Decisions taken in 114th meeting of the Genetic Engineering Appraisal Committee (GEAC) held on 14.12.2011

The 114th meeting of the GEAC was held on 14.12.2011 in the Ministry of Environment & Forests under the chairmanship of Shri M. F. Farooqui, Additional Secretary, MoEF and Chairman, GEAC.

The deliberations and decisions taken in the GEAC meeting in respect of Agenda items 4 to 7 are as follows:

Agenda item No 4: Consideration of applications for confined field trials of transgenic crops (Seed production/Event selection/Biosafety Research Level Trials (BRL-I and BRL-II) as recommended by the RCGM.

4.1 Permission to conduct event selection trials on *Artemisia annua L.* (Sweet worm) transgenic lines (Event-hmgr-ads) developed in an Institute-Industry Collaborative Research Project Sponsored by DST-DPRP, Govt. of India by M/s. IPCA Pvt. Ltd., Mumbai and Faculty of Science, Jamia Hamdard, New Delhi .

4.1.1 The Committee considered the application submitted by Faculty of Science, Jamia Hamdard, New Delhi., and M/s. IPCA Pvt. Ltd., Mumbai for permission to conduct event selection trials on *Artemisia annua L.* (Sweet worm) transgenic lines (Event-hmgr-ads) developed in an Institute-Industry Collaborative Research Project Sponsored by DST-DPRP, Govt. of India and M/s. IPCA Pvt. Ltd., Mumbai to enhance the artemisinin content of *Artemisia annua L* plants by over expressing two genes *hmgr* and *ads* genes encoding key enzymes of mevalonate pathway and artemisinin biosynthesis in a strain of *A. annua L.* with artemisinin content of 0.6% . This strain was provided by M/s IPCA Pvt Ltd., Ratlam. These genes were driven by 35S and Ubi3 promoters.

4.1.2 *Artemisia annua L* a highly aromatic annual herb of Asiatic and Eastern European origin. It is occurring naturally as part of steppe vegetation in the northern parts of Chahar and Suiyuan provinces in China and the artemisinin content in the herb is known for its medicinal property as a anti-malarial agent. It is also grown in wild in many countries such as Argentina, Bulgaria, France, Hungary, Romania, and also cultivated Italy, Spain, USA and Yugoslavia for its essential oil. It has also been introduced into experimental cultivation in India, Vietnam, Thailand, etc.

4.1.3 The intended purpose of the genetic modification is to enhance the artemisinin content and yield.

4.1.4 The trials will be conducted at two locations- (1) Herbal Garden, Jamia Hamdard, New Delhi and (2) at Green Field, IPCA Ratlam Code RTM.

4.1.5 The Committee noted that the main objective of the trials is to:

- select the best transgenics lines in terms of transgene stability as well as inheritance, high artemisinin content (>1%) and artemisinin yield.
- evaluate the artemisinin content (% dW) in these transgenic lines at three phenological stages i.e. rosset, bolting and pre-flowering.
- evaluate growth, biomass, leaf dry matter, leaf stem ratio and artemisinin besides artemisinin content.

4.1.6 The Committee noted that the following isolation measures are common for both the proponents:

- Bagging reproductive isolation distance as per the regulatory requirements.
- At pre–flowering stage, the inflorescence on each plant will be bagged using rice bags. The inflorescence will be fully covered and bags will be tied with stem.
- The trial site is within the boundary of herbal garden.
- The land will be used for the next trial of genetically modified A. annua L.
- The trial site will be marked by using iron fence with single entry point.

4.1.7 The Committee also highlighted the variation in isolation measures on following account:

a). **Herbal Garden, Jamia Hamdard** :

- The distance to nearest cultivated crop of the same species >100m.
- No commercial crop will be grown near the campus.

b). **Green Field, IPCA Ratlam**

- The distance to nearest cultivated crop of the same species >400m.
- The distance to nearest commercial crop at any type will be >1000m.

4.1.8 The Committee observed that the request for event selection trials of Jamia Hamdard was recommended by the IBSC in the meeting held on 17.8.2011 and by RCGM in its 106th meeting held on 21.10.2011.

4.1.9 Whereas, as per the information forwarded by RCGM, in case of trials at Ratlam (M.P) by M/s. IPCA Pvt. Ltd., no IBSC has been constituted so far. RCGM has advised the applicant to constitute the IBSC and resubmit the application along with IBSC minutes.

4.1.10 After detailed deliberation, it was decided to approve the event selection trials on *Artemisia annua* L. in the Herbal Garden, Jamia Hamdard. Whereas with respect to M/s. IPCA Pvt. Ltd., Ratlam (M.P) the Committee recommended constitution of IBSC and resubmission of the application subsequent to receipt of IBSC minutes and RCGM approval.

4.1.11 Further, taking notice of the fact that, the instant proposal is sponsored by DST-DPRP, it was decided that the matter regarding non-compliance of EPA, 1986 by one of the partner institution needs to be brought to the notice of DST. It was agreed that Chairman GEAC would request Secretary, Ministry of Science and Technology to issue necessary instructions in this regard to all DST sponsored projects involving recombinant research.

4.1.12 It was also agreed that a two member Committee comprising of Dr. Swapan Datta, DDG, ICAR and Dr. Ranjini Warrier, Director, MoEF would inspect the event selection trials in Jamia Hamdard.

4.2 . Permission to conduct BRL-II trials of Bollgard II Roundup Ready Flex (BGII RRF™) cotton hybrids namely MRC 8017 BGII RRF™ and MRC 8031 BGII RRF™ in North Zone containing (Event MON 15985 X MON 88913) by M/s. Mahyco, Mumbai .

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Request for extension of the validity to conduct (BRL-II) trials of Bollgard II R Roundup Ready Flex (BGII RRF™) cotton hybrids namely MRC 8347 BGII RRF™ and MRC 8351 BGII RRF™ in Central and South Zones containing (Event MON 15985 X MON 88913) by M/s. Mahyco, Mumbai.

4.2.1 The Committee noted that the GEAC in its meeting held on 6.7.2011 decided to reject the appeal submitted by M/s. Mahyco to consider the BRL-II data generated during Kharif 2010 in the meeting held on 6.7.2011. The applicant has now submitted an application seeking permission of the GEAC to conduct BRL-II trials of Bollgard II Roundup Ready Flex (BGII RRF™) cotton hybrids in the north zone during Kharif 2012.

4.2.2 The Committee noted that the trials will be conducted with cotton hybrids namely MRC 8017 BGII RRF™ and MRC 8031 BGII RRF™ in North Zone (Event MON 15985 X MON 88913) containing *cry 1Ac, cry 2Ab and* CP4 EPSPS genes at Bhatinda (Punjab), Hanumangarh (Rajasthan) at company's long leased farm and Sirsa (Haryana) at Central Institute for Cotton Research (CICR) farm.

4.2.3 The Committee noted that the applicant has also requested the GEAC to extend the validity of the GEAC approval to conduct BRL-II trials of Bollgard II Roundup Ready Flex (BGII RRF™) cotton hybrids namely MRC 8347 BGII RRF™ and MRC 8351 BGII RRF™ in Central and South Zones

containing event MON 15985 X MON 88913 to 2012-13 as the trials could not be initiated during Kharif 2011 due to delay in getting NOC from the State Government.

4.2.4 In view of the above stated facts the Committee approved the request to (i) conduct BRL-II trials of Bollgard II R Roundup Ready Flex (BGII RRFTM) cotton hybrids namely MRC 8347 BGII RRF ^{TM} and MRC 8351 BGII RRF ^{TM} containing cry 1Ac, cry 2Ab genes and cp4epsps gene (Event MON 15985 X MON 88913 in the North zone during appropriate season in 2012-13; and (ii) extend the validity of the of GEAC approval to conduct BRL-II with Bollgard II R Roundup Ready Flex (BGII RRF^{TM}) cotton hybrids namely MRC 8347 BGII RRF^{TM} and MRC 8351 BGII RRF^{TM}(Event MON 15985 X MON 88913) in Central and South Zones from 2011-2012 to 2012-13.

4.2.5 The above approvals are subject to the conditions that (i) Protocol for BRL-2 trials shall not include RRF refugia and (ii) submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

4.3 Permission to conduct pollen flow trial on glyphosate tolerant Roundup Ready® (RR) wheat (*Triticum aestivum L.*) Lines containing the *cp4 epsps* gene (event MON 71800) by M/s. Mahyco, Mumbai .

4.3.1 The Committee considered the request of M/s. Mahyco to conduct pollen flow trial on glyphosate tolerant Roundup Ready® (RR) wheat (*Triticum aestivum L.*) lines containing the *cp4 epsps* gene (event MON 71800) at company's research farm at Jalna. Glyphosate-tolerant Roundup Ready (RR) wheat (MON-71800) has been developed by M/s Monsanto. Transgenic wheat seeds containing MON-71800 event were imported by M/s. Mahyco as per import clearance accorded by DBT vide letter No. BT/BS/17/02/94 –PID, dated 5.1.2007.

4.3.2 The Committee noted that the main objectives of the trial is to study the pollen flow from wheat plants expressing the *cp4 epsps* gene to:

- Monitor the extent of out-crossing
- Determine the distance traversed by pollen from RR Wheat plants.

4.3.3 The Committee also noted that the following isolation measures are proposed:

- non-transgenic wheat will be planted surrounding the transgenic RR wheat block on all four side at specific distance up to 200 m. as per the Indian Minimum Seed Certification Standard.
- seeds will be packed, labelled and transported as per the guidelines and SOPs for confined field trials.
- seeds will be transported in double- layered cloth bag with proper labeling. After planting the bags will be destroyed by burning.
- a compact block of RR wheat line in an area of 20m x 20 m will be planted at the center of this experiment. This central block containing RR Wheat plants will be surrounded by non-transgenic wheat with male sterile trait in all directions.

4.3.4 It was further noted that the male sterile wheat line planted in different patterns as a pollen accepter non transgenic source surrounding the central block of RR wheat, setting of seeds in non-transgenic male sterile line will be an indicative of cross pollination. Seed samples will be tested for the extent of pollen flow from the central RR wheat block; first by grow-out test and followed by PCR analysis. Samples showing potential cross-pollination will then be confirmed by PCR method for detection of the cp4 epsps gene.

4.3.5 The Committee noted that the proposal has been recommended by both IBSC and RCGM.

4.3.6 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to conduct pollen flow trial on glyphosate tolerant Roundup Ready® (RR) wheat (*Triticum aestivum L.*) lines containing the *cp4 epsps* gene (event MON 71800) at company's research farm at Jalna during the appropriate season in 2012-2013 subject to submission of NOC from the State Government where the trials will be conducted.

4.4 Permission to conduct event selection trials on salt tolerant rice (*Oryza sativa L.*) events namely; OsN-1 to OsN-25 containing the *OsNHX1* gene by M/s. Mahyco, Mumbai.

4.4.1 The Committee considered the application submitted by M/s Mahyco to conduct event selection trials with salt tolerant rice (*Oryza sativa L.)* events**;** OsN-1 to OsN-25 containing *OsNHX1* gene, at SAU's research farm at Panvel, Dist. Raigad, Maharashtra during Rabi 2011.

4.4.2 The Committee noted that the purpose of the field trials is to evaluate the efficacy of transgenic rice events expressing *OsNHX*1 protein compared to their non-transgenic counterparts and checks for salinity tolerance.

4.4.3 The Committee noted the following proposed isolation measures with respect to the trial:

- border rows of non- transgenic rice will be planted all around the replicated block up to a distance of 5 m. There will be a gap of 2 m between replicated block and the border rows.
- an isolation distance of 200 m from the periphery of the border row will be maintained all around the trial site.
- the area proposed is in naturally saline zone along the coastal side.
- during the trial, standard rice growing practices will be followed in both the treatments, and observations on stress-related symptoms such as leaf tip burning will be recorded along with plant height, tiller number, days to flowering, panicle number and total grain yield.
- total grain yield per plant in saline versus control plots will be used as the measure for event performance. Efficacy will be defined as events with significant grain yield increase, as compared to the non-transgenic counterpart.

4.4.4 The Committee further noted that the proposal has been recommended both by IBSC and RCGM. RCGM recommended the proposal in its 106th meeting held on 21.10.2011 wherein the applicant was directed to use proper checks which are susceptible and non-tolerant to salt.

4.4.5 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to conduct event selection trials with salt tolerant rice (*Oryza sativa L.)* events**;** OsN-1 to OsN-25 containing *OsNHX1* gene, at SAU's research farm at Panvel, Dist. Raigad, Maharashtra during appropriate season in 2012-13 subject to NOC from the State Governments where the trials will be conducted.

4.5 Permission to conduct event selection trials on transgenic rice (*Oryza sativa L.*) Events namely MW-01 to MW-25 containing *AlaAt* gene by M/s. Mahyco, Mumbai

4.5.1 The Committee considered the application of M/s Mahyco to conduct event selection trials with transgenic rice (*Oryza sativa L.)* events; namely MW-01 to MW-25 containing the *AlaAt* gene at Anand Nagar, Dist. Nizamabad (Andhra Pradesh) or Dr Balasaheb Sawant Konkan Krishi Vidhyapeeth, Dapoli, Dist Ratnagiri (Maharashtra). Transgenic rice events expressing AlaAt gene produces rice with yields that are equivalent to conventional varieties but require significantly less nitrogen fertilizer because they use it more efficiently or at conventional level of fertilization, these plants are expected to give higher yield.

4.5.2 The objective of the proposed trial is to evaluate the efficacy of transgenic rice events expressing the AlaAt protein compared to their non-transgenic counterparts and checks for enhanced Nitrogen Use Efficiency (NUE).

4.5.3 The Committee noted the following proposed isolation measures:

- the border rows of non- transgenic rice will be planted all around the replicated block up to a distance of 5 m. There will be a gap of 2 m between replicated block and the boarder rows
- an isolation distance of 200 m from the periphery of the outmost boarder row will be maintained all around the trial site.
- for growth and yield under various Nitrogen regimes, nitrogen fertilizer will be applied at 4 doses of 35%, 70%, 100%, and 130% of recommended dose. Dose will take into account residual

fertilizer content of soil. The N applications will be split as 40% at tillering and booting stages each.

- during the trial, standard rice growing practices will be followed in all the treatments, and observations will be recorded for growth and yield parameters such as plant height, tiller number, days to flowering, panicle number and total grain yield.
- total grain yield per plant in saline versus control plots will be used as the measure for event performance calculating nitrogen use efficacy. Efficacy will be defined as events with significant grain yield increase, as compared to the non-transgenic counterpart.

4.5.4 The Committee also noted that the proposal has recommendation of both IBSC and RCGM. The RCGM considered the proposal in its 106th meeting held on 21.10.2011.

4.5.5 During the deliberation, the Committee gave an opportunity to the applicant to provide the following clarifications:

- Detail about the alanine aminotransferase (*AlaAt)* gene;
- Background in whi*ch th*e gene is being inserted
- Information on how the gene works;
- Source of the gene.

4.5.6 The following points were noted:

- The alanine aminotransferase cDNA was isolated from barley (*Hordeum vulgare* L.)
- The gene is the key enzyme in the biosynthesis pathway of alanine. NUE is increased in plants expressing AlaAT, and the N source could be nitrates and/or urea. The mechanism of the N efficient phenotype is proposed to be more availability of alanine, and is still being worked out.
- A Mahyco proprietary hybrid parent line was used for transformation.
- Publication on how the mechanism aids biosynthesis and how it helps utilization of urea more efficiently will be submitted.

4.5.7 The Committee advised the applicant to provide the detailed information in writing subsequent to which a final view will be taken in the next GEAC meeting. Accordingly decision on the proposal was deferred.

4.5.8 The Committee requested the Member Secretary to check with RCGM on whether the above information was submitted for consideration by the RCGM.

4.6 Request for change of location to conduct of BRL-1 trials and seed production with herbicide tolerant Glytol cotton hybrids *containing 2mEPSPS gene* from Karnataka to Andhra Pradesh by M/s. Bayer BioScience Pvt. Ltd., Gurgaon.

4.6.1 The GEAC in its meeting held on 6.7.2011 had accorded approval for conduct of BRL-I trials and seed production of transgenic with herbicide tolerant Glytol cotton hybrids containing *2mEPSPS gene* in the North , Central and South as per details given below :

- Bhatinda, Punjab, Sirsa, Haryana (North),
- Jalna, Maharashtra, Rajkot, Gujarat (Central),
- Davangere, Karnataka and Ranga Reddy District, A.P (South)
- Seed Production at Tumkur district, Karnataka

4.6.2 The Committee noted that Karnataka State Government has refused to give NOC for GM trials in their state. Accordingly the applicant has now requested GEAC approval for change of location from Karnataka to Andhra Pradesh for conduct of BRL-1 and seed production trials of Glytol cotton hybrids at the following locations:

i) **BRL-1 trial location in AP**:

M/s. Bayer BioScience Pvt. Ltd., C/o R. Rama Rao, Survey No. 100, Vill. Alivedu, Vijayrai-534475, Pedavegi Mandal, West Godawari District, Andhra Pradesh.

ii) **Seed Production**:

a) M/s. Bayer BioScience Pvt. Ltd., C/oK. Satyanarayana & K. Sarwasthi, Vill. Kothapalli, Mandal Lingapalem, Taluka Chintalpudi, Dist. West Godavari, Andhra Pradesh.

b) M/s. Bayer BioScience Pvt. Ltd., C/o P. Ramesh & M. Laxmi Narayana, Vill. Devenivarai Gudem, Mandal Dwarka Timumala, Taluka Bhimadolu, Dist. West Godavari, Andhra Pradesh.

4.6.3 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request for change of location for conduct of BRL-1 trials and seed production on herbicide tolerant Glytol cotton hybrids *containing 2mEPSPS gene* from Karnataka to Andhra Pradesh by M/s. Bayer BioScience Pvt. Ltd., Gurgaon during appropriate seasons in 2012-14 subject to submission of NOC from the State Governments where the trials will be conducted. .

4.7 Request for extension of the validity period to conduct BRL-1 trials on herbicide tolerant Glytol cotton hybrids from 2011 to 2012-2013 in North zone by M/s. Bayer BioScience Pvt. Ltd., Gurgaon.

4.7.1 The GEAC in its meeting held on 6.7.2011 had accorded approval for conduct of BRL-I trials and seed production of transgenic on herbicide tolerant Glytol cotton hybrids containing *2mEPSPS gene* at Bhatinda, Punjab and Sirsa, Haryana (North), Jalna, Maharashtra and Rajkot, Gujarat (central) and Davangere, Karnataka and Ranga Reddy District, A.P and Seed Production at Tumkur district, Karnataka .

4.7.2 The applicant has informed they could not conduct trials in North zone as the sowing season is over and would like to undertake two years of BRL-1 during Kharif 2012 and Kharif 2013.

4.7.3 The Committee noted that RCGM has recommended the request in its 106th meeting held on 21.10.2011.

4.7.4 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request of M/s. Bayer BioScience Pvt. Ltd., Gurgaon, to extend the validity of the permit to conduct BRL-1 trials with herbicide tolerant Glytol cotton hybrids to 2012-2014 in the North zone subject to submission of NOC from the State Government where the trials will be conducted. .

4.8 Request for extension of validity period to conduct BRL-I trials on Roundup Ready Flex cotton *(Gossypium hirsutum L)*. hybrids namely MRC 8017 RRF ™ and MRC 8031 RRF ™ in North Zone, MRC 8347 RRF ™ and MRC 8351 RRF ™ from 2011-2012 to 2012-2014 in Central and South Zones containing *cp4epsps* gene (Event MON 88913) by M/s. Mahyco.

4.8.1 The GEAC in its meeting held on 6.7.2011 had accorded approval for conduct of BRL-I trials during 2011 to 2013, of Roundup Ready Flex cotton *(Gossypium hirsutum L)*. hybrids namely MRC 8017 RRF ™ and MRC 8031 RRF ™ in North Zone; and MRC 8347 RRF ™ and MRC 8351 RRF™ in Central and South Zones containing *cp4epsps* gene (Event MON 88913).

4.8.2 The applicant has informed that they have received NOCs from Government of Gujarat and Andhra Pradesh and are in the process of getting NOCs from other states. As appropriate season for cotton planting in 2011 is over, they have requested GEAC to extend the validity of the approval from 2011-2013 to 2012-2014 in North, Central and South Zones.

4.8.3 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request by M/s. Mahyco for extension of validity period to

conduct BRL-I trials with Roundup Ready Flex cotton *(Gossypium hirsutum L)*. hybrids namely MRC 8017 RRF ™ and MRC 8031 RRF ™ in North Zone; and MRC 8347 RRF ™ and MRC 8351 RRF ™ in Central and South Zones containing *cp4epsps* gene (Event MON 88913) from 2011-2013 to 2012-2014 subject to submission of NOC from the State Government where the trials will be conducted. .

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4.9 Permission to conduct event selection trial of salt tolerant rice (*Oryza sativa L.)* events containing *the nhx1* transcription factor by M/s. Mahyco.

4.9.1 The Committee noted that decision on the application of M/s. Mahyco to conduct event selection trial of salt tolerant rice (*Oryza sativa L.)* events containing *the nhx1* transcription factor was deferred on the following grounds::

"The Committee noted that the transgenic rice expressing nhx1 gene have gus A gene in their expression cassettes. The biosafety issues are to addressed in respect of such transgenic crops are more complex as the transcriptional factors are known to trigger production of a large number of proteins downstream. These issues need to be discussed and guidelines for biosafety testing need to be developed. The Committee also of the view that because of the presence of gratuitous gene such as gus in the food crop, it may not be considered for environmental release when such a proposal is mooted by the project proponents, these are approved for contained research only. The Committee did not approve the request for event selection for eventual commercial development because both constructs contain gus gene. However, these are approved for contained research only."

4.9.2 It was noted that the applicant has clarified that salinity tolerant (ST) rice lines incorporating *OsNHX1* gene are free of GUS marker gene. The plant population carrying GUS marker gene were eliminated during the early generations of transgenic line development and plants carrying only OsNHX1 gene were selected for further advancements.

4.9.3 It was also noted that the applicant has obtained NOC from Andhra Pradesh State Government for conduct of event selection trials. However, as Kharif season of 2011 is over, the applicant has also requested the GEAC to consider this proposal for appropriate season during 2012.

4.9.4 In view of the above stated facts, the Committee approved the request by M/s. Mahyco to conduct event selection trial of salt tolerant rice (*Oryza sativa L.)* events containing *the nhx1* transcription factor free of GUS marker gene during appropriate season in Kharif 2012 subject to submission of NOC from the State Government where the trials will be conducted.

4.10 Permission to conduct F2 grain production of insect resistant TC1 maize hybrid containing *cry1F* gene [TC1507 event (DAS-01507-1)]" by M/s. Dow AgroSciences India Pvt. Ltd., Mumbai.

4.10.1 The GEAC in its meeting held on 6.7.2011 had accorded approval for conduct of second year BRL-I trials and seed production with transgenic maize hybrids (TC1 and TC-3) containing event TC150 (DAS-01507-1) at three locations to test hybrids containing TC-1507 expressing Cry IF for biosafety, bio-efficacy and agronomy evaluation 2011-2012.

4.10.2 The Committee noted that the present request of the applicant is to conduct F2 grain production of insect resistant TC1 maize hybrid containing *cry1F* gene [TC1507 event (DAS-01507-1)] at two locations in Gujarat and Tamil Nadu in an area of 0.25 acres at each for conducting animal feeding studies.

4.10.3 The Committee noted that the seed production will be carried out as per the guidelines and SOPs for confined field trials and the seed production plot will be surrounded by 8 m refugia of non-GM maize followed by 300 m isolation distance.

4.10.4 The Committee also noted that the proposal has been recommended by the RCGM in its 106th meeting held on 21.10.2011.

4.10.5 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request by M/s. Dow AgroSciences India Pvt. Ltd. to conduct F2 grain production of insect resistant TC1 maize hybrid containing *cry1F* gene [TC1507 event (DAS-01507-1)] at two locations in Gujarat and Tamil Nadu in an area of 0.25 acres at each for conducting animal feeding studies subject to submission of NOC from the State Governments where the seed production will be undertaken

4.11 Permission to conduct seed production on BGII RRF cotton (*Gossypium hirsutum L.*) hybrids namely; MRC 8017 BGII RRF™, MRC 8031 BGII RRF™ (North zone) and MRC 8347 BGII RRF™, MRC 8351 BGII RRF™ (Central and South Zone) containing cry 1Ac, cry 2Ab and cp4 epsps genes (Event MON 15985 XMON 88913) by M/s Mahyco, Mumbai.

4.11.1 The Committee considered the request of M/s. Mahyco to conduct seed production on BGII RRF cotton hybrids namely; MRC 8017 BGII RRF™,MRC8031 BGII RRF™ (north zone) and MRC 8347 BGII RRF™, MRC 8351 BGII RRF™ (Central and South Zone) at Jalna, (Dist), and Buldhana (Dist.) in Maharashtra. at company's contracted seed grower's farms as per the details given below:

S.N.	Hybrids	Area of seed production
Hybrids for North Zone		
1	MRC 8017 BGII RRF™,	25 acre
2.	MRC 8031 BGII RRF™	25 acre
Hybrids for Central zone		
3.	MRC 8347 BGII RRF™	25 acre
4.	MRC 8351 BGII RRF™	25 acre
Hybrids for South Zone		
5.	MRC 8347 BGII RRF™	25 acre
6.	MRC 8351 BGII RRF™	25 acre
Total production area		**150 acre**

4.11.2 The Committee noted that the purpose of seed production is for commercial seed availability in anticipation of approval for environmental release.

4.11.3 The Committee noted that the applicant's request for seed production for environmental release does not merit consideration at this stage as the applicant has yet to complete BRL-II trials. The Committee opined that the applicant may submit a revised estimate based on the seed requirement for additional trials/ safety assessment studies, if any, that may be prescribed by the GEAC during the review process.

4.11.4 Accordingly decision on the proposal was deferred.

4.12 Permission to conduct event selection trials on transgenic rice (*Oryza sativa cv Taipae 309*) events namely Godawari-8 and Salween-2 over-expressing chloroplast targeted Manganese Superoxide Dismutase (MnSOD) by M/s. Atash Seeds Pvt. Ltd., Hyderabad.

4,12.1 The GEAC in its meeting held on 6.7.2011 had considered the request of M/s. Atash Seeds Pvt. Ltd, Hyderabad to conduct event selection trials on two transgenic rice lines (*Oryza sativa cv. Taipae* 309) namely Godawari 8 & Salween-2 over expressing chloroplast targeted manganese superoxide dismutase (MnSOD) for their tolerance to drought and other agronomic characters. Decision on the proposal was deferred as it was decided to obtain information pertaining to (i) the background genotype in which the transgene was developed, (ii) origin and source of the gene.

4.12.2 The Committee considered the following information submitted by the applicant: :

(i) Oryza sativa (japonica) rice variety TP-309 was used as the host plant to transfer the transgene; and

(ii) The MnSOD gene (Manganese SuperOxide Dismutase) has been isolated from a plant source i.e. *Nicotina plumbaginifolia*. This gene has been used to transform the rice variety TP-309.

4.12.3 During the deliberations, one of the Members pointed out that TP-309 is neither a safe material for testing in Indian environment nor it is an appropriate background for testing drought tolerance. Therefore the purpose of the proposed event selection trials is not clear. It was therefore recommended that the trials be conducted in green house conditions.

4.12.4 The Committee further noted that M/s. Avesthagen has out sourced the work of conducting event selection trials of MnSOD transgenic rice to M/s Atash Seeds Pvt. Ltd, Bangalore after obtaining approval of the GEAC in its 88th meeting held on 13.08.2008. While the Project Transfer letter from Avesthagen has been provided by the applicant, there has been no communication from M/s Avesthagen informing the GEAC that the proposed event selection trials is being conducted by M/s Atash Seeds Pvt Ltd on behalf of M/s Avesthagen.

4.12.5 After detailed deliberations, the Committee was of the view that M/s Avesthagen who is the actual recipient of the approval for event selection trials cannot outsource the work to another agency. The Committee further opined that M/s Avesthagen, in the first instance, should inform GEAC that they are not in a position to take up the event selection trials subsequent to which GEAC may consider the application of M/s Atash Seeds Pvt Ltd as an independent case.

4.12.6 Accordingly, decision on the proposal was deferred.

4.13 Request for change in location to conduct event selection trials of Bt rice (referred to as EST-1; EST-2 & EST-3) by M/s. E.I. Dupont India Pvt. Ltd., Dupont Knowledge Center, Hyderabad.

4.13.1 The Committee noted that due to non issue of NOC from the Government of Andhra Pradesh for conduct of event selection trials on transgenic rice, none of the following trials could be initiated:

i. Event selection trials of fourteen transgenic rice (Oryza sativa L.) events generated using Bt39 (Cry1C + Cry2Ad), Bt40 (Cry1Ab+Cry2Ad) construct and Bt43 (Cry1C+Cry1Ab).
ii. Event selection trials on 27 transgenic rice (*Oryza sativa L.*) events generated using 5 constructs i.e Bt38 (Cry1Ab+Cry2Ad), Bt39 (Cry1C+Cry2Ad), Bt40 (Cry1Ab+Cry2Ad), Bt43 (Cry1C+Cry1Ab) and pTVE544 (Cry1Ca +bar) & pTSVH0207 (Cry1Ab+bar).
iii. Event selection trials on four events of transgenic rice (*Oryza sativa L.*) generated using SPT1 construct and two events generated using SPT6 construct expressing OS-MSCA1, ZM-AA1 and DsRed2 protein.
iv. Event selection on 23 transgenic rice events against Yellow Stem Borer and Rice Leaf Folder pests.

4.13.2 The applicant has now requested the GEAC to allow conduct of event selection trials in Gujarat, Tamil Nadu and Maharashtra in addition to Andhra Pradesh for all the above mentioned cases.

4.13.3 The Committee also noted that RCGM has recommended the proposal in its 107th meeting held on 22.11.2011.

4.13.4 In view of the above stated facts and taking into consideration the recommendation of RCGM, the Committee approved to the request by M/s. E.I. Dupont India Pvt. Ltd., Dupont Knowledge Center to conduct event selection trials in Gujarat, Tamil Nadu and Maharashtra in addition to Andhra Pradesh for all the above mentioned cases during appropriate season in 2012 subject to NOC from the State Governments where the trials will be conducted.

4.14 Request for extension of the validity upto March 2012 to conduct four event selection trial by Central Institute for Cotton Research (CICR), Nagpur.

4.14.1 The Committee noted that the following event selection trials have been initiated at CICR, Nagpur during ongoing Kharif:

(i) event selection trials on three events of transgenic cotton (*Gossypium hirsutum*) variety Anjali-AcBt namely; Anjali-AcBt-1, Anjali-AcBt-2 and Anjali-AcBt-3 containing *cry1Ac* gene.

(ii) event selection trials on two events of transgenic cotton (*Gossypium hirsutum*) variety Anjali-FBt namely; Anjali-FBt-1 and Anjali-FBt-2 containing *cry1F* gene at CICR,

(iii) event selection trials on ten events of transgenic cotton (*G. arboreum*) varieties viz. RG-822-Bt (4 events) and PA255-Bt (6 events) containing *cry1Ac* gene.

(iv) conduct event selection trials on transgenic cotton (*Gossypium hirsutum*) variety namely ILK-Bt 77 (events ; ILK-Bt 77-1 to ILK-Bt 77-7) containing *cry1Ac* gene.

4.14.2 However, since approval for the field trials is valid for one year from the date of issue of the letters, CICR, Nagpur has requested GEAC to extend permission upto March 2012 to complete the harvesting and other field related observations.

4.14.3 In view of the above stated facts, the Committee conveyed its 'no objection' to the request from CICR, Nagpur to extend the time period of the permit upto March 2012 to complete the above mentioned four event selection trials.

4.15 Request for extension of the validity upto December 2012 to conduct event selection on transgenic rice events at Tamil Nadu Agricultural University (TNAU), Coimbatore by M/s. BASF India Ltd., New Delhi.

4.15.1 The Committee noted that the GEAC in its meeting held on 15.11.2010 had approved the conduct of event selection trials on 140 transgenic rice (*Oryza sativa*) events at TNAU Coimbatore. As the applicant is awaiting NOC from the State Government of Tamil Nadu, they have requested GEAC to extend the time period of the permit till December 2012.

4.15.2 RCGM has recommended the proposal in its 107th meeting held on 22.11.2011.

4.15.3 In view of the above sated facts and taking into consideration the recommendations of RCGM, the Committee approved the extension of the validity upto December 2012 to conduct event selection on transgenic rice events at Tamil Nadu Agricultural University (TNAU), Coimbatore by M/s. BASF India Ltd., subject to NOC from the State Government where the trials will be conducted.

4.16 Permission to conduct event selection trials with 168 events of transgenic rice and F1 Hybrid seed production (Two cycles per year) from constructs RPD5-RPD17 at BASF owned site at Bellathi (Coimbatore) by M/s. BASF India Ltd., New Delhi

4.16.1 The Committee noted that the GEAC in its 113th meetings held on 12.10.2011 had requested the applicant to make a presentation before the meeting wherein the following points were noted:

i. As part of a global initiative, BASF is working towards developing transgenic rice hybrids having increased yield as compared to conventionally developed hybrids with special focus on India and SE Asia.
ii. The proposed event selection trials are a research activity for trait development for yield enhancement. A total of seven genes and nine constructs have been deployed. The sources of genes are all plant genes.
iii. The transgenic events will be tested in a first phase as an inbred and in a second phase in hybrids with several tester lines under confined open field conditions. After multiple testing rounds, inbred followed by hybrids, the Elite Event will be nominated based on its agronomic performance, specially enhanced yield when compared to the non-transgenic parental line. This Elite Event will be introgressed into elite germplasm of different seed partners of BASF to produce

commercial varieties with higher yield compared to the non-GMO version and adapted to the different agro-ecological zones in India.

iv. The event selection trials will be conducted at BASF owned site at Bellathi (Coimbatore) in an area of 6000 m^2

4.16.2 Since the complete proposal was submitted by the applicant only during the GEAC meeting, the Committee had requested Dr Arjula Reddy, Co-Chair to examine the proposal and give his views. Accordingly decision the proposal was deferred.

4.16.3 The Committee considered the Report submitted by Dr Reddy wherein it has been recommended that "*developer must disclose and describe the pedigree of original transgenic lines and their attributes(such as disease susceptibility etc), and also the female lines to be used in hybrid production /testing—all under confidentiality".*

4.16.4 After detailed deliberations, it was decided to obtain the above information before a final decision is taken. Accordingly decision on the proposal was defer.

Agenda Item No 5 : Consideration of applications related to Pharmaceuticals

5.1 Permission for import of 'Gumbin VP_2' Inactivated poultry vaccine from Abic Biological Laboratories Ltd, Israel by Zydus Animal Health Care, Ahmadabad.

5.1.1 M/s Zydus Animal Health Care, Ahmedabad has submitted a proposal seeking GEAC approval for import of 'Gumbin VP_2' Inactivated poultry vaccine from Abic Biological Laboratories Ltd, Israel . Gumbin VP_2 is intended for use in pullets before point of lay as a booster vaccine. Its purpose is to produce a strong and lasting immune response which will protect layers and breeders during the laying period and their offspring chicks during the early life after hatch.

5.1.2 Decision on the proposal was deferred as it was decided to obtain comments from the Department of Animal Husbandry, Ministry of Agriculture before the application is considered by the GEAC

Agenda Item No 6 : Other items:

6.1 Constraints in getting NOC from the State Governments for conduct of GM crop field trials

6.1.1 The Committee considered the following points enumerated in the communications received from RCGM and Industry Association (ABLE) regarding the requirement of NOC from the State Government for conduct of GM crops field trials:.

(i) In view of the decision taken by some of the State Governments not to allow GM crop field trials, the location of the trials have been shifted to non-traditional crop growing States.

(ii) Some State Governments have also been insisting that the trials be conducted in non-traditional crop growing areas and NOCs have been granted only for such locations. Trials in non-traditional growing areas will not provide correct results on the efficacy and safety of the introduced trait. In this regard, RCGM has requested the GEAC to provide appropriate guidelines to the State Governments.

(iii) Some State Governments have not granted NOC for the GM crop field trials on the ground that sufficient safety information on the insecticidal protein expressed in GM food crop and non availability of data from previous trials. As field trials are integral part of the biosafety assessment and are carried out to generate safety information, the safety information can be provided only on completion of two seasons, BRL-I trials.

(iv) As regards the submission of data from the previous trials, several GM crop trials have been initiated only for event selection trials for which no previous field trial data is available. Also the

objective of event selection trial being different from BRL-I trials, the first stage at which biosafety and efficacy data can be made available is only after BRL-I trials.

(v) As RCGM and GEAC have examined the proposals before according approval for GM crop field trials, an additional review by the State Government on the biosafety data may not be necessary at this stage. The full focus of the State Government needs to be on the compliance and safeguards stipulated in the guidelines and SOP for confined field trials.

(vi) In view of the above constraints, the GEAC may reconsider its decision on the requirement of NOC from states for these research trials. However, if it is still considered necessary to obtain NOC, the GEAC may send a communication to all State Governments providing clear cut guidelines on giving NOC so that a scientific decision is taken and uniformity is maintained across the country.

6.1.2 On the basis of detailed deliberations, the Committee concluded that the issue of non issuance of NOC by the State Govt. is mainly due to lack of clarity on the role State Govt. officials and lack of awareness on highly technical issues associated with biotechnology and biosafety measures. However, the Committee reiterated that the role of the State Government is very critical for compliance monitoring and therefore it is important to have a dialogue with the State Government to provide necessary clarification.

6.1.3 During the deliberations, DDG ICAR pointed out that Department of Agriculture & Cooperation (DoAC) jointly with ICAR is regularly organizing National Conferences under the Chairmanship of Secretary, DoAC preceding the Kharif and Rabi seasons to discuss limitations faced by the State Government in enhancing agriculture productivity. The Conference is attended by Secretary, State Department of Agriculture and Director/Commissioner of the respective State Governments, representatives of the State Agriculture Universities and ICAR. It was informed that the next meeting is scheduled in February 2012. It was agreed, that the GEAC may give a detailed presentations with a view to address the concerns of the State Government and provide more clarity on the role of the State Government. The presentation would essentially encompass the comprehensive GEAC process for biosafety assessment, the safety measures prescribed during field trials, compliance of guidelines and SoPs for GM crop field trials, the reason for introducing NOC and the expected role of State Govt. with respect to compliance monitoring and issuance of NOC. The Committee requested Chairman, GEAC to send a communication in this regard to Secretary, DoAC.

6.2 Constitution of a Sub-Committee for formulating Biosafety Guidelines to conduct and monitor confined research trials on Genetically Engineered (GE) Trees and Insects.

6.2.1 The Committee noted that the Department of Biotechnology has constituted two Sub-Committees, namely:

(i) Sub-Committee for formulating Biosafety Guidelines to conduct and monitor confined research trials on Genetically Engineered Trees under the chairmanship of Dr K. Gurumurthi, Former Director, Institute of Forests, Genetics and Tree Breeding, Coimbatore; and
(ii) Sub-Committee for formulating Biosafety Guidelines to conduct and monitor confined research trials on Genetically Engineered Insects under the chairmanship of Dr Raj Bhatnagar, Group Leader (Insect Resistance), ICGEB, New Delhi.

6.2.2 The Terms of Reference of the Sub-Committee are:

1. The Sub-Committee will formulate general guidance to conduct and monitor confined research trials (CRTs) and will develop Tree-specific/Insect specific supplementary guidelines.
2. The Sub-Committee shall bring out Tree specific/Insect specific manuals/guidelines specifying procedure for regulatory processes for CRTs and its effective monitoring.
3. The Sub-Committee, if required, can generate or examine the research projects, proposals for conduct of workshops, symposia, training courses etc. creation of information systems/data banks in electronic media, websites, etc.

4. The Sub-Committee, if desired, can recommend to the DBT for funding of specific projects for fostering the cause of generating Tree specific biosafety data related to use of GMOs in the environment and strengthening infrastructure facilities & dissemination of tree/insect-specific biosafety rules, regulations and guidelines in the country.
5. The Sub-Committee may also invite, induct or appoint experts in their individual capacities for reviewing set of guidance available for confined research trials and for developing Tree/insect specific additional guidelines.
6. The Sub-Committee shall maintain the classified information provided by the applicants as confidential.
7. The Sub-Committee shall function in DBT.
8. The Sub-Committee shall function for a period of one year from the date of notification.

6.2.3 Member Secretary, GEAC informed that the above initiative is in line with the initiative under Cartagena Protocol on Biosafety (CPB). In accordance with the provision of Article 15 and 16 including Annex-III of the CPB and decision taken in COP-MOP 4 and COP-MOP-5, the development of guidance on risk assessment of LMOs have been initiated at the global level through an AHTEG followed by online real time conference. The modified draft has been forwarded to Parties for testing of the guidance document on risk assessment. This includes a component on GM trees and transgenic mosquitoes. The protocol also requires that the provisions of the CPB and decisions taken by COP-MOP are harmonized in the domestic regulations. Therefore, the Sub-Committee has been advised to take into consideration the above initiative under CPB while developing the guidelines. It was also informed that Member Secretary, GEAC is a member on both the Committees.

6.2.4 The Committee took note of the information.

Agenda Item No 7: Other Items with the permission of the Chair

7.1 Application for environmental release of two transgenic cotton hybrids namely; WS 103 and WS 106 expressing Cry 1Ac and Cry 1F genes Widestrike = Event 281-24-236) in South Zone by M/S Dow Agro-sciences India Pvt. Ltd , Mumbai.

7.1.1 The Committee noted that the applicant had made a detailed presentation in the 113th meeting of the GEAC held on 12.10.2011 with respect to their application for environmental release of two transgenic WideStrike cotton namely WS103 & WS106 containing *cry1F* (Event 281-24-236) + *cry1Ac* (Event 3006-210-23) effective against Helicoverpa and Spodoptera in the South Zone. The presentation covered information on the chronological sequence of development of Widestrike cotton in India, details of inserted gene/modification, details of field trials, and summary of the results of various environmental and food feed safety studies submitted to the RCGM/GEAC.

7.1.2 In response to the decision taken in the above meeting, M/s Dow has submitted the following additional clarifications for consideration of the GEAC:

(i) Detailed response for the queries raised in 12th October 21011 meeting.
(ii) Evaluation of the safety and nutritional equivalence of a genetically modified cottonseed meal in a 90-day dietary toxicity study in rats (Published paper)
(iii) Cry1F/Cry1Ac Cottonseed meal: 90-day dietary toxicity study in CRL:CD (SD) rats (Dow AgroSciences Study ID 051088)
(iv) Expression of the partial PAT Open Reading Frame in *B.t.* Cry1F Cotton Event 281-24-236 Revision Report GH-C 5573 (Dow AgroSciences Study ID GH-C 5712)
(v) Expression of the partial PAT Open Reading Frame in *B.t.* Cry1F Cotton Event 281-24-236 (Dow AgroSciences Study ID GH-C 5573)

7.1.3 After a brief discussion on the matter, it was decided that the information submitted by the applicant may be reviewed by the expert members of the GEAC. It was decided to consider the matter in the next GEAC meeting.

7.2 Strengthening the Monitoring Mechanism for GM Crop Field Trials:

7.2.1 During the deliberations, the need for strengthening the GM crop field trials monitoring was also discussed. The Committee was of the view that a pre-determined approach for monitoring BRL-I and BRL-II trials is essential to avoid an ad-hoc approach. It was noted that in the GEAC meetings held on 8.12.2010 and 12.01.2011, the need to prepare a detailed proposal on modalities for setting up a GM crop monitoring system which includes (i) crop specificity, creation of a rooster of experts, criteria for selection of monitoring panel, fees to be levied, and criteria to be followed by SAUs taking into account the best practices in other countries and the NABL accreditation system followed in India and (ii) organize several workshops under the aegis of MoEF and technical support from ICAR to enhance the capacity of the State Agriculture Universities and the monitoring teams to conduct/evaluate the GM crop field trials in the country. It was informed that the above matter was referred to a Sub-Committee under the Chairmanship of DDG, ICAR.

7.2.2 DDG, ICAR informed the Committee in response to the GEAC requirement, ICAR is putting in place a detailed monitoring mechanism as part of the All India Coordinated Research Programs for GM crop field trials. This would be similar to the AICRP program for non-GM crops. The proposed monitoring mechanism under AICRP for GM crops would include pre-identified location for GM crop field trials, separate monitoring teams for each crop, web site indicating the location of the trial for transparency, etc. The results of the trial will be discussed in the All India Coordinators' meeting and the report will be submitted directly to the GEAC.

7.2.3 While the Committee appreciated the initiative taken by ICAR, the need for a third party audit under the aegis of GEAC was also emphasized.

7.2.4 The Chairman underscored the urgent need of an efficient monitoring system and proposed that a monitoring mechanism under the aegis of GEAC complementing the ICAR initiative should be set up without any further delay. In this regard, he proposed that preparation of a detailed proposal for monitoring of GM crop field trials and its implementation be outsourced to an agency through a tendering process. It was agreed that the above cited course of action should be activated within three months.

Next meeting of the GEAC: February 8, 2012