accordance with the Pakistan Biosafety Rules, 2005 and National Biosafety Guidelines, 2005; and

- Approval from the National Biodiversity Authority, Chennai.

6.3 Representation from M/s. Bayer Biosciences Pvt. Ltd., Hyderabad informing that M/s Greenpeace has raided the field trials of Bt Rice containing *cry1Ab, cry1Ca* and *bar* genes in Chinakanjaria village near Hyderabad.

6.3.1 The Member Secretary GEAC informed that three issues namely (i) attack on GM field trials by NGOs; (ii) requirement of 'NOC from Panchayat before initiating the trials, and (iii) complaint regarding non-submission of information regarding field trials to the SBCC/DLC and other functionaries in the State by the applicant have been cropping up quite often.

6.3.2 The Committee considered the following representations:

- A complaint from M/s Bayer BioSciences informing that M/s Greenpeace has raided the field trials of Bayer Crop Science in Chinakanjaria village near Hyderabad and a

similar complaint was earlier received regarding attack on Bt Brinjal trials in two locations at Hamdipur and Alipur near Delhi and Bt Rice trials in Karnal.

- A letter from Special Secretary to Government of Andhra Pradesh, Department of Environment, Forests, Science and Technology informing that a meeting had been convened on 17.8.2009 at 3.00 PM in Hyderabad under the chairmanship of Chief Secretary, Govt. of AP and Chairman, SBCC to discuss non-submission of information regarding field trials to the SBCC/DLC and other functionaries in the State by M/s Bayers.

- Letter from Dr. K. Gayatri Prasad Yadav, Sarpanch, China Kanjaria Gram Panchayat, Patencheru Mandal, AP seeking clarification on (i) how the company has initiated the trials without obtaining 'no objection' from Gram Panchayat; (ii) why certificates of safety on human and cattle have not been submitted; and (iii) why the company has not put up any warning boards near the farm regarding the cultivation of dangerous GM crops.

- Letter from M/s Greenpeace confirming that their activity involved trespassing the fences of Bayer's rice field trials but they did not raid or damage the field trials.

6.3.3 After detailed deliberations, the Committee concluded the following:

1. The company has initiated the trials in conformity with the regulatory procedures and has obtained the approval of RCGM and the GEAC to conduct the event selection trials within the company's own institutional farm. Copy of the approval issued by the RCGM which contains the location of the trials was issued to the Chief Secretary, SBCC as well as Director Research of ANGRAU University. However, the applicant was required to submit information on the field trials to the SBCC/DLC and other state functionaries within seven days. In the instant case the applicant had submitted information only to the RCGM and therefore there had been a lapse on their part which should be avoided in future.

2. As per 'Rules 1989', the applicant is not required to obtain approval of the Panchayat prior to conduct of GM crop field trials. However as a matter of caution, the applicants have been advised by the GEAC to inform the Panchayat if the trials are conducted in farmers' field.

3. As regards the certificate of safety on human and animal health demanded by the Panchayat, it was agreed that field trials form an integral part of research and development and are necessary to collect the agronomic and ecological data required to complete the environment safety assessment of genetically modified plant. These trials also allow the production of sufficient quantities of plant material for use in livestock feeding studies/trials and to conduct compositional analyses, which are necessary for food safety assessment. Therefore, certificate of safety cannot be provided by the applicant at this stage. All the biosafety data generated by the applicant during various stages of field trials are posted on the GEAC website (www.envfor.nic.in) as and when biosafety data are submitted to the regulatory agencies.

4. As regards the attack on GM field trials by NGOs, the Committee noted that under section 18 of Rules 1989, only the authorized personal can enter the trial site. This has been reiterated in the approval letter which states "You would further ensure that only company authorized personnel is allowed to visit the experimental plot and persons visiting the experimental plot shall enter the name, designation and purpose

of visiting the experimental plot in a bound book which should be made available to the Government when requested for". While this being a law and order issue, such kind of sabotage is highly risky as it may lead to release of untested GM material and therefore strict action against the violators should be initiated by the State Govt. As security of the GM field trials is of utmost importance, the Committee opined that the State Government may be requested to issue strict instructions to prevent such incidences in future.

6.4 Action taken on the representation from M/s Monsanto and Ms. Aruna Rodrigues on the illegal sale of herbicide tolerant (HT) cotton seeds in the country.

6.4.1 On the basis of a complaint received from M/s Monsanto in 2008 regarding the sale and cultivation of illegal HT cotton seeds in Gujarat, Madhya Pradesh and Andhra Pradesh, the GEAC had constituted a sub-committee to verify the complaint. However the investigation could not be completed as the harvesting of the crop was over. The State Governments were directed to continue the investigation and take timely action. Subsequent to the complaint received from Ms Aruna Rodrigues, Petitioner in WP (Civil) 260 of 2005 in 2009, regarding the sale and cultivation of illegal HT cotton seeds in Gujarat, the GEAC has been pursuing with the State Governments to take stringent action against the dealers/distributors dealing in illegal Bt cotton seeds and submit an action taken report.

6.4.2 The Committee noted that in accordance with the decision taken in the 95th GEAC, the Chairman GEAC requested the:

1. Chief Secretaries of Govt of Gujarat, Govt of Madhya Pradesh and Govt of Andhra Pradesh to verify the complaints received and take stringent action against the dealers/distributors dealing in illegal Bt cotton seed.
2. Secretary, Ministry of Agriculture to notify CICR, Nagpur as one of the referral laboratories for testing and verification of all transgenic traits in cotton crop under the Seed Act, 1966. The MOA was also requested to notify crop specific referral laboratories.
3. Dr. J. Nagaraju, Scientist, Centre for DNA Fingerprinting and Diagnostics, (CDFD) Hyderabad to forward a copy of the test reports of transgenic cotton seeds received from Govt of Madhya Pradesh and Andhra Pradesh confirming to contain Herbicide Tolerant (HT) traits.
4. Dr K R Kranthi, Acting Director CICR, Nagpur not to return samples alleged to contain unapproved gene events received from the State Govts on procedural grounds.
5. DGFT to enhance the vigilance at the ports of entry to ensure illegal seeds do not enter the country.

6.4.3 Dr. J. Nagaraju, a Staff Scientist informed vide their letter dated 18.8.2009 that CDFD, had not received any sample for testing the Herbicide Tolerant (HT) traits in cotton seeds.

6.4.4 The Commissioner & Director of Agriculture, Hyderabad and Assistant Director of Agriculture (DNA seeds fingerprinting Lab) Hyderabad subsequently forwarded the following information to the GEAC:

i. Herbicide Tolerant Cotton analytical reports pertaining to the Andhra Pradesh which confirmed that all 8 samples analyzed were tested positive for HT traits containing Monsanto event MON 1445.

ii. Herbicide Tolerant Cotton analytical reports pertaining to the Madhya Pradesh which confirmed that all 4 samples analyzed were tested positive for HT traits containing Monsanto event MON 1445.

iii. HT test results of Guntur District court samples which confirmed that one sample was tested positive for HT traits containing Monsanto event MON 1445 whereas the second sample tested negative.

6.4.5 The Government of Andhra Pradesh, Madhya Pradesh and Gujarat have been directed to submit action taken reports. An action taken report from the Commissioner of Agriculture, Govt of Andhra Pradesh has been received wherein it was informed that based on the oral disclosures made by the farmers, administrative action against the firm M/s Ushasree Enterprises has been initiated. The Joint Director, Agriculture (JDA) Guntur has reported that the seed license issued under Seed Control Order 1983 and also the Certificate of Registration under the AP Cotton Seeds Act 2007 of the firm were suspended. The JDA's Guntur and Prakasham have reported that the said HT cotton crop was destroyed. The JDA East Godawari has informed that no instances of illegal production and sale of HT cotton seed have been reported. The Commissioner of Agriculture has informed that reports from other JDAs of cotton growing districts are awaited and a consolidated report will be submitted on receipt of the same.

6.4.6 M/s Monsanto, the technology provide has also been pursuing the matter with the State Government and their sub-licensees. M/s Monsanto has informed that the seeds released by Director Agriculture, Gujarat in April 2009 to M/s Parvardhan Seeds and M/s Akshay Seeds have been destroyed. It was agreed that the State Govt. will be directed to initiate punitive action against the erring companies. It was also agreed that follow up with the respective State Govts to curb the illegal cultivation of HT cotton should continue on a regular basis.

6.4.7 As regards the request from Aruna Rodrigues requesting the GEAC to prescribe a procedure whereby civil society can obtain phytosanitary clearances from the concerned departments to send seeds abroad for testing, it was clarified that the procedure outlined under the Seed Act, 1966 and EPA, 1986 should be followed. The Committee also noted that M/s Gene Campaign had earlier sent alleged GM rice from Jharkhand to Germany for verification without the approval of NBA / GEAC and such incidences should be strictly avoided in future, in the national interest. It was also noted that Ministry of Agriculture is in the process of notifying crop specific referral laboratories. The Committee concluded that, while it is not desirable to send samples abroad, a well defined mechanism should be available within the country. This information should be available in the public domain.

Agenda Item No 7: Any other matter with the permission of the Chair.

The Chairman GEAC was of the view that there is always scope for improvement and the GEAC should play a proactive role in streamlining the regulatory mechanism on a continuous basis. He requested Member Secretary, GEAC to prepare a base paper identifying (i) gaps in the implementation, (ii) strengthening the monitoring mechanism, and (iii) strengthening the enforcement mechanisms within three months for consideration of the GEAC.

The next meeting of the GEAC is scheduled for 13.1.2010

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