Decisions taken in the 113th meeting of the Genetic Engineering Appraisal Committee (GEAC) held on 12.10.2011

The 113th meeting of the GEAC was held on 12.10.2011 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 6 are as follows:

Agenda item No 4 : Presentations:

4.1 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.

4.1.1 In accordance with the decision taken by the GEAC in its meeting held on 21.9.2011 M/s Dow AgroSciences made a detailed presentation 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

4.1.2 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.

4.1.3 In respect of issues raised by the Committee, the applicant submitted the following clarifications:

Q1. Acute oral toxicity studies with PAT (phophinothricin acetyl transferase) protein. Have these been done elsewhere? Please provide references and data**.**

Response: Dow AgroSciences has generated data on acute oral toxicity data with PAT protein. A comprehensive summary of the safety information available with the applicant are:

- Acute Oral Toxicity study in CD-1 Mice with PAT protein
- Comparison of plant-derived PAT protein to Toxin database
- Comparison of plant-derived pPAT protein to Toxin database
- Comparison of plant-derived PAT protein to Allergen database
- Comparison of plant-derived pPAT protein to Allergen database
- OECD Consensus document No. 11 (1999)
- Acute oral toxicity in mice with PAT protein (2000)
  - LD_{50} of PAT protein > 6000 mg/kg body weight
- Safety evaluation of PAT protein in transgenic plants
  - **Regulatory Toxicology & Pharmacology, 41 (2005): 134 – 149**
- Review of the Environmental safety of PAT
  - **CERA, ILSI Res. Foundation (2011): 1 – 21**

Q2. Partial PAT ORF containing 77 amino acids from the N-terminal region and 8 additional amino acids from the C-terminal end. This is an additional novel ORF in WideStrike cotton. Acute oral toxicity studies to be done with purified protein encoded by this ORF.

Response: The putative amino acid sequence of the ORF consists of 77 aa from the amino terminus of the PAT protein and an additional 8 aa carboxyl terminal tail. Transcription of the pat fragment is approx. 16 – fold less than the full length pat gene and that no protein expression was detected from the second pat fragment. Presence of the additional fragment is not considered of consequence to safety of cotton products derived from cotton event 281-24-236

Q3. Does PAT inactivate any antibiotics that are currently in clinical use/or have been used clinically in the past.

Response: No reference in literature has been found

Q4. Rationale should be provided for expressing PAT genes using different promoters in the two constructs and in the hybrid.

Response: Cotton event 281-24-236 contains a pat gene driven by *Zm*Ubi1 promoter. Cotton event 3006-210-23 contains a pat gene driven by *Atu*Mas promoter. These two events were crossed to produce WideStrike cotton through conventional breeding. These were simply the events (and constructs) that had the best agronomic and trait performance among those characterized.

Q5. Is phosphinothricin/ glufosinate registered for use or is it being used as an herbicide in India? Is it being used as an herbicide in any other country?

Response: Dow AgroSciences does not own or sell glufosinate ammonium technical. However, glufosinate ammonium is registered in India per Central Insecticides Board (CIB) for use **only on tea by Bayer** who are selling small quantities of Glufosinate-ammonium 15% SL in tea plantations. Also it is registered in many countries like Australia, Canada, Cyprus, Finland, Germany, Greece, Hungary, Netherlands, New Zealand, Philippines, Portugal, South Africa, Tanzania, United Kingdom, USA and Viet Nam.

Q6. Why are there two copies of PAT genes in Cry1F event? Do both the copies express same protein or different. Is there any data available on the individual gene expression and biosafety of all these PAT genes?

Response: There is only one intact copy of PAT gene in Cry1F event that express PAT protein. The second PAT sequence is partial and its putative protein was not detected as confirmed by Western blot.
Moreover, the plant derived PAT proteins expressed by the events 281-24-236 (Cry1F) and 3006-210-23 (Cry1Ac) are identical to the microbe-derived PAT protein, as confirmed by Western Blot techniques. All have 183 amino acids and 43 kDa size.

Q7. Results of the 90 day study on sub-chronic toxicity should be provided to GEAC. The 'published paper' is to be provided to Committee; if necessary, the original data tables.

Response: Both the original full-report and the published paper were submitted to GEAC.

Q8. In the 90 day study, comparison should be between WideStrike cotton and the corresponding non-transgenic cotton. Why were four conventional bred lines of cotton used?

Response: In the global study on WS, one isoline control and 3 commercial controls were employed. It is important to point out that they were 'not needed' per se, but as we know with GM testing, we include multiple lines of controls so as to be able to provide a robust background and basis for comparison to the test substance. This provides an opportunity to showcase and assess the natural variation and accompanying influences, if any, that might exist in a particular crop when tested in such a design.

Q9. The WideStrike hybrid to be released in India is different from that used in the 90 day sub-chronic toxicity study that was conducted in the USA. The 90 day sub-chronic toxicity study should be conducted again in India with the wide strike hybrid being released in India and the corresponding non-transgenic hybrid.

Response: Animal feeding studies are not recommended by existing guidelines (2008) when a GM crop has been shown to be compositionally equivalent to the non-GM counterpart as is the case for WS cotton tested in India. There is no biological or toxicological basis for conducting additional studies on WS hybrids beyond our existing 90-day study with WS in which the NOEL was the maximum amount consumed – there were no toxicological observations or effects that would merit further investigation and no reason to believe that the protein in a hybrid would act any differently (metabolically or toxicologically) such that additional studies would be useful. Global GM crop regulations have uniformly used a single germplasm to run 90-day rat studies, and extended results to the many lines into which the transgenic event is bred. Moreover, a 90-day goat feeding study which was conducted in India with locally produced hybrid grains of WS106 also proved the biosafety of WideStrike.

We know of no GM crop regulations in any country requiring an additional toxicology study for additional lines into which a transgenic event is incorporated using traditional breeding.

Q10. What are the clinical parameters assessed in Poultry feeding study? Were any differences observed?

Response: There were clinical observations, observations on body weights, weight gains, mortality, food consumption and feed conversion. The clinical observations included behavioural changes, toxicity (fecal material condition, presence of diarrhea, nervousness, accessibility to water and feed, general bird appearance).

Results: Cottonseed Meal from Cry1F/Cry1Ac Cotton vs. Cottonseed Meal from a Non-Transgenic Isoline. No statistically significant differences were observed in mortality, body weight gain or feed conversion between broilers fed a diet containing cottonseed meal from Cry1F/Cry1Ac or cottonseed meal from a non-transgenic isoline cotton.

Cottonseed Meal from Cry1F/Cry1Ac Cotton vs. Cottonseed Meal from Commercial Sources. No statistically significant differences were noted in mortality or body weight gain between groups of broilers fed diet containing cottonseed meal from Cry1F/Cry1Ac cotton or cottonseed meal from commercial sources. Feed conversion by broilers fed cottonseed meal from one of the two commercial sources (DOW01-1) was found to be statistically worse than that of broilers fed cottonseed meal from Cry1F/Cry1Ac. No differences in feed conversion were seen between broilers fed cottonseed meal from the second commercial source (DOW01-2) and those fed cottonseed meal from Cry1F/Cry1Ac.

These results confirm the nutritional equivalence of cottonseed meal derived from Cry1F/Cry1Ac cotton, a non-transgenic isoline cotton (non-GM cotton) and two sources of commercial cotton when fed to broiler chickens for 42 days.

Q11. Feeding study on goats: details about the observed changes in haematology and clinical parameters are to be provided.

Response: Details were given in the presentation

Q12. If the Fl parents are heterozygous for transgenes, segregation will occur and some of the seeds produced on Fl plants will have only one or the other of the transgenes. Therefore, the seeds produced on Fl plants will be a genetic admixture and their use in sub-chronic toxicity and feeding studies would not give a complete picture of possible adverse effects that individual transgenes might carry. To prevent the above, both male and female parents should have both genes in homozygous condition (this will avoid segregation in the seeds produced on Fl plants). If this is not possible, sub-chronic toxicity and feeding studies should be conducted using seeds from each of the parental lines.

Response: F2 grains were used for goat feeding studies from risk assessment perspective. The assumption was that quantum of risk of exposure to the environment will be higher (~7000x) from F2 grains rather than from F1 seeds (seeds sold to farmers) or parental seeds (breeder seeds). Hence, the feeding study was designed to use F2 grains generated exclusively for this purpose. Moreover, the protocol for the feeding study was presented to and approved by RCGM.

Q13. Environmental biosafety studies. A few differences in rhizospheric microflora are indicated. What are these differences? P1. elaborate.

Response: There were few differences between transgenic and non-transgenic entries. As discussed in the meeting these differences were not showing any correlation between soil microflora population and Bt (including commercial traits). The differences observed may be attributed to variety of factors - plot differences, soil micro-climate, edaphic factors etc and not to the trait *per se*.

4.1.4 Subsequent to completion of the presentation the Committee discussed in detail the information presented by the applicant regarding various biosafty assessment which encompasses food feed biosafety studies, environmental biosafety studies and bisoafety research trials done by the applicant. They also deliberated on the requirements to establish bioafety of events as per 'Guidelines

for safety assessment of foods derived from genetically engineered plants' which encompasses acute oral safety limit study in mice, sub chronic feeding study in mice, protein thermal study, pepsin digestibility assay and livestock feeding study. Committee noted that except for nutritional equivalence study with goat and compositional equivalence study with indigenously grown cotton all other food feed biosafety studies of Widestrike cotton have been conducted outside India. Committee realized that none of these studies have been conducted with respect to Indian transgenic Widestrike cotton.

4.1.5 Summary of discussion and decisions taken in the GEAC on wide strike cotton includes the following:

1. Acute Oral Toxicity studies should be done with protein encoded by the partial PAT ORF encoding 77 amino acids from the N-terminal region of PAT and 8 additional amino acids at the C-terminal end. An E. coli expressed and purified version of this ORF should suffice. As the applicant has indicated that the protein encoded by this ORF is not expressed in wide strike cotton, a final decision on this matter was deferred until this data (to be submitted by the applicant) is reviewed.

2. The 90 day sub-chronic toxicity study should be conducted with the wide-strike cotton hybrid being released in India. The corresponding non-transgenic hybrid is to be used as a control. The study is to be conducted as per guidelines of DBT. Although the applicant indicated that studies conducted with material released in the USA should suffice, the general consensus in the Committee was that for the first release of a gene/s (event/s) in India, the 90 day sub-chronic toxicity study in rats and the 90 day goat feeding studies should be done with material to be released in India.

3. The results of the 90 day study conducted using the wide strike variety released in USA should be submitted to the Committee. The "paper" published regarding the same and a report of the study including the original data tables and summary tables should be provided. This report should highlight any statistically significant differences observed between "wide strike cotton" and the corresponding "non-transgenic" line.

4. Details should be provided about the statistically significant differences in haematological and clinical parameters that were observed in the goat feeding assays.

5. Details should be provided about the clinical parameters assessed in the poultry feeding study and whether any statistically significant differences were observed. If so, details to be provided.

6. The Committee felt that it was not necessary for sub-chronic toxicity studies to be done with each of the parental lines containing cry1Ac and cry1F, respectively, as only two genes are involved. However, the Committee has noted that the development of stacked lines (involving even greater numbers of genes) is likely to be more common in the future and that considerable amounts of heterogeneity (caused by segregation of events that are in heterozygous state in the F1 plants) is likely to occur in the F2 seeds. The need to conduct sub-chronic toxicity studies and feeding studies, in such cases, on the two parental lines (that are used to make the hybrid) is an issue that has been flagged for further discussion in the Committee.

7. Acute oral toxicity studies with purified PAT protein to assess it's safety need not be done again as these have been done elsewhere.

8. The issue of whether the tests recommended by the GEAC can be conducted in any OECD accredited laboratory in India or abroad with the same material being released in India was another issue that was flagged for further discussion by the Committee.

4.1.6 It was decided to consider unresolved issues in the next GEAC meeting.

4.1.7 During the deliberations, the need for additional studies such as chronic toxicity, proteomics, transcriptomics etc was reiterated by one of the experts. It was agreed that these issues are already

under consideration by the GEAC and therefore its applicability to the present case will be decided when a final view is taken on the matter. For the present it was decided that the GEAC will focus on issues applicable under the current regulations. The Committee requested the Chairman to convene a meeting of the experts at the earliest.

4.2 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.

4.2.1 In accordance with the decision taken by the GEAC in its meeting held on 21.9.2011 M/s. BASF India Ltd. made a brief presentation on their proposal to conduct event selection trials with 168 events of transgenic rice and F1 Hybrid seed production (two cycles per year) from constructs RPD5-RPD17 imported from USA and Belgium. 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 is a research activity for trait development for yield enhancement. A total of seven genes and nine constructs have been deployed. The source of genes is 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

4.2.2 During the deliberation, the applicant informed that confidential business information pertaining to source of gene / gene constructs etc have been submitted to the RCGM. A copy of the same was submitted during the meeting for consideration by the GEAC.

4.2.3 After detailed deliberation the Committee requested Dr Arjula Reddy, Co-Chair to examine the proposal and give his views. Accordingly decision the proposal was deferred.

Agenda item No. 5: Consideration of applications for confined field trials of transgenic crops (Event selection/ BRL-I) as recommended by the RCGM:

5.1 Permission to conduct 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) by M/s. E.I. Dupont India Pvt. Ltd., Hyderabad.

5.1.1 The Committee considered the application submitted by M/s. E.I. DuPont India Pvt. Ltd., DuPont Knowledge Center, Hyderabad to conduct event selection trials of following transgenic rice (*Oryza sativa L.*) events developed from five different constructs i.e. Bt38 (Cry1Ab+Cry2ad), Bt39 (Cry1C+Cry2Ad), Bt40 (Cry1Ab+Cry2Ad), Bt43 (Cry1C+Cry1Ab) and pTVE544 (Cry1Ca +bar) & pTSVH0207 (Cry1Ab+bar)**:**

- One event generated using Bt38 (Cry1Ab+Cry2ad) construct, namely MP-38H-95-8-12 in inbred as well as in hybrid.
- Four events generated using Bt39 (Cry1C+Cry2Ad) construct, namely N-H39-95-7-94C, H39-5-76B, N39-95-11-18 and H39-12-72 in inbred as well as in hybrids.
- Five events generated using Bt40 (Cry1Ab+Cry2Ad) construct, namely SK-40H-95-5-419, SK-40H-95-7-691, SK-40H-95-7-692, SK-40H-95-7-849 AND SK-40H-95-5-602 in inbreds as well as in hybrids.

- Thirteen events generated using Bt43 (Cry1C+Cry1Ab) construct, namely H43-4-91A,, 16BT43+HSGE-14, P43-H-10-32, P-43H-9-15, SK-43H-95-12-1761, SK-43H-95-11-1777,, SK-43H-95-13-1828, SK-43H-95-7-964, SK-H43-95-12-1755, SK-H43-95-13-1817, SK-H43-95-5-284, SK-H43-95-5-359, SK-H43-95-6-724 in inbreds as well as in hybrids.
- The 4 events generated using pTVE544 & pTSVH0207 (Cry1Ab+Cry1Ca) constructs, namely RICE1551, RICE 1552, RICE 1557 and RICE 1558 in inbred as well as in hybrids

5.1.2 All the events generated using construct Bt38, Bt39, Bt40 and Bt43 were developed by transforming elite Indica rice, IRV95. The hybrid was developed by crossing transgenic event with IRI25F. All the events are single copy event. The events generated using pTVE544 & pTSVH0207 (Cry1Ab+Cry1Ca) constructs were developed by transforming Rice line, 6G4317. These are all single copy and with bar genes.

5.1.3 The Committee noted that the purpose of the trial is to evaluate the efficacy of dual molecular stacked Cry genes in Bt rice events in both inbreds and hybrids against Yellow Stem Borer and Rice Leaf Folder pests in the confined field trial. The trials will be conducted at Medak District, Andhra Pradesh.

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

- Spatial reproductive isolation distance of 200 m from the last row of transgenic plant on all four sides will be maintained.
- Non transgenic related lines will be planted as the control.
- Seedlings of 21 to 25 days old or 5 leaf stage will be transplanted
- Spacing of 20X15 cm will be followed
- Single seedlings/hill will be transplanted
- Gap filling will be undertaken within 5 to 7 days after transplanting
- The seed set on all lines will be retained for laboratory studies and will be destroyed after the completion of laboratory studies as per DBT guidelines.

5.1.5 It was also noted that IBSC in its 15th meeting has recommended the proposal on 02.09.2011. RCGM also recommended the proposal in its 105th meeting held on 27.09.2011.

5.1.6 Further, that GEAC in its meeting held on 21.9.2011 had permitted M/s. E.I. Dupont India Pvt. Ltd., Hyderabad to conduct event selection trials on fourteen transgenic rice (*Oryza sativa L.*) events generated using Bt39 (Cry1C+Cry2Ad), Bt40 (Cry1Ab+Cry2Ad) construct and Bt43 (Cry1C+Cry1Ab) constructs:

- Six events generated using Bt39 (Cry1C+Cry2Ad) construct, namely Bt39-101, Bt39-102, Bt39-103, Bt39-104, Bt39-105 and Bt39-106 of T3 generation.

- Four events generated using Bt40 (Cry1Ab+Cry2Ad) construct, namely Bt40-101, Bt40-102, Bt40-103 and Bt40-104 of T3 generation.

- Six events generated using Bt43 (Cry1C+Cry1Ab) construct, namely Bt43- 101, Bt43-102, Bt43-103, Bt43-104, Bt43-105 and Bt43-106 of T3 generation.

5.1.7 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 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) by M/s. E.I. Dupont India Pvt. Ltd., during the appropriate season in 2011-12 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

5.2 Permission to conduct 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 by M/s. E.I. Dupont India Pvt. Ltd., Hyderabad.

5.2.1 M/s. E.I. DuPont India Pvt. Ltd., DuPont Knowledge Center, Hyderabad has requested permission to conduct event selection trials on four events of transgenic rice (*Oryza sativa L.*) generated using SPT1 construct, namely JH17, JH26a, DKC376 and DKC1049a of BC4 generation and two events generated using SPT6 construct namely J6-1-4d and J6-1-7d.

5.2.2 All the events were developed by transforming M2O2XT65 lines and then backcrossed into VIR54G9. All events are single copy events expressing OS-MSCA1, ZM-AA1 and DsRed2 protein. The trials will be conducted at Medak District, Andhra Pradesh.

5.2.3 The Committee noted that the purpose of the study is:

i) To assess the frequency of transgene transmission through pollen in different events.
ii) To assess the seed productivity of the events.
iii) To evaluate the expression levels of DsRed2 and ZM-AA1 in tissues of Rice SPT maintainer events.

5.2.4 The Committee also noted that the following isolation measures and field design parameters are proposed:

- Spatial reproductive isolation distance of 10 m from the last row of transgenic plant on all four sides will be maintained.
- Male sterile (CMS) lines will be planted as the pollen recipient. Out crossed seeds set on these male sterile plants will be used to assess any transgene transmission through pollen.
- Seedlings of 21 to 25 days old or 5 leaf stage will be transplanted.
- Leaf tips will be clipped before transplanting if required.
- Differential date of transplanting will be followed based on the seedling age.
- Row ratio of 2:4 will be maintained for Rice SPT male: female lines (M:F).
- Spacing followed will be as follows: M:M-Between and within a row-20cm, M:F row-25 cm, F:F-Between and within row-20cm.
- Number of seedling/hill will be maintained at two seedlings for female and single seedling for male lines.
- Gap filling will be undertaken within 5 to 7 days after transplanting.

5.2.5 IBSC in its 15th meeting has recommended the proposal on 02.09.2011. RCGM also recommended the proposal in its 105th meeting held on 27.09.2011.

5.2.6 It was also noted that GEAC in its earlier meetings had permitted M/s. E.I. Dupont India Pvt. Ltd., Hyderabad; to conduct event selection trials on transgenic rice events containing SPT1 construct expressing OS-MSCA1, ZM-AA1 and DsRed2 protein and using SPT I and SPT6 construct, expressing OS-MSCA1, ZM-AA1 and DsRed2 protein:

- 8 events of transgenic rice (*Oryza sativa L.*) using SPT1 in its meeting held on 29.9.2010
- 20 events of transgenic rice (*Oryza sativa L.*) using SPT1 in its meeting on 21.9.2011
- 5 events of transgenic rice (*Oryza sativa L.*) using SPT6 in its meeting held on 29.9.2010
- 20 events of transgenic rice (*Oryza sativa L.*) using SPT1 in its meeting on 21.9.2011

5.2.7 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 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 by M/s. E.I. Dupont India Pvt. Ltd., during the appropriate season in 2011-12 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

5.3 Permission to conduct Biosafety Research Level-1 (BRL-1) second year trials on transgenic maize (*Zea mays*) hybrids namely TC1 and TC3 containing *cry1F* gene [TC1507 event (DAS-01507-1)] at 10 locations by M/s. Dow AgroSciences India Pvt. Ltd., Mumbai.

5.3.1 The Committee noted that the GEAC in its meetings held on 29.9.2010 had approved second year trials on transgenic maize (*Zea mays*) hybrids namely TC1 and TC3 containing *cry1F* gene [TC1507 event (DAS-01507-1)] at two locations in UAS Bangalore and TNAU, Coimbatore. However, the trials could not be conducted as NOC from the State Governments could not be obtained.

5.3.2 The present request of the applicant is to conduct Biosafety Research Level-1 (BRL-1) second year trials on transgenic maize (*Zea mays*) hybrids namely TC1 and TC3 containing *cry1F* gene [TC1507 event (DAS-01507-1)] at 10 locations namely TNAU, Coimbatore; Bhavani Nagar (TNAU, Coimbatore); UAS, Bangalore; UAS, Dharwad; ANGRAU, Hyderabad; MPUAT, Udaipur; AAU, Anand; AAU, Anand; GBPAU, Pant Nagar; PAU, Ludhiana.

5.3.3 The Committee noted that the purpose of the study is:

i) To study the impact of TC1507 transgenic maize hybrids against target *lepidopteran* pests, secondary pests and non-target insect species.
ii) Comparative assessment of soil ecosystem & weediness, morphology & phenotypic characters of transgenic corn and its non-transgenic counterpart hybrids.
iii) Undertake gene expression studies of transgenic event TC1507 at different crop growth stages.

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

- Spatial reproductive isolation distance as per RCGM recommendation i.e 300 m will be maintained.
- Non-transgenic hybrids would be used for comparison.

5.3.5 It was also noted that IBSC has recommended the proposal in its meeting held on 26.08.2011. RCGM also recommended the proposal in its 105th meeting held on 27.09.2011.

5.3.6 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to conduct Biosafety Research Level-1 (BRL-1) second year trials on transgenic maize (*Zea mays*) hybrids namely TC1 and TC3 containing *cry1F* gene [TC1507 event (DAS-01507-1)] at 10 locations by M/s. Dow AgroSciences India Pvt. Ltd., during the appropriate season in 2011-12 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

5.4 Permission to conduct event selection trials on transgenic rice (*Oryza sativa*) events (14 events containing *cry1Ab, cry1Ca* and *bar* gene from M/s. Bayer Bioscience Pvt. Ltd. and 23 events containing *cry1Ab, cry1C* and *cry2Ad* gene transformed from M/s. Dupont India Pvt. Ltd.) at 4 locations by M/s. Bayer Bioscience Pvt. Ltd., Gurgaon.

5.4.1 M/s. Bayer Bioscience Pvt. Ltd., Gurgaon has requested for permission to conduct event selection trials on transgenic rice (*Oryza sativa*) events (14 events containing *cry1Ab, cry1Ca* and *bar* gene from M/s. Bayer Bioscience Pvt. Ltd. and 23 events containing *cry1Ab, cry1C* and *cry2Ad* gene transformed from M/s. Dupont India Pvt. Ltd.).

- Four events generated using pTVE544+pTSVH0207 construct, namely RICE1551, RICE1552, RICE1557 and RICE1558 containing Bt & bar gene in hybrid genetic background (Line 6G4317 and G7186).

- One event generated using pTVE545+pTVE543 namely RICE1576 containing Bt & bar gene in inbred line i.e 6G4317 .

- Four events generated using pTIBE67 construct, namely RICE4001, RICE4002, RICE4003 and four events generated using pTIBE68 construct RICE4004, RICE4101, RICE4102, RICE4103 and RICE4104. All the eight events contain Bt gene in inbred line of 6G4317.

- One event generated using Bt38 construct, namely MP-38H-95-8-12.

- Four events generated using Bt39 construct, namely N-H39-95-7-94C, H39-5-76B, N39-95-11-18, H39-12-72.

- Five events generated using Bt40 construct, namely SK-40H-95-5-419, SK-40H-95-7-691, SK-40H-95-7-692, SK-40H-95-7-849 and SK-40H-95-5-602.

- Thirteen events generated using Bt43 construct namely H43-4-91A, 16 BT43+HSGE-14, P43-H-10-32, P-43H-9-15, SK-43H-95-11-1777, SK-43H-95-12-1761, SK-43H-95-13-1828, SK-43H-95-7-964, SK-H43-95-12-1755, SK-H43-95-13-1817, SK-H43-95-5-284, SK-H43-95-5-359 and SK-H43-95-6-724. All the above mentioned 23 events generated using Bt38, Bt39, Bt40 and Bt43 constructs contain Bt gene in PHI-07 plant genotype.

5.4.2 The trials will be conducted at 4 locations namely Crop Development Centre (CDC-1st location), Patancheru; Chandrapur (Maharashtra); Surat (Gujarat) and Coimbatore (Tamil Nadu) (during Dec., 2011).

5.4.3 The Committee noted that the purpose of the study is:

i) To evaluate the Bt events in comparison to non-transformed genotype for agronomic parameters and insect efficacy.
ii) Also Bt events would be tested for effect, if any, on restoration capacity, seed producibility of the transformant and herbicide efficacy caused due to presence of bar gene.
iii) Data would be generated for agronomic parameters (days to flowering, no. of tillers & panicles, plant height, paddy yield etc.), insect efficacy (dead heart/white heads etc), seed producibility (weight of F1 seed produced per unit area), herbicide efficacy and restorability (paddy yield per unit area).

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

- Spatial reproductive isolation distance as per regulatory requirements will be maintained.
- The non-transformed genotype will be planted in between the events to compare the agronomic parameters. Also the border rows of non-transformed will be planted.
- Nursery of transgenic rice is to be grown inside contained greenhouse/screenhouse conditions till complete germination and seedlings are ready for transplanting.
- Before transplanting, required numbers of the seedlings from the nursery are taken out, tied with label tag and kept row and event wise in separate small buckets.
- Seedlings are arranged replication wise.
- The seedlings transferred to puddle field to be transplanted.
- Transplanting is done at the designated trial plot.
- A few of the remaining seedlings in nursery may be transplanted under greenhouse for seed production; the other remaining seedlings are dried under nursery itself.
- Plants in trial to be monitored and taken care by Trial Site Manager.
- Only the authorized personnel would enter confined field trial site for daily operations.

5.4.5 It was noted that IBSC in its 38th meeting has recommended the proposal on 06.08.2011. RCGM also recommended the proposal in its 105th meeting held on 27.09.2011. Further, the GEAC in its earlier meetings had permitted M/s. Bayer Bio-Science Pvt. Ltd; to conduct event selection trials on transgenic rice events containing cry1Ab, cry1Ca and bar genes:

- on 28 transgenic rice in its 88th meeting held on 13.8.2008
- on 41 transgenic rice in its 91st meeting held on 14.1.2009
- on 88 transgenic rice in its 94th meeting held on 10.6.2009
- on 49 transgenic rice in its 97th meeting held on 14.10.2009
- on 56 transgenic rice in its 100th meeting held on 12.5.2010 and
- on 34 transgenic rice in its 104th meeting held on 15.11.2010

5.4.6 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to event selection trials on transgenic rice (*Oryza sativa*) events (14 events containing *cry1Ab, cry1Ca* and *bar* gene from M/s. Bayer Bioscience Pvt. Ltd. and

23 events containing *cry1Ab, cry1C* and *cry2Ad* gene transformed from M/s. Dupont India Pvt. Ltd.) at 4 locations by M/s. Bayer Bioscience Pvt. Ltd., during the appropriate season in 2011-12 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

5.5 Request for extension of the validity to conduct BRL-1 trial of Roundup Ready Flex® (RRF ™) cotton hybrids (MRC 8347 RRF ™ and MRC 8351 RRF ™) in Baroda in Gujarat during 2011-2013 to 2013-2014 by M/s. Maharashtra Hybrid Seeds Company Ltd. (MAHYCO), Mumbai.

5.5.1 The GEAC in its meeting held on 6.7.2011 had accorded approval to conduct BRL-1 trial of Roundup Ready Flex® (RRF ™) cotton hybrids (MRC 8347 RRF ™ and MRC 8351 RRF ™) in Baroda in Gujarat during 2011-2013.

5.5.2 The Committee conveyed its 'no objection' to extend the validity period to Kharif seasons 2011-2012 and 2013 -2014 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

5.6 Request for extension of the validity upto end of 2012 to conduct event selection trial on transgenic rice events against yellow stem borer and rice leaf folder pests at Andhra Pradesh which was valid for Kharif 2011 season by M/s. E.I. Dupont India Pvt. Ltd., Hyderabad.

5.6.1 The GEAC in its held on 106th meeting held on 12.01.2011 had accorded permission to conduct event selection on 23 transgenic rice events against Yellow Stem Borer and Rice Leaf Folder pests by M/s. E.I. Dupont India Pvt. Ltd., Hyderabad.

5.6.2 The Committee conveyed its 'no objection' to extend the validity of the permit letter upto end of 2012 to conduct event selection trial on transgenic rice events against Yellow Stem Borer and Rice Leaf Folder pests at Andhra Pradesh subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted

Agenda Item No 6 : Consideration of applications related to Pharmaceuticals:

6.1 Permission to import Tetravalent Dengue Vaccine for Phase II Clinical trials from Sanofi Pasteur, SA Lyon, France to study Immunogenicity and Safety in India by M/s Sanofi Pasteur India Pvt. Ltd, Mumbai (Protocol No CYD 47)

6.1.1 The Committee noted that decision on the proposal from M/s Sanofi Pasteur India Pvt. Ltd, Mumbai, to import Tetravalent Dengue Vaccine from France for Phase II Clinical trials from Sanofi Pasteur, SA Lyon, France was deferred in the GEAC meeting held on 21.9.2011 for want of comments from the experts.

6.1.2 The Committee noted that DCGI vide their letter No. 12-127/SANOFI/10-BD dated 1.6.2011 and other experts have recommended the proposal to conduct Phase II Clinical trials from Sanofi Pasteur, SA Lyon, France to study Immunogenicity and Safety in India.

6.1.3 In view of the above stated facts, the GEAC approved the proposal.

The Next meeting of the GEAC is scheduled for December 14, 2011.

****