Decision taken in the 115th meeting of the Genetic Engineering Appraisal Committee (GEAC) held on 08.02.2012

The 115th meeting of the GEAC was held on 8.2.2012 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 8 are as follows:

Agenda item No 4: Policy issues

4.1 Extending the tenure of the Standing Committee to review applications for commercial release of Bt cotton hybrids expressing Approved Events.

4.1.1 The Committee noted that, during 2002-2009, GEAC has approved Bt cotton hybrids expressing six events Cry 1 Ac gene (MON 531 event) and stacked genes Cry1 Ac and Cry 2Ab (MON 15985 event)—BG-II developed by M/s Mahyco; encoding fusion genes (cry 1Ab+Cry Ac) 'GFM developed by M/s Nath Seeds; cry 1Ac gene (Event-1) developed by M/s J. K. Agri Genetics Ltd; Cry 1AC gene (Dharwad event) developed by Central Institute of Cotton Research (CICR); and Cry 1C (event 9124) developed by M/s Metahelix Life Sciences for environmental release. Subsequently in 2009, the GEAC had adopted the Event Based Approval Mechanism and constituted a Standing Committee to operationalize the new procedure.

4.1.2 The Committee noted that the tenure of the 'Standing Committee' constituted by the GEAC to review applications for commercial release of approved Bt cotton events at the Central which is currently being serviced by DBT expires on 16.04.2012.

4.1.3 The Committee noted that report of the Sub Committee constituted by the GEAC under the Chairmanship of DDG-ICAR to review measures to streamline the regulatory process which includes review of the current procedure for 'Event Based Approval Mechanism is still awaited. As the sowing season for Kharif 2012 is fast approaching and in the absence of a formal proposal from ICAR, the Committee opined that the tenure of the Standing Committee may be extended subject to consent from DBT.

4.1.4 To a query on whether the TOR of the Standing Committee needs to amended to include the requirement of (i) one year field testing; (ii) morphological characteristics using DUS descriptors as per PPVF&RA guidelines; & (iii) data on curl Leaf Curl Virus (CLCuV) for the North Zone as recommended by the Standing Committee in its 6th meeting it was decided to await the report of the Sub-Committee.

4.1.5 In view of the above stated facts and taking into consideration the affirmation from DBT to continue servicing the Standing Committee, the Committee agreed to extend the tenure of the Standing Committee with the same TOR as notified in the OM dated 17.04.2009 for a period of six months or till such time an alternate mechanism is put in place by the GEAC whichever is earlier. On the composition of the Standing Committee it was decided to nominate Dr. Shruti Rai, Deputy Director, MoEF as an additional member of the Standing Committee. The next meeting of the Standing Committee was fixed for 14.02.2012.

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 of 12 nitrogen use efficient cotton (*Gossypium hirsutum L)* events namely; MAH-11501 to MAH-11512 containing the *AlaAt* gene by M/s. Maharashtra Hybrid Seeds Co. Ltd. (MAHYCO), Mumbai.

5.1.1 The Committee considered the application of M/s. MAHYCO to conduct event selection trials with 12 nitrogen use efficient cotton (Gossypium *hirsutum L)* events namely; MAH-11501 to MAH-11512 containing the *AlaAt* gene at Company's own research farm at Jalna, Maharashtra.

5.1.2 The Committee noted that the purpose of the field trials is to evaluate the efficacy of transgenic cotton events expressing *AlaAt* protein compared to their non-transgenic counterparts and checks for enhanced Nitrogen Use Efficiency (NUE).

5.1.3 The Committee also noted details of the field experiment and proposed isolation measures as given below:

- Replicated Randomized Complete Block Design will be used.
- An isolation distance of 50 m from the periphery of the outmost boarder row will be maintained all around the trial site.
- The Border rows of non- transgenic cotton will be planted all around the replicated block up to a distance of 5 m. There will be a gap of 1.2 m between replicated block and the boarder rows.
- For growth and yield under various Nitrogen regimes, nitrogen fertilizer will be applied at 3 doses of 35%, 70% and 100% of recommended dose. Dose will take into account residual fertilizer content of soil. The N applications will be split as 40% as basal application, 30% at square formation and flowering stages each.
- During the trial, standard cotton growing practices will be followed in all the treatments, and observations will be recorded for growth and yield parameters such as plant height, boll number, days to 50% flowering and cotton yield.
- Total cotton yield per plant in all treatment will be used as the measure for event performance calculating nitrogen use efficacy. Efficacy will be defined as events with significant cotton yield increase, as compared to the non-transgenic counterpart.

5.1.4 The Committee observed that the proposal has been recommended both by IBSC and RCGM. RCGM recommended the proposal in its 94th meeting held on 9.11.2011 and advised that the trial design should be split block with three replicates.

5.1.5 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 of 12 nitrogen use efficient cotton (*Gossypium hirsutum L)* events namely; MAH-11501 to MAH-11512 containing the *AlaAt* gene at Company's own research farm at Jalna, Maharashtra during appropriate season in 2012 subject to submission of NOC from the State Government where the trials will be conducted.

5.2 Permission to conduct event selection trials of 10 water use efficient cotton(*Gossypium hirsutum L)* events namely; MAH-10001 to MAH-10010 containing the i*pt* gene by M/s. Maharashtra Hybrid Seeds Co. Ltd. (MAHYCO), Mumbai.

5.2.1 The Committee considered the application of M/s MAHYCO to conduct event selection trials with 10 water use efficient cotton (*Gossypium hirsutum L)* events namely; MAH-10001 to MAH-10010 containing the *ipt* gene at Company's own research farm at Jalna, Maharashtra.

5.2.2 The Committee noted that the purpose of the field trials is to evaluate the efficacy of transgenic cotton events expressing the *ipt* protein compared to their non-transgenic counterparts and checks for drought tolerance.

5.2.3 The Committee also noted the following proposed isolation measures:

- Replicated Randomized Complete Block Design will be used.
- An isolation distance of 50 m from the periphery of the outmost boarder row will be maintained all around the trial site.
- Five trap rows of non- transgenic cotton will be planted all around the replicated block up to a distance of 5 m. There will be a gap of 1.2 m between replicated block and the trap rows.
- Drought stress will be given to plants by withholding water in treatments as mentioned ;
    - Water stress will be given at square initiation stage in M1 and M3 treatments (45-50 days after sowing).

- In M2 and M3 treatments water stress will be given at boll development stage (75-90 days after sowing).
- The extent of water stress applied will depend on phenotypic and physiological symptoms.
- Treatment M4 (control) will be irrigated on a regular basis.
- Rainout shelter will be constructed over the experimental plot.

5.2.4 The Committee further noted the treatment details for conducting trials is as given below:

Main plot treatment (Stress Regimes):
M1 – Moisture (drought) stress at square initial stage (45-50 DAS)
M2 -- Moisture (drought) stress at boll development stage (75-90 DAS)
M3--- Moisture (drought) stress at both square initiation and boll development stages boll.
M4 -- Control (No stress)

5.2.5 The Committee also observed that the proposal has been recommended by IBSC and RCGM on 9.11.2011 and 27.12.2011 respectively.

5.2.6 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 of 10 water use efficient cotton (*Gossypium hirsutum L)* events namely; MAH-10001 to MAH-10010 containing the i*pt* gene at Company's own research farm at Jalna, during appropriate season in 2012 subject to submission of NOC from the State Government where the trials will be conducted.

5.3 Permission to conduct event selection trials transgenic Chickpea *(Cicer arietinum*) containing *cry2Aa* gene by International Crops Research Institute for the Semi-Arid Tropics (ICRISAT), Patancheru.

5.3.1 The Committee considered the proposal of ICRISAT to conduct event selection trials on four transgenic Chickpea *(Cicer arietinum*) events namely; BS5A.1 (T2), (BS5A.1 (T2)18-1 PI), BS5A.1 (T2)18-2 PI), BS5A.2(T2) (BS5A.2(T2) 19-1 P2, BS5A.2(T2) 19-2 PI, BS5A.2(T2)19-3 P1), BS5A.2(T2)19-3P2), BS6H.3 (T6) (BS6H.3(T6) 10-1P1), BS6H.5(T6) (BS6H.5 (T6)12-1PI). containing *cry2Aa* gene, Semsen (control) and ICC 506 (Resistant check) The trials will be conducted at ICRISAT, experimental field, Patancheru .

5.3.2 The Committee noted that the main objective of the trial is to carry out phenotyping of transgenic chickpea carrying the synthetic *cry2Aa* gene driven by the Arabidopsis SSU promoter and its intended to be carried out for event selection for resistance to pod borer, Helicoverpa armigera. The transgenic events will be planted in replicates along with the untransformed control, Semsen, susceptible (ICCC 37) and resistant (ICC 506 EB) checks. Second instar larvae of *Helicoverpa armigera* will be released at the vegetative and at the podding stage of the crop to study the response of the larvae to the transgenic events, for event selection in a confined field at ICRISAT, Patancheru. Data will be recorded on larval leaf feeding scores, larval survival, and larval weights. Data will also be recorded on pod numbers, pod damage, and grain yield. Data will be subjected to analysis of variance, to select the best performing events.

5.3.3 The Committee also noted the following proposed isolation measures:

- Chickpea is a self pollinating, diploid (2n=2x=16) with genome size 1C=740 Mbp. As per the Indian Minimum Seed Standard Certification, an isolation distance of 10 m. will be adhered to.
- Four rows of non-transgenic chickpeas (ICCC 37) will be planted around the experiment for further testing of gene flow, if any. Surrounding this, another four rows of sorghum will be planted to prevent pollen drift due to wind. All the weeds present in the proximity of field will be destroyed using herbicides.
- Distance from the nearest cultivated crop of the same species will be 500 m.

5.3.4 The Committee also observed that the proposal has been recommended by IBSC on 21.11.2011. The RCGM has recommended the proposal in its 108th meeting held on 27.12.2011.

5.3.5 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 transgenic Chickpea *(Cicer arietinum*) containing *cry2Aa* gene at Patancheru during appropriate season in 2012 subject to submission of NOC from the State Government where the trials will be conducted.

5.4 Permission to conduct field trial for event selection with 32 transgenic Rice (Oryza sative L.) events using 4 constructs namely; DKHT3, DKHT4, DKHT5 and DKHT6 constructs (8 events from each construct) by M/s. E.I Dupont India Pvt. Ltd., Dupont Knowledge center, Hyderabad.

5.4.1 The Committee considered the application of M/s. E.I Dupont India Pvt. Ltd. to conduct event selection trials with 32 transgenic Rice (Oryza sative L.) Glyphosate Tolerant Rice events and corresponding null segregants generated using DKHT3, DKHT4, DKHT5 and DKHT6 constructs (8 events from each construct) of T3 generation will be tested in the event selection trial. The trials will be conducted at any one location in Andhra Pradesh/Gujarat.

5.4.2 The Committee noted details of the constructs as follows.

- **Construct DKHT3** – Events are DKHT3.1, DKHT3.2, DKHT3.3, DKHT3.4, DKHT3.5, DKHT3.6, DKHT3.7, DKHT3.8
- **Construct DKHT4** – Events are DKHT4.1, DKHT4.2, DKHT4.3, DKHT4.4, DKHT4.5, DKHT4.6, DKHT4.7, DKHT4.8
- **Construct DKHT5** – Events are DKHT5.1, DKHT5.2, DKHT5.3, DKHT5.4, DKHT5.5, DKHT5.6, DKHT5.7, DKHT5.8
- **Construct DKHT6** – Events are DKHT6.1, DKHT6.2, DKHT6.3, DKHT6.4, DKHT6.5, DKHT6.6, DKHT6.7, DKHT6.8

5.4.3 The Committee also noted that eight events from each of the 4 GAT constructs as described above have been tested for efficacy in green house in T1 generation and found to be resistant to glyphosate. T2 seeds from homozgyous T1 GAT plants were grown in the green house to obtain T3 seeds which will be used for the event selection trial. All the events have been extensively characterized at the molecular level (qPCR and Southern) and are single copy, independent events and free of vector backbone. Herbicide tolerant (HT) rice events were generated using Agro bacterium mediated transformation of Indica inbred line with four GAT constructs and callus was selected using Glyphosate.

5.4.4 The Committee observed that the trials will be conducted at any one location in Gujarat or Andhra Pradesh.

5.4.5 The Committee noted that the purpose of the field trials is to assess trait efficacy in the field and to test the efficacy to various doses of glyphosate in the field.

5.4.6 The experimental design for conducting trials is SPD (Split Plot Design)

5.4.7 The Committee also noted the following proposed isolation measures:

- A spatial isolation of 10 meters (events are in inbred background) from the last row of transgenic plant on all four sides will be maintained.
- All regulatory conditions of RCGM including SOP for conduct of confined field trials will be compiled.
- Non transgenic VIR54G9 will be planted as control.

5.4.8 The Committee also observed that the proposal has been recommended by IBSC in its 17th meeting held on 9.12.2011. The RCGM has recommended the proposal in its 109th meeting held on 24.1.2012.

5.4.9 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to conduct field trial for event selection with 32 transgenic Rice (Oryza sative L.) events using 4 constructs namely; DKHT3, DKHT4, DKHT5 and DKHT6 constructs (8 events from each construct) at any one location in Andhra Pradesh/Gujarat during appropriate season in 2012 subject to submission of NOC from the State Government where the trials will be conducted.

5.5 Permission to conduct event selection trials on 30 transgenic Rice (*Oryza sativa L.*) events using Bt constructs namely; Bt 39, Bt 40 and Bt 43 by M/s. E.I. Dupont India Pvt. Ltd., Dupont Knowledge Center, Hyderabad.

5.5.1 The Committee considered the application of M/s. E.I. Dupont India Pvt. Ltd., Dupont Knowledge Center, Hyderabad to conduct event selection trials on with 30 transgenic Rice (*Oryza sativa L.*) events using Bt constructs namely; Bt 39, Bt 40 and Bt 43. All the rice events and their corresponding null segregates (T3 generation) are derived from the following three Bt constructs, namely Bt39 (Cry1C + Cry2Ad), Bt40 (Cry1Ab + Cry2Ad) and Bt43 (Cry1C + Cry1Ab):

- The eight Bt rice events generated using Bt39 (Cry1C + Cry2Ad) construct, namely Bt39-101, Bt39-102, Bt39-103, Bt39-104, Bt39-105, Bt39-106, Bt39-107 and Bt39-108 of T3 generation.
- The twelve Bt rice events generated using Bt40 (Cry1Ab + Cry2Ad) construct, namely Bt40-101, Bt40-102, Bt40-103, Bt40-104, Bt40-105, Bt40-106, Bt40-107, Bt40-108, Bt40-109, Bt40-110, Bt40-111, and Bt40-112 of T3 generation.
- The ten Bt rice events generated using Bt43 (Cry1C + Cry1Ab) construct, namely Bt43-101, Bt43-102, Bt43-103, Bt43-104, Bt43-105, and Bt43-106, Bt43-107, Bt43-108, Bt43-109, and Bt43-110 of T3 generation.

5.5.2 The Committee noted that Bt rice events were generated using Agro bacterium mediated transformation of Indica inbred rice (IRV95). Co-transformation was done with 'two binary in one Agro' system, one binary containing two cry genes and another containing Hygromycin. Hygromycin was used as the selectable marker but was segregated out in the subsequent generation to generate marker free BT events. All 30 Bt rice events were determined to be single Bt copy insertion in the genome and efficacious against Yellow Stem Borer and Rice Leaf Folder in greenhouse and laboratory experiments. The trials are proposed at any two locations in Gujarat, Maharashtra, Andhra Pradesh or Tamil Nadu.

5.5.3 The Committtee also noted that the objective of the trial is to evaluate the efficacy of dual molecular stacked Cry genes in Bt rice events against Yellow stem borer (YSB) and rice leaf folder (RLF).

5.5.4 The Experimental design for conducting trials is SPD (Split Plot Design)

5.5.5 The Committee observed the following proposed isolation measures:

- Spatial isolation of 10 m from the row of transgenic plant on all four sides will be maintained as per guidelines.
- No cultivation of rice in the same plot during the post harvest restricted use period
- All the trials will be marked for clear identification
- The surplus planting material will be seedlings. The excess seedlings will be burnt at the trial site.
- Non transgenic IRV95 will be planted as controls.

5.5.6 The Committee also observed that the proposal has been recommended by IBSC in its 17th meeting held on 9.12.2011. The RCGM has recommended the proposal in its 109th meeting held on 24.1.2012.

5.5.7 The Committee also observed that the GEAC in its meeting held on 12.1.2011 and 21.9.2011 had accorded approval to M/s. E.I. Dupont India Pvt. Ltd., Dupont Knowledge Center to conduct event selection trials on transgenic rice events against Yellow Stem Borer and Rice Leaf

Folder pest using constructs Bt 38 (Cry1Ab+ Cry 2Ad), Bt39 (Cry1C+Cry2Ad), Bt40 (Cry1Ab+Cry2Ad) and Bt43 (Cry1C+Cry1Ab).

5.5.8 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 30 transgenic Rice (*Oryza sativa L.*) events using Bt constructs namely; Bt 39, Bt 40 and Bt 43 at any one locations in Gujarat, Maharashtra, Andhra Pradesh or Tamil Nadu during appropriate season in 2012 subject to submission of NOC from the State Government where the trials will be conducted.

5.6 Permission to conduct event selection trials on 20 transgenic SPT1 Rice (*Oryza sativa L.*) events containing *Zm-AA1, Os-Msca1* and *DsRed2* genes by M/s. E.I. Dupont India Pvt. Ltd., Dupont Knowledge Center, Hyderabad.

5.6.1 The Committee considered the application of M/s. E.I. Dupont India Pvt. Ltd., Dupont Knowledge Center, to conduct event selection trials on 20 transgenic Rice (*Oryza sativa L.*) events using SPT1 construct, namely : SPT1-4001, SPT1-4002, SPT1-4003, SPT1-4004, SPT1-4005, SPT1-4006, SPT1-4007, SPT1-4008, SPT1-4009, SPT1-4010, SPT1-4011, SPT1-4012, SPT1-4013, SPT1-4014, SPT1-4015, SPT1-4016, SPT1-4017, SPT1-4018, SPT1-4019, SPT1-4020 of **BC2** generation containing *Zm-AA1, Os-Msca1* and *DsRed2* genes. The trials will be conducted at any one of the three locations in Andhra Pradesh, Gujarat or Maharashtra.

5.6.2 The Committee noted that the Rice Seed Production Technology (Rice SPT) is a process that facilitates large-scale production of male sterile rice lines. These male sterile lines can be used as female inbred parents for subsequent hybrid seed production Rice SPT is a transgene based process for production of maintainer lines, rather than a trait or a product. The Rice SPT maintainer was generated by *Agrobacterium* mediated transformation of male sterile (*Os-mscal/Os-mscal)* mutant rice line with the plasmid SPT that contains three genes namely **,** *Os-Msca1(Modl), Zm-AA1,* and *DsRed2* (*Altl)* . These genes are essential for the functioning of the Rice SPT process.

5.6.3 The Committee also noted that the Rice SPT events were generated in Japonica rice line M2O2 using *Agrobacterium* mediated transformation using SPT1 vector. After molecular characterization, single copy events were backcrossed into the Pioneer inbred line VIR54G9, All the twenty events proposed in this trial have 3 doses of indica inbred genome. These BC4F2 (back cross) plants will be used as pollinator parent to produce the seeds on non-transgenic male sterile line. Since the events are in inbred background and not in hybrid, 10 meter isolation distance will be maintained in this trial.

5.6.4 The Committee observed the following objectives of the trial:

- assess the frequency of transgene transmission through pollen in different events.
- assess the seed producibility of the events
- evaluate the expression levels of DsRed 2 and ZM-AA1 proteins in tissues of Rice SPT manitainer.

5.6.5 The Committee further noted the following proposed isolation measures:

1. Spatial isolation of 10 m from the row of transgenic plant on all four sides will be maintained.
2. Distance to the nearest cultivated crop of the same species >220 m.
3. Non transgenic VIR54G9 will be planted as the controls.

5.6.6 The experimental design for conducting trials is CRD (Completely Randomized Design).

5.6.7 The Committee also observed that the proposal has been recommended by IBSC in its 17th meeting held on 9.12.2011. The RCGM has recommended the proposal in its 109th meeting held on 24.1.2012.

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5.6.8 The Committee also observed that the GEAC in its meeting held on 12.1.2011 had accorded approval to M/s. E.I. Dupont India Pvt. Ltd., Dupont Knowledge Center, Hyderabad to conduct event selection on seven transgenic rice events namely; DKC118, DKC45, JH02, JH04, JH11, JH22, and JH25a of BC4 containing *DsRed2-Os-Msca1-ZM-AA1* gene (Hybrid Rice SPT maintainer events to maintain male sterile female parental lines) generated using the SPT1 construct for use in hybrid seed production

5.6.9 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 20 transgenic SPT1 Rice (*Oryza sativa L.*) events containing *Zm-AA1, Os-Msca1* and *DsRed2* genes at any one location in Andhra Pradesh/Gujarat or Maharashtra during appropriate season in 2012 subject to submission of NOC from the State Government where the trials will be conducted.

5.7 Permission to conduct event selection trials on 20 transgenic SPT6 Rice (*Oryza sativa L.*) events containing *Os-Msca, Zm-AA1* and *DsRed2* genes. by M/s. E.I. Dupont India Pvt. Ltd., Dupont Knowledge Center, Hyderabad.

5.7.1 The Committee considered the proposal of M/s. E.I. Dupont India Pvt. Ltd., Hyderabad to conduct event selection trial on 20 transgenic rice events (Hybrid Rice SPT maintainer events to maintain male sterile female parental lines) generated using the SPT6 construct namely; SPT6-2001, SPT6-2002, SPT6-2003, SPT6-2004, SPT6-2005, SPT6-2006, SPT6-2007, SPT6-2008, SPT6-2009, SPT6-2010, SPT6-2011, SPT6-2012, SPT6-2013, SPT6-2014, SPT6-2015, SPT6-2016, SPT6-2017, SPT6-2018, SPT6-2019, SPT6-2020 of BC2 generation containing Os-Msca1-ZM-AA1-DsRed2 gene. The trial will be conducted at any one of the locations in Andhra Pradesh, Gujarat or Maharashtra during Kharif 2012.

5.7.2 The Committee noted that the SPT6 events were generated in M2O2 Japonica line which has a dose of T65 rice line genome. This Japonica line was used for transformation of SPT genes. The transgenic events were then backcrossed with Pioneer's Indica rice line VIR54G9. BC2F2 seeds will be used for planting. All the events are single copy events containing *Os-Msca, Zm-AA1 and DsRed2* genes.

5.7.3 The Committee also noted that Rice Seed Production Technology (Rice SPT) is a process that facilitates large-scale production of male sterile rice lines. These male sterile lines can be used as female inbred parents for subsequent hybrid seed production Rice SPT is a transgene based process for production of maintainer lines, rather than a trait or a product. The Rice SPT maintainer was generated by *Agrobacterium* mediated transformation of male sterile (*Os-mscal/Os-mscal)* mutant rice line with the plasmid SPT6 that contains three genes namely **,** *Os-Msca1(Modl), Zm-AA1,* and *DsRed2* (*Altl)* . These genes are essential for the functioning of the Rice SPT process.

5.7.4 The Committee further noted that the purpose of the trials is:

1. To assess the frequency of transgene transmission through pollen in different events.
2. To assess the seed producibility of the events.
3. To evaluate the expression levels of DsRed2 and ZM-AA1 in tissues of Hybrid Rice SPT maintainer events.

5.7.5 The Committee considered the following proposed isolation measures:

- Spatial isolation of 10 m from the row of transgenic plant on all four sides will be maintained.
- Distance to the nearest cultivated crop of the same species >200 m.
- Non transgenic VIR54G9 will be planted as the controls.

5.7.6 The Committee also observed that the proposal has been recommended by IBSC in its 17th meeting held on 9.12.2011. The RCGM has recommended the proposal in its 109th meeting held on 24.1.2012.

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5.7.7 The Committee observed that the GEAC in its meeting held on 12.1.2011 had accorded approval to M/s. E.I. Dupont India Pvt. Ltd., Dupont Knowledge Center for event selection trial on transgenic rice events namely; J6-1-139c, J6-1-129d, J6-3-36a, J6-3-31-4c, J6-2-16c, J6-4-M-1a of **BC2** and J6-1-130, J6-1-76-3a, J6-1-142d, J6-1-105h, J6-3-33-3c, J6-350b, J6-3-6'a, J6-2-10b and J6-1-126c of **BC1** generation containing *Os-Msca1-ZM-AA1-DsRed2* gene.

5.7.8 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 20 transgenic SPT6 Rice (*Oryza sativa L.*) events containing *Os-Msca, Zm-AA1* and *DsRed2* genes at one of the location in Andhra Pradesh /Gujarat or Maharashtra during appropriate season in 2012 subject to submission of NOC from the State Government where the trials will be conducted.

5.8 Permission to conduct event selection trials on SPT transgenic Rice (*Oryza sativa L.*) events containing *Os-Msca, Zm-AA1* and *DsRed2* genes. by M/s. E.I. Dupont India Pvt. Ltd., Dupont Knowledge Center, Hyderabad.

5.8.1 The Committee noted that the application of M/s. E.I. Dupont India Pvt. Ltd., Dupont Knowledge Center for conduct of event selection trials of SPT1 and SPT6 constructs on transgenic rice containing *Os-Msca1-ZM-AA1-DsRed2 gene* was approved by the GEAC in its meeting held on 12.5.2010, 15.9.2010 and 12.1.2011. Details are as follows:

- SPT1 Events (generated using SPT1 construct), namely DKC118, DKC45, JH02, JH04, JH11, JH22 and JH25a containing Zm-AA1-Os-msca1-DsRED2 genes of BC4 generation and
- SPT6 events (generated from SPT6 construct) namely, JH 15b, JH 16a, JH 16b, JH 17, JH 25b, JH 26a, JH 36, J6-1-45a, J6-1-8, J6-1-4d, J6-1-10b, J6-1-7d in its J6-1-139c, J6-1-129d, J6-3-36a, J6-3-31-4c, J6-2-16c, J6-4-M-1a of BC2 and J6-1-130, J6-1-76-3a, J6-1-142d, J6-1-105h, J6-3-33-3c, J6-3-50b, J6-3-6'a, J6-2-10b, J6-1-126c of BC1 generation.

5.8.2 The Committee also noted that the present request of the Company is to retest the selected events from advanced generation of the constructs SPT1 and SPT6. The three events generated using SPT1 construct of BC5 generation and ten events from SPT6 construct of BC4 generation are being re-tested as per details given below:

- **SPT1** construct: JH04, JH02, DKC45 containing *ZM-AA1-Os-MSCA1-DsRED2* genes.
- **SPT6** construct: J6-1-105h, J6-1-126c, J6-1-129d, J6-1-130, J6-1-139c, J6-1-142d, J6-1-76-3a, J6-2-16c, J6-3-31-4c, J6-4-M-1a containing *ZM-AA1-Os-MSCA1, DsRED2* genes .

5.8.3 The Committee also noted that these events were developed by transforming M2O2 (Japonica line)X T65 (rice lines) lines and then backcrossed into VIR54G9 (Pioneer's indica rice lines). All events are single copy events. This technology enables maintenance of male sterile female parental lines for use in hybrid seed production.

5.8.4 The Committee further noted that the objective of the trials is to asses:

- frequency of transgene transmission through pollen in different events.
- seed producibility of the event.
- expression levels of DsRed2 and ZM-AA1 in the tissues of hybrid rice SPT maintainer events.

5.8.5 The Committee observed that the event selection will be conducted at one location among the three locations in Andhra Pradesh, Gujarat or Maharashtra.

5.8.6 The Committee also observed the following proposed isolation measures:

- 10 m isolation distance from the last row of transgenic plant on all four sides will be maintained (as inbred lines will be used).
- 8 ft tall polythene sheets as barriers between each event.

5.8.7 The Committee also observed that the proposal has been recommended by IBSC in its 17th meeting held on 9.12.2011. The RCGM has recommended the proposal in its 109th meeting held on 24.1.2012.

5.8.8 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 SPT transgenic Rice (*Oryza sativa L.*) events containing *Os-Msca, Zm-AA1* and *DsRed2* genes at one location in Andhra Pradesh /Gujarat / Maharashtra during appropriate season in 2012 subject to submission of NOC from the State Government where the trials will be conducted.

5.9 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

5.9.1 The Committee noted that the request of M/s. BASF India Ltd., New Delhi 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) was considered by the GEAC in its meetings held on 21.9.2011 wherein the Committee had requested Dr Arjula Reddy, Co-Chair to examine the proposal and give his views.

5.9.2 The Committee considered the views of Dr Arjula Reddy, Co-Chair in the 114th meeting held on 14.12.2011 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".*

5.9.3 The Committee taking into consideration the information submitted by the Company, approved the request 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) during appropriate season in 2012 subject to submission of NOC from the State Government where the trials will be conducted.

5.10 Permission to conduct Biosafety Research Level-1 (BRL-1) trials on two transgenic maize (*Zea mays L.*) hybrids namely Hishell & 900 M Gold containing event MON 89034 by M/s. Monsanto India Ltd. (MIL), New Delhi

5.10.1 The Committee considered the application of M/s. Monsanto India Ltd to conduct BRL-I trials on transgenic Maize hybrids namely Hishell & 900M Gold containing Event MON NK603 at any three locations in Anand (Gujarat); Aurangabad (Maharashtra); Karnal (Haryana) or Dharwad (Karnataka) during Kharif season and at Anand (Gujarat), Coimbatore (Tamil Nadu), Dharwad (Karnataka) or Hyderabad (Andhra Pradesh) during Rabi season.

5.10.2 The Committee noted that the transgenic hybrid corn event Mon 89034 produces two structural different Bt proteins, Cry 1A.105 and Cry2Ab2 which are highly efficacious against a variety of lepidoptern insect pests. The transgenic maize hybrid provides tolerance to the target pests of maize viz. stem borers (*chilo partellus and Sesamia inferns*) and cob borer (*Helicoverpa arimigera*).

5.10.3 The Committee also noted that the MON 89034 is 2nd generation Bt corn technology effective against lepidopteron insect pests with a unique dual mode of action. MON 89034 produces the Cry1A.105 and Cry2Ab2 proteins derived from *Bacillus thuringiensis*, for consistent and enhanced control of the target lepidopteron insect pests.

5.10.4 The Committee further noted that the objectives of the proposed trial as under:

i) To study efficacy of insect resistant transgenic corn (MON 89034) hybrids against target *lepidopteran* pests and monitor occurrence of beneficial and non-target insects on transgenic corn hybrids, non-transgenic counterparts and checks.
ii) To study the level of expression of candidate proteins expressed by the inserted genes in plant tissues at regular intervals during the growing season/trial period at selected locations.
iii) To generate baseline susceptibility data of candidate protein on representative insect pest population of key target lepidopteran pests i.e *Chilo partellus* and *Helicoverpa armigera* insects pests collected from various locations.
iv) To produce sufficient plant material to undertake research on food and feed safety studies and compositional analysis.

5.10.5 The Committee was informed that the following information has been uploaded in the IGMORIS website:

i) Molecular characterization of MON 89034.
ii) Validation of detection protocol at LOD of 0.1% from National Botanical Research Institute, Lucknow.
iii) Thermal Stability of Cry1A.105 and Cry2Ab2 proteins.
iv) Pepsin digestibility of Cry1A.105 protein.
v) Pepsin digestibility of Cry2Ab2 protein.
vi) Acute oral toxicity study of Cry1A.105 protein.
vii) Acute oral toxicity study of Cry2Ab2 protein.
viii) Bioinformatics analysis against TOXIN database for Cry1A.105 protein.
ix) Bioinformatics analysis against allergen database for Cry1A.105 protein.
x) Bioinformatics analysis against TOXIN database for Cry2Ab2 protein.
xi) Bioinformatics analysis against allergen database for Cry2Ab2 protein.
xii) Compositional analysis of corn forage and grain of MON 89034.

5.10.6 The Committee also considered the following proposed isolation measures:

- An isolation distance of 300 m will also be maintained surrounding the trial plot area.
- Thirteen border rows of African Tall maize will also be planted surrounding the trial plot.
- Any alternate recommended methods will be deployed based on need which may include temporary isolation of the trial plot.

5.10.7 The Committee observed that the single event MON 89034 is approved for cultivation in six countries and as stack of MON 89034 x NK603 in Brazil, Canada, Philippines, South Africa and USA.

5.10.8 The Committee also observed that the proposal has been recommended by IBSC in its meeting held on 3.11.2011. The RCGM has recommended the proposal in its 109th meeting held on 24.1.2012.

5.10.9 In view of the above stated facts and taking into consideration the recommendations of RCGM, the Committee approved the request to conduct Biosafety Research Level-1 (BRL-1) trials on two transgenic maize (*Zea mays L*.) hybrids namely Hishell & 900 M Gold containing event MON 89034 during appropriate season in 2012-13 and 2013-14 subject to submission of NOC from the State Government where the trials will be conducted.

5.11 Request for change of location to conduct Biosafety Research Level-1 (BRL-1) trials on two transgenic maize (*Zea mays L.)* hybrids containing *cry1F, cry2Ab* & *cp4epsps* genes from ANGRAU, Hyderabad to AAU, Anand, Gujarat and TNAU, Coimbatore to DSKAU, Dantiwada, Gujarat by M/s. Pioneer Overseas Corporation, Hyderabad.

5.11.1 The Committee noted that the GEAC in its meeting held on 6.7.2011 had accorded approval for conduct of BRL-I trials on two transgenic maize (*Zea mays L.)* hybrids containing *cry1F, cry2Ab* & *cp4epsps* genes at the following locations:

1. Regional Agricultural Station, CCS Haryana Agricultural University, Karnal, Haryana
2. University of Agricultural Sciences, Dharwad, Karnataka
3. Acharya N. G. Ranga Agricultural University, Hyderabad, Andhra Pradesh
4. Maharana Pratap University of Agriculture and Technology, Udaipur, Rajasthan
5 Punjab Agricultural University, Ludhiana, Punjab
6. Tamil Nadu Agricultural University, Coimbatore, Tamil Nadu

5.11.2 The Committee noted that the applicant has informed that NOCs from the States of Andhra Pradesh and Tamil Nadu have not been received; while the State of Haryana has granted the NOC. Therefore, they have requested the GEAC to change the location of BRL-I trials from Andhra Pradesh and Tamil Nadu to two locations in Gujarat.

5.11.3 The Committee also noted that the RCGM has recommended the request in its 109th meetings held on 24.1.2012.

5.11.4 In view of the above stated facts and taking into consideration the recommendations of RCGM, the Committee approved the request for change of location to conduct BRL-1 trials on two transgenic maize (*Zea mays L.)* hybrids containing *cry1F, cry2Ab* & *cp4epsps* genes from ANGRAU, Hyderabad to AAU, Anand, Gujarat and and from TNAU, Coimbatore to DSKAU, Dantiwada, Gujarat during appropriate season in 2012-13 and 2013-14 subject to submission of NOC from the State Government where the trials will be conducted.

5.12 Request for extension of the validity period and change of location to conduct event selection trials with transgenic rice generated using SPT1 and SPT6 construct from Koppalapally (AP) during 2011 to Gujarat or Maharashtra during 2012 by M/s. E. I. DuPont, Hyderabad.

5.12.1 The Committee noted that the GEAC in its meeting held on 15.9.2011 had granted approval for conducting event selection trials with transgenic rice generated using SPT1 and SPT6 constructs during 2011 at Koppalapally, Andhra Pradesh.

5.12.2 The Committee also noted that the applicant has now informed that they could not conduct the event selection trials on time because of delay in getting NOC from the Govt of Andhra Pradesh. Therefore they have requested the GEAC to extend their validity to conduct event selection trials during 2012-2013 in Maharashtra/ Gujarat.

5.12.3 The Committee also noted that the RCGM has recommended the request in its 109th meeting held on 24.1.2012.

5.12.4 In view of the above stated facts and taking into consideration the recommendations of RCGM, the Committee approved the request for extension of the validity period and change of location to conduct event selection trials with transgenic rice generated using SPT1 and SPT6 construct at Gujarat or Maharashtra during appropriate season in 2012-2013 subject to submission of NOC from the State Government where the trials will be conducted.

5.13 Request for extension of the validity period to conduct of BRL-1 trial on Glytol cotton (*Gossypium hirsutum*) hybrids namely SP7139 G and SP7230 G containing *2mEPSPS* gene in Central zone (Gujarat) from Kharif 2011 to Kharif 2012 & 2013 by M/s. Bayer BioScience Pvt. Ltd., Gurgaon

5.13.1 The Committee noted that the GEAC in its meeting held on 6.7.2011 had accorded approval for conduct of BRL-I trials with herbicide tolerant Glytol cotton hybrids containing *2mEPSPS gene* at Rajkot, Gujarat.

5.13.2 It was also noted by the Committee that the applicant has informed that they have received NOC from Gujarat State Government. However, since receipt of NOC was delayed, the BRL-I trials could not be conducted during 2011. Therefore, they have submitted a request for extension of the validity period to conduct BRL-I trials during 2012-2013.

5.13.3 The Committee also noted that the RCGM has recommended the request in its 109th meeting held on 24.1.2012.

5.13.4 In view of the above stated facts and taking into consideration the recommendations of RCGM, the Committee approved the request for extension of the validity period to conduct of BRL-1 trial on Glytol cotton (*Gossypium hirsutum*) hybrids namely SP7139 G and SP7230 G containing *2mEPSPS* gene in Gujarat during appropriate season in 2012 and 2013 subject to submission of NOC from the State Government where the trials will be conducted.

5.14 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

5.14.1 The Committee noted that the GEAC in its meeting held on 14.12.2011 had 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) wherein the applicants were advised to submit the following information in writing for consideration of the GEAC:

- 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.

5.14.2 The Committee taking into consideration the information submitted by the applicant, approved the request for conduct of event selection trials on transgenic rice (*Oryza sativa L.*) Events namely MW-01 to MW-25 containing *AlaAt* gene during appropriate season in 2012 subject to submission of NOC from the State Government where the trials will be conducted.

Agenda Item No 6 : Consideration of applications related to Pharmaceuticals

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

6.1.1 The Committee noted that the request of M/s Zydus Animal Health Care, Ahmedabad for import of 'Gumbin VP_2' Inactivated poultry vaccine from Abic Biological Laboratories Ltd, Israel was considered by the GEAC in its meeting held on 14.12.2011. Decision on the proposal was deferred for want of comments from the Department of Animal Husbandry, Ministry of Agriculture and other experts.

6.1.2 The Committee taking into consideration views of the Experts and the Department of Animal Husbandry, Dairying & Fisheries, approved the request for import of 'Gumbin VP_2' Inactivated poultry vaccine from Abic Biological Laboratories Ltd, Israel.

Agenda Item No 7 : Other items

7.1 Press Report regarding violation of Patent issues concerning Bikaneri Nerma (BN Bt Cotton) variety approved by the GEAC.

7.1.1 The Committed noted that issues raised in the Press Report dated December 30, 2011 regarding Bikaneri Nerma (BN Bt cotton variety) are of a serious nature and action needs to be taken to ensure such situations which questions the credibility of public institutions do not arise in future.

The Committee discussed the matter in the absence of Dr B. M. Khadi who was the former Director, CICR, Nagpur during the BN Bt (Variety) approval process. The Committee requested DDG, ICAR to brief the Committee on the factual position. He informed that ICAR has constituted an 'Inquiry Committee' to look into the matter. He further informed that he would not like to comment on the matter until the report of the Inquiry Committee is received.

7.1.2 To a query on whether the regulatory process related to biosafety assessment has been compromised in any way, some members opined that the regulatory process may have been compromised in way of conflict of interest. The Committee also noted the following facts of the case:

(i) The Research and development of Bikaneri Narma (BN) Bt (variety) and NHH 44 Bt including multi-locational field trials by CICR was initiated with the approval of RCGM. The proposal for large scale trials (LST) was referred to the GEAC by the RCGM only in 2007. The recommendation of RCGM was based on the biosafety data presented by Director CICR, Nagpur with respect to toxicity, allergenicity and feeding studies in small laboratory animals (rats, rabbits & guinea pigs); livestock animals (cows & goats), birds (chicken), fish; gene flow, out crossing, impact on non-target organism and soil biota in the RCGM meeting held on 22.5.2007. While recommending the proposal for LST and ICAR trials and seed production in the North, Central and South zone, RCGM also observed that the applicant has not completed the following requirements:

- Feeding studies in large animals (cows and goats);
- The Institute has not submitted a validated event-specific test protocol at a LoD of at least 0.01 % as per the requirement of Supreme Court Order;

As the above studies are in progress and the data will be available within six months, RCGM recommended that the GEAC may consider according approval for LST and ICAR trials and seed production.

(ii) The Committee noted the chronological sequence of events subsequent to RCGM recommendation falls under the purview of the GEAC and is as given under:

a. The recommendations of RCGM and application submitted by CICR, Nagpur was considered by the GEAC in its meeting held on 22.6.2007 wherein it was noted that (i) BN Bt (variety) and NHH 44 Bt indigenously developed transgenic cotton developed by CICR expresses Bt cry 1 Ac (Truncated and codon-modified) gene which is very similar to the Cry 1Ac toxin expressed by MON 531 event developed by M/s Monsanto as well as event 1 of IIT, Kharagpur both of which are already under commercial cultivation; (ii) The Bt technology has been deployed for the first time in a known varietal background; (iii) BN Bt (variety) was developed by CICR in accordance with the prescribed protocol and procedures and after obtaining the approval of RCGM; and (iv) The biosafety studies conducted by the Institute so far indicate that there is no adverse effects on the environment and human health. However, the GEAC after detailed deliberation recommended that the request for LST and ICAR trials and seed production will be recommended only after completion of the biosafety studies and submission of event specific test protocol at LoD of 0.01%.

b. On completion of the feeding studies and submission of event-specific test protocol, the request of CICR for LST and ICAR trials and seed production of BN Bt (variety) and NHH44 Bt in the North zone was considered by the GEAC meeting held on 2.4.2008. During the deliberations, the following points emerged:

- Bt technology has been for the first time introduced in a varietal background whereby the farmers can save the seeds.
- Bt technology has been introduced in a popular and well established agronomic background.
- No cost to the trait value which would provide cheaper options to the farmers.
- Adequate data on Cry 1Ac protein is available.
- The seeds generated during the trials would be made available to the farmers free of cost.

c. The Committee noted that in the above meeting, the Supreme Court invitee, Dr P.M. Bhargava opined that since the Bt crops expressing cry1 Ac toxin is already under commercial cultivation and in the national interest, he suggested that as an exceptional and unique situation, the GEAC may consider commercial release of the BN Bt (variety). However, CICR, Nagpur informed that currently seeds are available only for LST and ICAR trials. The GEAC further opined that several public sector institutions are developing new GM crops with new traits and therefore it is advisable that the regulatory procedure is complied with in all cases.

d. In light of the above discussions, the GEAC in its meeting held on 2.4.2008 approved the LST and ICAR trials and seed production in an area of 100 hectares in the North zone.

e. In the GEAC meeting held on 2.5.2008, the request of CICR for LST and ICAR trials and seed production of BN Bt (variety and NHH 44 Bt in the Central and South zones was considered by the GEAC wherein it was felt that there is a need for review of the decision directing CICR to conduct larger scale trials with the BN Bt (variety) on the following grounds:

- Bt technology has been for the first time introduced in a varietal background whereby the farmers can save the seeds;
- Bt technology has been introduced in a popular and well established agronomic background; and
- No cost to the trait value which would provide cheaper options to the farmers and
- approvals for LST for a variety and a hybrid have a different implications because in the case of a variety, approval for large scale trials would tantamount to commercial release as the farmers can save the seeds for planting in the next season.

f. In light of above discussions, the GEAC in its meeting held on 2.5.2008 approved the commercial release of BN Bt (variety) developed by CICR in the North, Central and South zones. In the same meeting NHH 44 Bt was approved for LST and ICAR trials and seed production in an area of 100 ha in the Central and South zones.

g. On completion of the LST and ICAR trials, the GEAC approved the commercial release of NHH 44 Bt in the meeting held on 13.5.2009.

7.1.3 The Committee observed that subsequent to the approvals granted by the GEAC, the Committee has not received any complaint or information from CICR/ICAR indicating that seed production of BN Bt (variety) or NHH 44 Bt (hybrid) has been discontinued as it contains Cry 1Ac gene MON 531 event; which is a proprietary of M/s Monsanto. On this matter, the Committee observed that this case also highlight the need of post release surveillance with regard to commercial performance of approved events. It was suggested that the applicants may be directed to submit an annual performance report giving the following information for a period of five years.

- Total area under cultivation with hybrid/event containing the particular event/s in a given year.
- Break-up of the same, state-wise?
- Critical feedback provided by farmers/seed producers.

7.1.4 During the detailed deliberation on the matter, one of the members opined that it's the agronomic performance of the material which is being questioned and not the biosafety studies. He noted that this is very surprising considering the excellent agronomic data presented by CICR to the GEAC during the BN Bt review process. He further emphasized that there is a need for setting up an independent testing laboratory to verify claims made by the developer.

7.1.5 On the issue of the regulatory process being compromised in way of Conflict of Interest, the Committee acknowledged that some steps have been taken to address the issue of Conflict of Interest in accordance with decisions taken in the GEAC meetings held on 8.12.2010 and 06.07.2011. The Committee further reiterated that it would continue to address this issue continuously and in a more comprehensive manner. The Chairman, GEAC further informed that the tenure of the current GEAC is coming to an end in March 2012 and accordingly, the process of reconstituting the GEAC has been initiated. This process, to a large extent, will address the issue of conflict of interest.

7.1.6 The Committee further noted with satisfaction that ICAR has constituted an Inquiry Committee with exhaustive Terms of Reference which is adequate to cover the entire process of research, development and commercialization of BN Bt (Variety) by CICR which was approved by the GEAC and other related allegations. DDG, ICAR further informed that CICR, Nagpur has been directed to keep all the disputed materials in safe custody to assess if that is the same material evaluated while doing biosafety studies. After detailed deliberation, the Committee decided to await the outcome of the report of the Inquiry Committee constituted by ICAR before deliberating on the further course of action.

7.2 Request from M/s Navbharat Seeds Pvt. Ltd to form IBSC and renewal of R & D unit which is withheld by Ministry of Science and Technology on the instructions of GEAC.

7.2.1 The Committee noted that M/s Navbharat Seeds Pvt. Ltd has been pursuing with the Department of Scientific and Industrial Research (DSIR) and DBT for recognition of the Navbharat R & D Centre and formation of IBSC respectively which was earlier revoked on the instructions of GEAC in view of the involvement of M/s Navbharat Seeds Pvt Ltd in the illegal production and sale of transgenic Bt Cotton seeds under the brand name 'Navbharat 151'. The basis for the request is on the following grounds:

1. Criminal complaint filed by the GEAC in the Court of Chief Metropolitan Magistrate's Ahmedabad vide Order dated 5.3.2009 from the Chief Metropolitan Magistrate's Court, Ahmedabad, has dismissed the complaint and accused are acquitted.

2. The Special Civil Application no 15431 of 2003 file by the Company in the Gujarat High Court against MoEF and NEAA has been withdrawn on 30.6.2010.

7.2.2 The Committee was briefed about the background of the above matter which is as given below:

i. M/s Navbharat Seeds Pvt Ltd in 2011 had released transgenic Cotton under the brand name 'Navbharat 151' in Gujarat without the approval of the GEAC. The GEAC had directed the State Government to take appropriate action vide Order dated 18.10.2002 and 02.11.2002 after scientific verification of the fact based upon field inspection that the 'Navbharat 151' was transgenic. An opportunity was also given to the MD of the Company to explain the findings to the GEAC. However the MD failed to appear before the GEAC.

ii. As per the GEAC's direction, the production, sale and cultivation of Navbharat 151 is prohibited. The State Government had cancelled the Company's license. The license issued by DSIR had also expired and the same has not been renewed till date.

iii. The GEAC had filed a criminal complaint no. 1286/2001 against Navbharat Seeds Pvt. Ltd. in the Court of Chief Metropolitan Magistrate, Ahmedabad in 2001 for violation of Rule 7, 8, 9 & 10 of the Rule, 1989 and revised guidelines of 1998; thereby making the accused punishable under Section 15 of EPA, 1986.

iv. In response to the GEAC's direction, an appeal was preferred by M/s Navbharat Seeds Pvt. Ltd. in Appeal No 1/2002 before the National Environmental Appellate Authority (NEAA) against the decision of the GEAC. The Appeal was disposed of on 19.9.2003 by NEAA in favor of GEAC.

v. M/s Navbharat Seeds Pvt Ltd. challenged the decision of GEAC and NEAA vide Special Civil Application no 15431 of 2003. After regular follow up with the Central Government Standing Counsel in High Court of Gujarat, Counter Affidavit was filed by the Ministry in February 2010. The case was subsequently withdrawn vide Hon'ble High Court of Gujarat order dated 30.6.2010.

vi. As regards the criminal complaint filed by the GEAC in the Court of Metro Politian Magistrate, Ahmedabad, the case continued in the Court for a long period and there has been no progress in the proceedings due to non-appearance of the Advocate for the

Ministry. Since the official of the Ministry was exempted from personal appearance (Section 200 of CrP) in the Court, notice about the date of hearing was communicated to the Advocate only and not directly to the Ministry. Accordingly, the notice for hearing for most of the time did not reach the MoEF. It has only recently been brought to the notice of the Ministry through a communication from M/o Science & Technology that the Chief Metropolitan Magistrate's Court, Ahmedabad, vide Court Order dated 5.3.2009 has dismissed the complaint in the absence of Complainant or their advocate and accused are acquitted.

7.2.3 The Committee noted that the fresh application dated 19.08.2010 submitted by the Company for re-recognition of their R&D centre was considered by the DSIR Screening Committee meant for recommendation of recognition of R&D centres. The Screening Committee desired to obtain views of MoEF, DBT and ICAR on the case before considering recognition to R&D centre for the Company. Accordingly, DSIR has requested the Ministry to convey to DSIR whether the Company could be considered as free from controversy regarding Bt cotton germplasm and therefore could be considered for re-recognition for their R&D centre based on their R&D infrastructure, R&D programmes and past R&D achievements. Alternatively, they have suggested that MoEF may kindly sort out other issues separately with the Company.

7.2.4 During the deliberations, Member Secretary RCGM informed that DBT has already approved the constitution of IBSC on the basis of the Court Order dated 5.3.2009.

7.2.5 After a detailed discussion, the Committee opined that the criminal case in the CMM court has been disposed off on grounds that the Government Counsel has not appeared and not on merit. It was noted that M/s Navbharat Seeds Ltd has not been acquitted of charges made against him for release of illegal Bt cotton hybrids in the name of 'Navbharat 151' which is a punishable offence under Section 15 of the EPA, 1986. The Committee therefore recommended that MoEF may take immediate action to file an appeal on the basis of legal advice. The Committee also expressed deep concern on the callous manner in which the Government Counsel in Gujarat has handled the matter of such a serious nature and further recommended that the case be shifted to Delhi from Gujarat.

7.2.6 As regards the request for re-recognition of the R&D centre or approval for constituting the IBSC, the Committee advised that necessary instructions may be issued to DSIR not to renew the recognition for the R&D centre. The Committee also advised Member Secretary RCGM to withdraw the approval granted by DBT for constituting the IBSC immediately.

Agenda Item No 8 : Any Other item with the permission of the Chair.

8.1 Representation from Coalition for GM Free India regarding Violation of GM field trial norm during the field trials of GM Maize in Karnataka.

8.1.1 The Committee considered the representation received from M/s Coalition for GM Free India informing that M/s Monsanto India Limited has violated the Biosafety norms during the BRL-II trials with transgenic maize expressing stacked events, namely, MON89034 and NK603 at UAS, Dharwad in Karnataka during Rabi 2010. It was informed that the representation is based on the RTI information obtained from the Ministry wherein it was noted that the Compliance Committee Report of 5 May 2011 has recommended "*Before planting NK 603 event treatment in future, the permission from competent authority may be obtained*". This has been construed as a case where field trials have been conducted using herbicide tolerant maize (NK603) without the approval of the GEAC.

8.1.2 The Committee was briefed about the facts of the case pertaining to BRL-II trials of transgenic Maize at UAS Dharwad as follows:

S.No.	Date	Chronology of events
1.	12.11.2008, 12.06.2009, 14.10.2009,	The GEAC had approved the recommendations of RCGM to allow BRL-I trials on two transgenic corn hybrids namely Hishell & 900M Gold containing stacked *cry2Ab2, cry1A 105* (Event MON 89034) &

	12.05.2010	*CP4EPSPS* (Event NK603) genes by M/s. Monsanto India Ltd., New Delhi. BRL-I trials were conducted during Kharif and Rabi 2009-2010 for two seasons each. The protocol/experimental design for BRL-I trials submitted by the applicant for field trials did not include the treatment with event NK603 as a comparator. BRL-I monitoring report indicates that the trials are in order.
2.	07.09.2010	Application for BRL-II trials submitted to RCGM on 7.9.2010.
3.	29.10.2010	RCGM advised the applicant to approach GEAC as the BRL-II trials did not fall under the mandate of RCGM. However, it may be noted that recommendations of RCGM based on BRL-I trial data and other biosafety data generated by the applicant is necessary.
4.	15.11.2010	The GEAC in its 104th meeting approved the request of the applicant to conduct BRL-II trials at nine locations. The objective of the trial and documents placed before the GEAC including experimental field design indicated inclusion of the treatment with event NK603 as a comparator. Consent of the concerned SAUs were also submitted by the applicant. BRL-I monitoring report indicated that the trials are in order.
5.	24.12.2010	GEAC approval letter was issued subject to condition that the trials will be carried out as per the protocol prescribed by the GEAC and Director, Directorate of Maize Research (DMR).
6.	03.01.2011	Director, DMR informed that the protocol submitted by the applicant is in order. However, he suggested the following to test the transgenic corn against insect pest : (a) Black headed stage of eggs in whorl @15 eggs/plant for *Chilo partellus* at 10-15 days after germination. (b) Neonate larvae in the whorl @ 15 larvae/plant for *Sesamia inferans* at 10-15 days after germination. (c) 5 eggs of *Helicoverpa* per plant in the silk for *Helicoverpa armigera.*
7.	07.02.2011	Director, DMR informed that due to difficulties faced in releasing stem borer for BRL-II trials, the following measures have been taken to study the impact of Bt gene on insect pests: 1. The evaluation of stem borers and corn ear worm in green house. 2. At least at one centre in Kharif and one centre in rabi. 30 percent plants should be artificially infested as suggested earlier. He also informed the composition of the monitoring team. 1. Dr. R.Saikumar/Dr. Pradyumn Kumar from DMR 2. Trial In Charge-from trial station 3. Local Entomologist from trial station 4. Local Breeder from trial station 5. Local Agronomist from trial station 6. DBT representative
8.	24.2.2011	Member Secretary GEAC informed that names of experts should be indicated and those included in the monitoring team should be free of any conflict of interest and should sign the Statement of Declaration of Independence. It was also advised that BRL-II trials are being conducted under the aegis of GEAC and therefore a representative of GEAC may be included in place of DBT representative. Dr B.M. Khadi was suggested as GEAC representative as he was located in UAS Dharwad.
11.	09.3.2011	Director, DMR informed that the monitoring team comprising of the following members has been constituted to monitor GM Maize trial in

		UAS, Dharwad: 1. Dr R. Sai Kumar, Project Director, DMR/ Dr Pradyumn Kumar, Principal Scientist, DMR (Entomologist) 2. Dr A.K. Singh/Dr C.M.Parihar/Dr S.L.Jat (Maize Agronomist) 3. Dr Avinash Singode/Dr Chikappa G. Karjagi/ Dr Manivannan – Maize Breeder 4. Dr B.M. Khadi, Dean PGS UAS Dharwad (GEAC Nominee)
13.	10.05.2011	Monitoring Report of BRL-II trials at UAS Dharwad received. While the compliance assessment of the monitoring team indicated that there is no compliance deviation, in Part G of the additional comments of the monitoring proforma, it has been indicated that "before planting NK603 event treatment in future, the permission of competent authority may be obtained". This was around the same time when the GEAC issued show cause notice to M/s Mahyco for use of RR Flex as refugia in the BG-II RRF trials. Subsequently, in the 112th GEAC meeting held on 21.9.2011, the GEAC had issued a warning to M/s Mahyco and also decided not to consider the data generated during the BRL-II trials which was in violation to the provision of Rules 1989.
14.	26.5.2011	M/s Monsanto has informed Director, DMR that they have submitted a letter to GEAC for change in trial location and they would like to revise the protocol excluding NK 603 treatment.
15.	06.07.2011	Representation received regarding alleged violation of norms and procedures by M/s Monsanto while undertaking seed production of transgenic corn in Bijapur District of Karnataka.
16.	19.07.2011	The State Government was requested to investigate the matter and submit a factual report.
17.	22.08.2011	Reminder sent to State Government.
18.	12.09.2011	The GEAC constituted a two-member Committee (Dr Arjula Reddy and Shri G. Hegde) to investigate the allegation since there was no response from the State Government. The site visit was scheduled for January 19, 2012. However, due to unavoidable circumstances, Shri Hegde informed that he could not participate in the site inspection. Subsequently, Dr Udaya Kumar has been requested to acCompany Dr Arjula Reddy for the inspection. The site visit is tentatively scheduled for the last week of February 2012.
19.	21.09.2011	The GEAC approved the request for extension of validity to conduct BRL-II trials and seed production during Rabi 2011-12 and Kharif 2012 at revised locations subject to submission of NOC from respective State Government.
20.	30.11.2011	Applicant submitted NOC from State Government of Gujarat for conduct of BRL-II trials at Anand agriculture University.
21.	13.12.2011	Approval letter issued by the GEAC for conduct of BRL-II trials subject to the condition that the trials will be conducted as per the protocol prescribed by GEAC and Director, DMR. The revised protocol did not include NK603 as treatment.
22.	30.01.2012	The Central Compliance Committee monitored the trials at Anand Agricultural University. The report indicates that there is no compliance deviation nor there is any mention about the use of NK603 as treatment.

8.1.3 On reviewing the details enumerated above, the Committee noted the fact that the GEAC in its 104th and 105th meeting held on 15.11.2010 and 08.12.2010 respectively had approved the

request of the applicant to conduct BRL-II trials with the inclusion of the treatment with event NK603 as a comparator. Subsequently in compliance with the conditions stipulated in the approval letter dated 24.12.2010, the experimental field design and protocol which included treatment with event NK603 as a comparator was approved by Director, Directorate of Maize Research (DMR). The Committee therefore opined that the statement made in the Compliance Committee report "*Before planting NK 603 event treatment in future, the permission from competent authority may be obtained*" is not correct..

8.1.4 Member of the GEAC who was part of the Compliance Committee informed that this suggestion was incorporated in part G of the monitoring proforma, keeping in view the recent policy decision taken by the GEAC in the meeting held on 06.07.2011 not to allow unapproved events in BRL-I and BRL-II trials. It was also noted that the current BRL-II ongoing GM Maize trial by M/s Monsanto at Anand, Gujarat is being conducted without treatment with NK 603. Accordingly the Committee concluded that there has been no violation in the instant case.

8.2 Report of the Sub-Committee constituted by the Ministry to inspect the adequacy of the safeguards and post-harvest measure site taken during BRL-II field trials of transgenic maize hybrids at IARI Campus in Samastipur, Bihar by M/s Monsanto India Ltd.

8.2.1 The Committee noted that subsequent to uprooting of the GM maize trials in Samastipur, Bihar, MoEF had constituted a three members Sub-Committee (DDG-ICAR / nominee of ICAR, Representative of MoEF and a member from the State Department of Agriculture, Government of Bihar) to investigate the matter and give a factual report on following the terms of reference:

- The field trials were conducted with the prescribed isolation distance and other conditions stipulated by the GEAC in its approval letter dated 24.12.2010.
- The procedures and record maintenance for harvest /termination prescribed in the Guidelines and SOP for confined trials of GE plants have been adhered to while terminating the field trials;
- Measures taken to comply with the post-harvest restrictions prescribed in the Guidelines and SOP for confined field trials of GE plants.

8.2.2 The Committee noted that Dr G.V.Subrahmanyam, Advisor MoEF; Dr. K.V.Prabhu (nominee of ICAR); and Dr Sushil Kumar, Deputy Director (the representative of Department of Agriculture, State Govt. of Bihar) visited the site (where the trials were undertaken / uprooted) at Samastipur on 18.10.2011. Dr. I.S.Solanki, Head, Regional Station, Pusa, Bihar and the trial in-charge for conducting BRL-II trials, was also present.

8.2.3 The report of the Sub-Committee was considered in the GEAC meeting wherein the following facts/ observations made by the Sub-Committee was noted:

i. The report has been prepared on the basis of field inspection and interaction with the concerned officials both at the Regional Station, Pusa and Department of Agriculture, Patna.

ii. Since the field trial was up-rooted on 11th March, 2011 and the order constituting the Committee was issued on 18th April, 2011 there was nothing to see in the field to verify the fact that whether the field trials were conducted with the prescribed isolation distance and other conditions stipulated in the MoEF letter dated 24th December, 2010. However; Dr.I.S. Solanki, Head, Regional Station, PUSA who is also the in-charge responsible for BRL-II maize trials informed that he had conducted the field trials as per the standard operating procedures and guidelines of August, 2008 issued by the DBT and MoEF.

iii. The "Guidelines and Standard Operating Procedures (SOPs) for confined field trials of Regulated, Genetically Engineered (GE) Plants" prescribe formats to be duly filled in during trials. Dr I.S. Solanki, I/C of the field trials has only provided record of harvest/termination in prescribed format. However, he has furnished a register giving details of record maintenance on information on date of fencing, date of sowing, date of up-rooting, transport details, post- up-rooting monitoring and planting of mung bean to the Committee.

iv. In the Guidelines and SOPs of August, 2008, the SOP for the harvest/termination of confined field trials relate to completion of the trial followed by harvest/termination. In the present case, the trials were withdrawn /terminated before completion of the trial. Though, the same SOP for harvest/termination which was meant for after completion of the trial was used, it would be desirable to have a mention with SOP exclusively for cases where such trials have been withdrawn/terminated before their completion.

v. Presently mango and cauliflower is raised in the field where Maize trials were conducted. In vicinity of the trial plot no other maize crop growing was seen.

vi. A soil seed bank study is also being carried out to rule out the possibility of presence of transgenic Maize seeds.

8.2.4 In view of the details enumerated at foregoing, the Committee opined that the post harvest measures taken by IARI subsequent to the uprooting of the BRL-II maize trials in Samastipur is satisfactory and proposed for closer of the case.

Date of next GEAC meeting: 19.03.2012

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