

No. C-12019/7/2015-CS-III  
Government of India  
Ministry of Environment, Forest & Climate Change  
CS-III Division

Indira Paryavaran Bhawan,  
Jor Bagh Road,  
New Delhi – 110 003

Dated 21/12/2015

To,

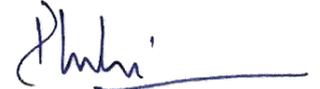
Shri Manvendra Singh Inaniya  
4 B, 4<sup>th</sup> Floor, HVS Paradise Apartments, No. 9/13,  
Andree Road, Near Yellama Desappa Hospital,  
Shanti Nagar – 560027, Karnataka

**Subject: Application under RTI Act, 2005 dated 11/12/2015 filed by Shri Manvendra Singh Inaniya–received in this Ministry on 11/12/2015 (Reg. No. MOENF/R/2015/61320, dated 11/12/2015).**

Sir,

With reference to your RTI application dated 11/12/2015, this is to inform you that the minutes of the 125<sup>th</sup> GEAC meeting have been submitted to the competent authority for approval. However, copies of the minutes of the 122<sup>nd</sup> and 123<sup>rd</sup> meeting of the GEAC are enclosed.

Yours faithfully,



(Dr. Ritesh Joshi)  
Joint Director & CPIO  
Tel.: 24695359 (Office)

Copy to:

- Under Secretary (RTI Cell), Ministry of Environment, Forest & Climate Change;
- IT Cell, Ministry of Environment, Forest & Climate Change



(Dr. Ritesh Joshi)

**Minutes of the 122<sup>nd</sup> meeting of the Genetic Engineering Appraisal Committee (GEAC) held on 28.08.2014**

The 122<sup>nd</sup> meeting of the GEAC was held on 28.08.2014 in the Ministry of Environment, Forests and Climate Change (MoEF& CC) under the chairmanship of Shri Hem Pande, Additional Secretary, MoEF& CC and Chairman, GEAC

**List of the participants is annexed as Annex 1**

**Agenda Item No 1 Leave of Absence**

The Committee granted leave of absence to Dr K. Veluthambi, Dr C.R. Babu, Dr S.K. Apte, Prof Akshay Kumar Pradhan, Dr Renee M. Borges, Dr Meenakhi Singh, Dr Vijay Kumar and Dr S.R. Rao as requested by them.

**Agenda Item No 2: Confirmation of Minutes of the 120<sup>th</sup> meeting**

Minutes were confirmed with the following editorial changes.

1. Agenda item No.1 Para 1 line 2 may be read as: "as requested by them".
2. Para 4.1.1 may be re-read as: The Committee considered the request of UPCSUR, Shahjahanpur to conduct event selection trials on five Sugarcane (*Saccharum* spp. CoS 96268) events namely; BtS1, BtS2, BtS3, BtS4 and BtS85 containing cry1Ac gene at one location within the Sugarcane Research Institute Farm at Shahjahanpur in an area of 571 sq.m.
  - 4.1.4 point 4 may be re-read as : "Post trial land will be used only for further trials with GM crops, as and when they are conducted. After harvesting, remaining canes will be disposed off by burning.
  - Para 4.1.6 may be re-read as: The Committee noted that the source of the Cry 1Ac gene has not been furnished. In the future, it is requested that this information be included along with the details of the gene construct.
  - Para-4.1.9 point '(ii) Material transfer Agreement' to be deleted as this information to be obtained from DBT.
- 4 Para 4.3.10, point 3, 4 and 6 may be re-read as follows amendments to:
  - Point 3: On the basis of insect bioassay and SDS-PAGE analysis the Cry1Fa1 recombinant protein can be considered heat labile at 95<sup>o</sup> C when the mortality of target insect of both the test proteins was less than the untreated control test proteins
  - Point 4: line 8 the word "test" may be deleted.

Point 6: In **90 days Rat feeding study** with leaves as well as fruit (2 studies), one female rat from non-transgenic leaf fed group died on day 38. No mortality in transgenic group was observed. There were no significant differences in body weight gain, organ weights between transgenic and non-transgenic groups. There were no histopathological changes which can be attributed due to the exposure to transgenic / non transgenic test material. However, some statically significant differences *between control and test animals for some of the other parameters that were tested although they were all within the normal range.* Compositional equivalence was established between non transgenic vs transgenic.

3. Para 4.3.11, line 6 the word 'just' may be read as 'only'.

4. Para 4.3.12, line1 may be re-read as "As regards the acceptability of the statistical variations in the toxicity studies."

5. Para 4.3.15 point ii & iii may be re-read as :

ii "Repeat Southern analysis".

iii the word "As decided" added the toxicity studies to be examined by a sub-Committee

6. Para 4.4.4 point 5 the word to may be reread as "of".

7. Para 4.4.8 (i) may be read as: The Barnase gene (333bp) has been derived from bacterium *Bacillus myoliquefaciens*, commonly occurring soil bacterium encoding a ribonuclease called Barnase, which degrades RNA. "The barnase gene is expressed" in the tapetum at early stages of pollen formation.

8. Para 4.4.9 line 4 may be re-read as: The other possibility that was considered was that barnase might also be expressed at a low level in other tissues but that cells expressing barnase would be dead due to toxicity of the protein. However, even if the last possibility is correct, it would have to occur in very few cells as otherwise the barnase expressing plants are expected to show developmental abnormalities (which they do not except as expected with regard to male sterility).

### **Agenda item No. 3 Action taken report on the decision taken in the 121<sup>th</sup>GEAC Meeting held on 18.7.2014.**

3.1 The Committee noted that decisions taken in the GEAC meeting held on 18.07.2014 have been communicated to the project proponents, concerned government departments and other agencies. Member Secretary further informed that a Sub-Committee to review the toxicity data for Bt Brinjal by M/s Bejo Sheetal and GM mustard by Delhi University would be constituted shortly.

### 3.2 Presentations:

#### 3.2.1 Protocol for cattle feeding study of transgenic and non-transgenic maize at NDRI by M/s. E. I. DuPont India Pvt. Ltd, Hyderabad.

3.2.1.1 GEAC in its 119<sup>th</sup> meeting held on 25.4.2014 had decided that a detailed presentation on Protocol for cattle feeding study of transgenic and non-transgenic maize at NDRI may be made before the Committee. The Presentation was made by the Principal Scientist, Shiv Prasad, NDRI. The following points were noted:

#### A Objective of the trials:

To evaluate the feed intake, milk production and milk composition in lactating crossbred dairy cows fed genetically modified maize forage containing the stacked event TC1507 and NK603 and compare with those cows consuming near-isogenic and commercially available (reference) non-transgenic maize forage during an 8-week feeding period.

#### B. Study Design:

4 Groups	No. of cows	Treatment Name	Treatment Description
Test 1	10	30B11HR	TC1507xNK603 transgenic maize
Control 2	10	30B11	Non-transgenic near isoline maize
References 3 4	10 10	Reference 1 Reference 2	Commercially available non-transgenic maize Commercially available non-transgenic maize

#### C: Materials & Methods:

1. Green Fodder Production: R1-R3 stage maize forage will be grown at NDRI farm
2. Animal Selection for Feeding Study:
  - 2nd/3rd parity lactating HF cross-bred cows
  - 60- 75 days in milk at the start of the study
  - Randomized block design for allocation of animals to groups
3. Standard practices will be followed for management, health care, feeding and milking of dairy cows
4. Animals will be maintained in a separate, well-protected shelter with individual - feeding and watering facility

**D. Observations:**

- Daily observations
- Daily feed intake & residue
- Body weights
- Body temperature
- Hematology & blood chemistry
- Milk production
- Milk composition
- Green fodder composition
- Molecular analysis of green fodder, milk and plasma

**E. Assessment during Acclimation and Feeding**

<b>Observations</b>	<b>Time Points</b>
Daily Observations	Daily
Feed Intake & Residue	Daily
Body Weights	Fortnightly (Days -28, -14, -1, 14, 28, 42, and 56)
Body Temperature	Daily
Hematology & Blood Biochemistry	Days -1, 28 and 54
Milk Production	Daily
Milk Composition	Fortnightly (Days -28, -14, -1, 14, 28, 42, and 56)
Green Fodder Composition	Samples from weeks 1, 5 and 8
Molecular Analysis	-Samples from weeks 1, 5 and 8
-Forage	-Fortnightly
-Milk	(Days -28, -14, -1, 14, 28, 42, and 56)
-Plasma	-Days -1, 28 and 54

**F. Key Points:**

- ✓ Fresh calves (HF cross-bred cows), yielding 12-14 liters, will be procured from Kamal area.
- ✓ At recruitment into the treatment groups, cows will be post-peak stage of lactation.
- ✓ Maize fodder will be fed at 2% body weight. To meet the additional requirements, standard concentrate will be fed.
- ✓ Staggered sowing will ensure adequate forage production throughout the 8-week feeding phase.
- ✓ Standardization for testing milk and sera, identify false positives.

**G. Approval Status:**

- i. Received NDRI IBSC approval

- ii. Received NDRI IAEC approval for the study.
- iii. Received RCGM approval for cattle feeding study at NDRI – recommended separate application for forage production
- iv. GEAC approved request for forage production at NDRI for cattle feeding study subject to NOC and sharing details about trial location/scientist details at NDRI.
- v. Request for State NOC submitted.

3.2.1.2 During the deliberations, the following clarifications/ information was provided in response to queries raised by members:

- i. NDRI has the facility to raise the fodder under confined and secure conditions.
- ii. The forage production would be similar to confined field trial condition and conducted with the approval of GEAC and NOC from the State Government.
- iii. NDRI will ensure similar age, parity and pedigree among the cows used in the study.
- iv. Cattle studies are done in the US but they are not for regulatory purpose. They are rather conducted with a stewardship perspective and published articles from US studies have been submitted to RCGM while seeking a waiver from conduct of all biosafety studies in 2011. Waiver was granted for pure protein studies. However, the present proposal to conduct the whole grain studies again in India using Indian germplasm is on the basis of direction from RCGM.
- v. NDRI will use the cows for their other experimentation or projects.
- vi. Approval from IAEC has been obtained by NDRI
- vii. No differences were seen and the transgenic grain and forage were found to be substantially equivalent to the non-transgenic counterpart.

### **3.2.2 Protocol for conducting feeding study in lactating cows for assessment of food and feed safety of transgenic corn (MON 89034XNK603) by M/s. Monsanto India Ltd., New Delhi.**

3.2.2.1 GEAC in its 119<sup>th</sup> meeting held on 25.4.2014 had decided that a detailed presentation on Protocol for cattle feeding study of transgenic and non-transgenic maize at NDRI may be made before the Committee. The Presentation was made by Dr David Saltmiras, Science fellow, Monsanto. The following points were noted:

1. MON89034 x NK603 has been approved for commercial cultivation in USA, Brazil, Argentina, Colombia, Canada, Honduras, Philippines and South Africa. It is approved for import (food and feed) in Australia/New Zealand, EU, Indonesia, Mexico, Japan, Korea, Taiwan and Philippines. Additionally, MON89034 and NK603 have also been approved for food/ feed import purposes in China.

2. Safety assessment data for proteins in event MON 89034 (Cry1A.105 & Cry2Ab2) and event NK603 (CP4 EPSPS) has been presented to RCGM and is available on IGMORIS website. This includes detailed analysis reports for:

- a. Molecular characterization of events
- b. Thermal stability
- c. Pepsin digestibility
- d. Acute oral toxicity study in Mice (very large margins of exposure)
- e. Bioinformatics analysis against allergen and toxin databases.

3. A validated event specific detection protocol was submitted to RCGM prior to BRL-1 trial application.

4. Following data has been generated on MON 89034 X NK603 maize during the course of BRL-1 and BRL-2 trials over a period of four years and has been presented to RCGM during its November 2013 meeting:

- a. **Compositional Analysis:** The forage and grain of transgenic entries were considered compositionally equivalent to conventional maize with a history of safe use.
- b. **90 day whole food rat feeding study:** No effects on the growth or health of rats were observed.
- c. **Chicken performance 42 days study:** Diets with MON 89034 X NK603 maize were as nutritionally wholesome as conventional counterparts
- d. **Fish performance 56 days study:** No significant difference in survival, growth rate, feed conversion rates and body composition between MON 89034 X NK603 maize and its conventional counterparts

5. During the period 2009-2013, 13 locations of BRL-1 and 5 locations of BRL-2 confined field trials conducted.

6. Details of Lactating Dairy Cow Feeding Study as approved by RCGM in August, 2011:

- The objective of the proposed study was to study "*Effects of feeding grain and green chop from Transgenic Corn Hybrids Containing Events MON89034 & NK603 on Milk Production of Crossbred Cows in India*" at National Dairy Research Institute, Karnal.
- Test and control materials: Grain & Green chop
- End points: Animal clinical observations and performance (body weight and feed consumption)
- Statistical Analyses: feed intake, milk production and milk composition.
- Study Design
  - a. 28 days duration
  - b. 20 lactating dairy cows
    - Ensure only use animals that are already at facility (acclimated)

- Select on lactation cycle: in-milk days 60-200 at start of pre-treatment
- 10 cows/group (test and control)

c. Nutritionally balanced diets include grain for the respective treatment groups

3.2.2.2 Based on the scientific evidence presented, the applicant concluded that the proteins Cry1A.105, Cry2Ab2 and CP4-EPSPS are safe for consumption as MON 89034 x NK603 maize does not show any mammalian toxicity based on 90 day sub chronic study (rat), is compositionally and therefore nutritionally equivalent to its conventional counterpart. The applicant suggested that the feeding study with lactating cows is unlikely to present any valuable insights to health impacts and requested for exemption.

3.2.2.3 The applicant also provided the following clarifications/ information in response to queries raised by the Members:

1. Cross bred cows are used for the study as they give more milk and are more suitable for the study. Further NDRI has majority of cross bred cows in their herd.
2. The protocol was prepared jointly by Principal Investigator from NDRI and Applicant based on NDRI's prior experience of doing five previous lactating dairy cattle studies. Applicant submitted this protocol to RCGM for review and approval. The protocol was approved by RCGM in Aug 2011.
3. Monsanto as of today has not conducted lactating dairy cow studies for regulatory submissions in other countries. However, the prevalence of MON 89034 x NK603 maize in the food/feed chain for many years in various countries mentioned in the cultivation and food/ feed import list suggests that this conventional breeding stack of GM maize is safe for cultivation and food feed purposes.

3.2.2.4 The Committee carefully examined the information provided in both the presentations and decided to consider whether feeding studies in cattle needs to be part of the biosafety studies in the next GEAC meeting.

**3.2.3 Proposal on GlyTol® X TwinLink® cotton (*Gossypiumhirsutum*) hybrids that express 2m EPSPS, cry1Ab, cry2Ae and bar genes; [GlyTol® event GHB614 (2mEPSPS) X TwinLink® [event GHB119 (cry2Ae/bar) X event T304-40 (cry1Ab/bar)] M/s. Bayer Bioscience Pvt. Ltd, Gurgaon**

3.2.3.1 GEAC in its 119<sup>th</sup> meeting held on 25.4.2014 had decided that a detailed presentation on Protocol for cattle feeding study of transgenic and non-transgenic maize at NDRI may be made before the Committee. The presentation was made by Dr Timothy Dennehy, Bayer Crop Sciences on (i) rationale of using two herbicide resistance genes, (ii) how resistance development would be managed and global scenario in this regard and (iii) the need for 30 entries in BRL-I trials. Following points were noted:

- (i) Rationale of using two herbicide resistance genes:

- Only glyphosate tolerance (2mEPSPS) is intended for use by growers.
- Glufosinate tolerance was utilized as a laboratory tool by our scientists. The selectable marker gene (PAT/bar) permits efficient identification of plants that had been successfully transformed with the two Bt genes in GLT. Cells of the component lines of GLT, T304-40 and GHB119 that survived exposure to glufosinate carried the respective Bt gene. This approach is a major improvement over the previously-used antibiotic resistance markers.

(ii) How resistance development would be managed and global scenario?

- Major GLT cultivation countries: USA, Brazil; future approvals possible for Mexico, South Africa, Cameroun and others.
- WRM plan for GLT cotton in India is under development. Currently herbicide use in Indian cotton is low. Although it is expected that the use of herbicides will increase in the coming decade, the risk of weed resistance will remain relatively low in cotton. Thus, for the foreseeable future, Bayer does not plan to develop or register glufosinate for use in cotton in India.
- The glyphosate WRM Program for India cotton will focus on methodologies for maintaining weed-free fields. These include need-based interculture, hand weeding and weedicide.
- Elsewhere in the world, resistance has developed in areas with high utilization of glyphosate. In such areas, glufosinate is important for delaying glyphosate resistance and controlling glyphosate-resistant weeds.
- Some countries with intensive use of herbicides (e.g. Australia) have launched glyphosate-resistant crops together with strong resistance management plans.

(iii) The need for 30 entries in BRL-I trials?

- As per GEAC norms only two test hybrids. There are 10 different treatments in each of the replications.
- Thus, the total number of treatments is 30.

3.2.3.2 The Committee noted that farmers of India will be using Glyphosate more than 3 times in a crop season to control the weeds. In future high use of Glyphosate will lead to the development of resistant weeds. The Committee also sought clarification on whether there is a proposal by the company to register Bayer's Glufosinate ammonium in India. In response the applicant clarified that:

- i. In such situation Bayer's Glufosinate ammonium is a good alternative. This will help to over the problem of Glyphosate resistance development.

- ii. Bayer expects glyphosate use in cotton in India is expected to be moderate throughout the coming decade. This moderate selection pressure, along with well-established non-herbicidal weed control methods will permit longevity of glyphosate in India. There will not be a compelling need for alternative herbicide tolerance in cotton for the foreseeable future.
- iii. Bayer has no foreseeable plans to develop and register glufosinate for commercial use on GLT cotton in India. If this changes in the future, Bayer will seek the necessary regulatory approvals and modify its WRM plans accordingly.

In light of the above discussion, the Committee approved the request to conduct BRL trials and experimental seed production of breeding stack of GlyTol® x TwinLink® cotton (*Gossypium hirsutum*) hybrids that express *2m EPSPS*, *cry1Ab*, *cry2Ae* and *bar* genes; [GlyTol® event GHB614 (*2mEPSPS*) x TwinLink® [event GHB119 (*cry2Ae/bar*) x event T304-40 (*cry1Ab/bar*)] by M/s. Bayer Bioscience Pvt. Ltd, Gurgaon

#### 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, pursuant to Bt cotton approvals (2002-2008), the GEAC had adopted the 'Event Based Approval Mechanism (EBAM)' and constituted a Standing Committee to operationalize the new procedure on 16.4.2009 for a period of three years (16.4.2012) under the aegis of DBT. The tenure of the Standing Committee was extended for a period upto October 2012. The matter was reconsidered in the GEAC meeting held on 22.3.2013. In the absence of an alternative mechanism and seasonality involved the tenure of the Standing Committee for four months with the revised composition as follows:

S.No.	Name and Designation of Experts	Designation
1.	Dr. N Gopalkrishnan, ADG (commercial crops), ICAR, Krishi Bhavan New Delhi.	Chairman
2.	Dr. D. Monga, Head, Regional Station, Central Institute of Cotton Research, Sirsa, Haryana.	Member
3.	Dr. Punit Mohan, Principal Scientist, Plant Breeding, CICR, Nagpur	Member
4.	Project Coordinator, All India Cotton Crop Improvement Project (AICCIP) or his nominee.	Member
5.	Prof Ramesh Poombar, Punjab Agriculture University	Member
6.	Dr S.J. Rahman, Principal Scientist & Head, Agriculture Research Institute (ANGRAU), Hyderabad	Member
7.	Director (Seeds), Ministry of Agriculture	Member
8.	Dr. S R Rao, Adviser, DBT and Member Secretary, RCGM	Member
9.	Ms Rajalakshmi Muralidharan, Scientist D, DBT	Member Secretary

4.1.2 The Committee observed that the Standing Committee is being serviced by the DBT since 2009 and till date they have convened 12 meetings. Further, as per the expanded TOR the Committee also took note of the list of Bt cotton hybrids recommended for withdrawal by the Standing Committee on the basis of voluntary submissions made by the applicants.

4.1.3 The Committee further noted that DBT has informed that they are not in position to continue serving the Standing Committee as the mandate of DBT is specific to biosafety assessment and not agronomic performance. The Committee opined that the position taken by DBT merits consideration as Rules 1989 is specific to biosafety assessment of an event in a specific crop whereas the review undertaken by the Standing Committee is specific to agronomic performance of Bt cotton hybrids expressing approved events and its suitability for commercial cultivation in a particular region.

4.1.4 During the interim period (2009 to 2013) the GEAC had requested ICAR to set up an alternate mechanism under the AICCIP to evaluate the performance of approved Bt cotton events before release. The Committee reiterated the above and requested DDG ICAR to reconsider the above matter. After detailed deliberations, it was decided that a formal communication would be sent to DG, ICAR by Chairman, GEAC.

4.1.5 The Committee further opined that ICAR while communicating its acceptance may also suggest the composition and TOR of the Standing Committee for consideration of the GEAC taking into consideration the various recommendations made by the previous Standing Committee. It was also suggested that for the sake of continuity Dr. N Gopalkrishnan, ADG, ICAR may be requested to continue as the Chair of the new Standing Committee in view of his experience and expertise on the subject matter. The Chairman, GEAC also suggested that other members may also forward names of experts in the areas of plant breeding, entomology, agriculture etc. for nomination to the Standing Committee.

5.1.6 As regards the list of Bt cotton hybrids recommended for withdrawal by the Standing Committee on the basis of voluntary submissions, it was decided that the State Governments may be informed of the same.

**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 with ten dwarf potato clones of potato (*Solanum tuberosum*. L) events namely; KS1, KS2, KS3, KS5, KS6, KS8, KS11, KH65, KH79, KH90 containing *GA20Oxidase 1 gene* by Central Potato Research Station(CPRS), Central Potato Research Institute(CPRI), Jalandhar.**

5.1.1 The Committee considered the request of CPRI, Jalandhar, to conduct event selection trials on ten dwarf potato clones of potato (*Solanum tuberosum*. L) events namely; KS1, KS2, KS3, KS5, KS6, KS8, KS11, KH65, KH79, KH90 containing *GA20 Oxidase 1 gene*. The trial will be conducted in the ICAR owned field at CPRS, Jalandhar in an area of 50.0 m<sup>2</sup>.

5.1.2 The Committee noted that the objectives of the trials are to:

- Evaluate plant height, harvest index and tuber yield.
- Collect data on plant height, number of nodes, total biomass at the time of harvest and tuber yield.
- Harvest index of transgenic plants will be compared with control plants to find out any advantage in transgenic plants.

5.1.3 The Committee also took note of the field experiment and proposed isolation measures as given under:

- The experiment will be conducted by planting each clone in single lines. Non transgenic plants of Kufri Surya and Kufri Himalini will serve as a control.
- An isolation distance of 5 m will be kept on all four sides of the trial plot.
- Potato flowers will be removed manually in the bud stage and destroyed by burning.
- Transgenic tubers harvested from this trial will be packed in muslin cloth bags, labeled both side and outside the bag will be put inside a cardboard carton.
- Unmodified plants will be used as control to compare the plant height and harvest index and tuber yield and tuber characteristics like shape, size, uniformity, eye depth and skin colour.

5.1.4 The Committee observed the following information on the gene construct and transformation method:

- (i) Transformation: Agrobacterium -mediated transformation
- (ii) Detailed information regarding the genes and vectors:

Detail of Plasmid	Events
Source of gene ( <i>GA20 oxidase 1</i> )	Potato
The name of the plasmid vector used for transformation.	pBI121:IRGA (Binary vector)
The antibiotic resistance marker used in transformation (inclusive of promoter and terminator).	Neomycin Phospho Transferase ( <i>NPT II</i> ) gene (Kanamycin resistance gene) with <i>NOS</i> promoter and <i>NOS</i> terminator
Are additional antibiotic resistance markers present in the transgenic plant?	No additional antibiotic resistance markers present in the transgenic plant
Is any reporter gene such as <i>GUS</i> or <i>GFP</i> present in the transgenic plant?	No, reporter gene such as <i>GUS</i> or <i>GFP</i> present in the transgenic plants
Is the plant a marker free transgenic?	No, the transgenic plants are not marker free, it has <i>NPTII</i> gene

	as marker
What is the promoter and the terminator used for expressing the gene of interest/s	CaMV 35S Promoter and NOS terminators are used for expressing the silencing cassette

5.1.5 The Committee observed that proposal has been recommended by the IBSC and RCGM in its 115<sup>th</sup> meeting held on 16.3.2012 and 28.8.2012 respectively subject to submission of information on (i) nature of the trial (event selection/ BRL-1) and (ii) submission of duly signed IBSC minutes wherein above proposal got approved.

5.1.6 The Committee noted that the applicant has clarified that the proposal is for event selection trials and has submitted the signed copy of the IBSC minutes held on 16.03.2012. As regards, information on the source of gene, the Committee noted that the gene is from potato but was of the the applicant may be requested to indicate from whom the gene has been sourced. It was agreed that this would be applicable for all cases in future.

5.1.7 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request for conduct of event selection trials with ten dwarf potato clones of potato (*Solanum tuberosum. L*) events namely; KS1, KS2, KS3, KS5, KS6, KS8, KS11, KH65, KH79, KH90 containing *GA20 Oxidase 1 gene* at ICAR owned field at Central Potato Research Station (CPRS), Jalandhar during any appropriate season subject to submission of NOC from the respective State Governments where the trials will be conducted.

## 5.2 Permission to conduct BRL-I trials for evaluation of the selected vacuolar acid on one invertase RNAi transgenic potato (*Solanum tuberosum. L*) event K.ChipINV RNAi-2214 by Central Potato Research Institute (CPRI), Shimla.

5.2.1 The Committee considered the request of CPRI, Shimla, to conduct BRL-I trials on one invertase RNAi transgenic potato (*Solanum tuberosum. L*) event K.ChipINV RNAi-2214. The trial will be conducted in the ICAR owned field at Central Potato Research Station (CPRS) at Jalandhar in an area of 50.0 m<sup>2</sup>.

5.2.2 The Committee noted that the GEAC in its earlier meeting held on 9.9.2009 had accorded permission to conduct event selection trials for evaluation of vacuolar acid on invertase RNAi transgenic potato (*Solanum tuberosum. L*) on eight events namely; K.Chipsona -1, K.ChipINV RNAi-2214, K.ChipInv RNAi-2013 K.ChipInv RNAi-2311, K.ChipInv RNAi-2123, K.ChipInv RNAi-2262, K.ChipInv RNAi-2213 and K.ChipInv RNAi-2015.

5.2.3 The Committee noted that only one invertase RNAi event K.ChipInv RNAi-2214 (out of above eight) produced acceptable chip colour after 45 days of cold storage when evaluated directly after cold storage. Highest level of reduction of reducing sugars (glucose + fructose) with concomitant increase in sucrose level was observed in K.ChipInv RNAi-2214 at all stages of cold storage. Based on yield performance from field trial for event selection

and cold-chipping performance, the RNAi event, K.Chiplnv RNAi-2214, was selected for further evaluation.

5.2.4 The Committee noted that the objectives of the trials are to:

- Multiply valINV RNAi transgenic potato event KChiplnvRNAi-2214
- Evaluate stability of introduced trait and improvement in processing attributes by reduction of cold-induced sweetening;
- Collect data on tuber shape, size, processing grade yield, marketable yield and total yield will be recorded

5.2.5 The Committee also took note of the field experiment and proposed isolation measures as given under:

- The experiment will be conducted by planting each clone in single lines. Non transgenic plants of Kufri Surya and Kufri Himalini will serve as a control.
- An isolation distance of 5 m will be kept on all four sides of the trial plot.
- Potato usually does not flower in the plains where the trial is to be conducted. In case of any chance flowering they will be removed manually and destroyed by burning.
- Distance to the nearest cultivated crop of the same species will be 100 m
- The valINV RNAi transgenic tubers harvested from this trial will be packed in muslin cloth bags and labeled bags will be put inside a cardboard carton for either storage or transportation
- Harvested tubers will be kept in cold storage and will be taken out from cold store at 45 days intervals to evaluate processing attributes like chip color, reducing sugars and sucrose content.

5.2.6 The Committee considered the following information on the gene construct and transformation method:

(i) Transformation method: Agrobacterium-mediated transformation

(ii) Detailed information regarding the genes and vectors:

Detail of Plasmid	Events
Source of gene	Potato
The name of the plasmid vector used for transformation.	pBI121:iIR-VallNV (Binary vector)
The antibiotic resistance marker used in transformation (inclusive of promoter and terminator).	Neomycin Phospho Transferase (NPT) II gene (Kanamycin resistance gene) with NOS promoter and NOS terminator  No additional antibiotic

Are additional antibiotic resistance markers present in the transgenic plant?	resistance markers present in the transgenic plant
Is any reporter gene such as GUS or GFP present in the transgenic plant?	No, reporter gene such as GUS or GFP present in the transgenic plants
Is the plant a marker free transgenic?	No, the transgenic plant Kufri Chipsona1iR-VallINV-2214 is not marker free, it has NPTII gene as marker
What is the promoter and the terminator used for expressing the gene of interest/s	CaMV 35S Promoter and NOS terminators are used for expressing the silencing cassette.

5.2.7 The Committee observed that proposal has been recommended by the IBSC and RCGM in its 115<sup>th</sup> meeting held on 16.3.2012 and 28.8.2012 respectively, subject to submission of information on (i) clarification on nature of the trial (event selection/ BRL-1) and (ii) submission of duly signed IBSC minutes wherein above proposal got approved.

5.2.8 The Committee noted that the applicant has clarified that the proposal is for event selection trials and has submitted the signed copy of the IBSC minutes held on 16.03.2012.

5.2.9 In view of the above stated facts, and taking in to consideration the recommendations of the RCGM, the Committee approved the request for conduct of BRL-I trials for evaluation of the selected vacuolar acid on one invertase RNAi transgenic potato (*Solanum tuberosum*. L) event K.ChipINV RNAi-2214 at Central Potato Research Station(CPRS), Jalandhar during any appropriate season subject to submission of NOC from the respective State Governments where the trials will be conducted. As regards, information on the source of gene, the Committee noted that the gene is from potato but was of the view that the applicant may be requested to indicate from whom the gene has been sourced.

### **5.3 Permission to conduct pollen flow studies with insect tolerant chickpea line (Event SSL-3) containing *Cry1Ac* gene by M/s. Sungro Seeds Ltd., New Delhi**

5.3.1 The Committee considered the request of M/s. Sungro Seeds Limited, New Delhi, to conduct pollen flow studies with insect tolerant chickpea (Event SSL-3) line containing *Cry1Ac* gene. The trial will be conducted at Company's owned farmat Village Janti Khurd, Haryana.

5.3.2 The Committee noted that the transgenic chickpea expressing *CryAc* gene is similar in phenotype to its non-transgenic counterpart except for resistance to pod borer insect (*Helicoverpa armigera*) of Class Lepidoptera.

5.3.3 The Committee also noted that the objectives of the trials are to:

- asses pollen flow from Bt chickpea plants by monitoring the extent of out-crossing and
- determine the distance traversed by pollen from Bt chickpea plants.

5.3.4 The Committee took note of the field experiment and proposed isolation measures as given under:

- Non –transgenic chickpea will be planted surrounding the transgenic chickpea block on all four sides at every 0.5.m distance up to 10 m.
- The transgenic entry will be planted in centre and surrounded by concentric rings on non-transgenic chickpea at every 0.5 m distance up to 10m. The extent of pollen flow will be determined using ELISA and GOT.
- The distance traversed by the pollen from the central Bt chicken plot will be recorded.
- Non transgenic chickpea varieties would be planted as trap rows.
- Seeds collected from surrounding non-transgenic chickpea blocks will be kept for grow-out –test to check the pollen flow.

5.3.5 The Committee considered the following information on the gene construct and transformation:

- Transformation method: Agrobacterium mediated transformation.
- Detailed information regarding the genes and vectors

Detail of Plasmid	Events
Source of Gene	Soil Bacteria ( <i>Bacillus thuringiensis</i> )
The name of the plasmid vector used for transformation	pBK203 vector
What are the promote and the terminator used for expressing the gene of interest/s?	The promoter used for expressing <i>Cry1Ac</i> gene is <i>Arabidopsis</i> SSU (Rubisco small sub unit) promoter and terminator is tobacco SSU terminator.
The antibiotic resistance marker used in transformation (inclusive of promoter and terminator).	The antibiotic marker used during the transformation process was neomycin phosphotransferase II ( <i>npt II</i> ) conferring resistance to kanamycin. The promoter used in the cassette is a SCSV 1 (Subterranean clover stunt virus) promoter and the terminator is a SCSV 3 terminator.
Are additional antibiotic resistance markers present in the transgenic plant?	No additional antibiotic resistance markers are present in the transgenic plants.
Is any reporter gene such as	No

GUS or GFP present in the transgenic plant	
Is the plant a marker free transgenic?	No, the plants are with <i>nptII</i> marker gene (Kanamycin resistance).

5.3.6 The Committee observed that the proposal has been recommended by IBSC in its 14<sup>th</sup> meeting and RCGM in its 124<sup>th</sup> meeting held on 9.9.2012 and 25.6.2013 respectively. RCGM observed that information pertaining to the pollen chickpea is not well documented.

5.3.7 In view of the above stated facts, and taking in to consideration the recommendations of the RCGM, the Committee approved the request for conduct of pollen flow studies with insect tolerant chickpea line (Event SSL-3) containing *Cry1Ac* gene at company's owned farm at Village Janti Khurd, Haryana during any appropriate season subject to submission of NOC from the respective State Governments where the trials will be conducted. The committee also directed that the applicant shall only use non-transgenic counter parts in the concentric rows surrounding the transgenic chick pea.

**5.4 Permission to undertake grain production of homozygous parental line and F1 seeds of Glytol® cotton (*Gossypium hirsutum*) hybrids SP7230G (GHB 614 event containing *2mEPSPS* gene) for small and large scale feeding studies by M/s. Bayer BioScience Pvt. Ltd., Gurgaon.**

5.4.1 The Committee considered the request of M/s. Bayer BioScience Pvt. Ltd., Gurgaon to undertake grain production of homozygous parental line and F1 seeds of Glytol® cotton (*Gossypium hirsutum*) hybrids SP7230G (GHB 614 event containing *2mEPSPS* gene) for small and large scale feeding studies. The trial will be conducted at one location at Andhra Pradesh/Gujarat in an area of 8000 sq meter.

5.4.2 The Committee noted the following justification given by the Company for production of seeds in an area of two acres:

- Average cotton production per acre under normal environmental conditions= 350kg to 400 kg.
- Amount of grain received after ginning= 200±10 kg.
- Amount of grain required for animal feeding = Rat study (600 Kg F160 Kg Homozygous)+Broiler chicken study (55 Kg Homozygous) + Cow study (200 Kg homozygous)= 375 Kg.
- Area required to produce the required quantity is approximate 2 acres.

5.4.3 The Committee noted that the objective of the trial is to produce parental homozygous and F1 grains for animal feeding studies.

5.4.4 The Committee took note of the field experiment and proposed isolation measures as given under:

- 50 m isolation as per the regulatory requirements will be maintained.

- Packets will be labeled with the specific seed lot code and also with the gene-event code
- Non transgenic male parent will be grown at the site.
- Distance from the nearest ecosystem will be > 200 meters.

5.4.5 The Committee also observed the following details on utilization, storage and destruction as given below:

- Full account of the cotton and grain receipt will be maintained at the production site.
- The site of production will be audited at regular interval by company's compliance and stewardship personnel. These records will be made available to the RCGM after harvest of trial.
- Seed storage record and seed utilization inventory will be maintained at the seed storage facility and audited at regular intervals and at the start of each study the seed quantity to be used according to the protocol approved by RCGM, will be intimated to the IBSC and minutes will be provide to the RCGM.
- Balance material after studies will be discarded and a record of destruction will be generated. This record will be presented to IBSC and the minutes will be submitted to RCGM.
- As per regulations, the site of production will be kept under post-harvest surveillance for at least 12 months.

5.4.6 The Committee considered the following information on the gene construct and transformation:

(i) Transformation method: Agrobacterium mediated transformation

(ii) Detailed information regarding the genes and vectors:

Detail of Plasmid	Events
source of Gene	<i>Zea mays</i>
The name of the plasmid vector used for transformation	Plasmid pTEM2 is used for event GHB 614 (2mEPSPS)
What are the promote and the terminator used for expressing the gene of interest/s?	<b>Vector: pTEM2</b> Gene of interest: 2mEPSPS Promoter: Ph4a748At Terminator: 3'histon At
The antibiotic resistance marker used in transformation (inclusive of promoter and terminator).	There is no antibiotic resistance markers used for plant transformation in any of the plasmid vectors mentioned above.
Are additional antibiotic resistance markers present in	

the transgenic plant?	
Is any reporter gene such as GUS or GFP present in the transgenic plant	No.
Is the plant markers free transgenic?	Yes, the plants are free of any antibiotic resistance marker or reporter genes.

5.4.7 The Committee observed that the proposal was recommended by IBSC in its 44<sup>th</sup> meeting and RCGM in its 130<sup>th</sup> meeting held on 27.12.2012 and 21.01.2014 respectively. RCGM noticed that for conduct of lactating cow feeding study three test groups of animals namely; GM (Homozygous parent), non-GM (Homozygous counterpart) and commercial genotype have been proposed. RCGM advised the applicant to include an additional test group of non-GM F1 hybrid counter parts or replace the test group of commercial genotype, and make necessary changes in the experimental design for grain production and feeding study and submit two copies of the revised application for record.

5.4.8 The Committee also noticed the clarifications provided by the RCGM vide their letter dated 02.07.2014 that the applicant has submitted the revised application with modifications and found to be in order.

5.4.9 In view of the above stated facts, and taking in to consideration the recommendations of the RCGM, the Committee approved the request to undertake grain production of homozygous parental line and F1 seeds of Glytol® cotton (*Gossypium hirsutum*) hybrids SP7230G (GHB 614 event containing *2mEPSPS* gene) for small and large scale feeding studies at Andhra Pradesh/Gujarat during any appropriate season subject to submission of NOC from the respective State Governments where the trials will be conducted.

#### RECONSIDERATION CASE:

**5.5 Permission to conduct confined field trials with transgenic maize (Event MON 89034 x NK603) to evolve a refuge strategy for transgenic maize hybrids. by M/s. Monsanto India Ltd., New Delhi**

5.5.1 The Member Secretary informed that the request of M/s. Monsanto India Ltd., New Delhi was considered by the GEAC in its meeting held on 15.11.2010 for conduct of IRM trials for transgenic maize (Event MON 89034 x NK603). The field studies are aimed to evolve a method for delivering IRM benefits through planting non-*Bt* maize plants interspersed within the main *Bt* maize crop. The application was deferred as the Committee noted that the corn hybrids expressing NK603 has not been approved for environmental release and therefore, rejected the request to use transgenic corn hybrids expressing NK603 while conducting IRM trials for ascertaining refuge strategy.

5.5.2 The Committee noted that the GEAC re-considered the request in its 119<sup>th</sup> meeting of GEAC held on 25.4.2014 with the revised protocol which does not include single event

NK603. The trials will be conducted at six locations during dry season of 2012 namely Andhra Pradesh, Karnataka, Tamil Nadu, Gujarat, Maharashtra and Bihar and eight locations during wet season of 2013 namely Gujarat, Rajasthan, Haryana, Madhya Pradesh, Tamil Nadu, Andhra Pradesh, Karnataka and Uttar Pradesh.

5.5.3 The proposal was reconsidered in the GEAC meeting held on 25.04.2014 wherein the Committee opined that in the first instance obtain chronology of approvals granted by the RCGM/GEAC and information on present status of field trials for both events namely stacked events (MON 89034 x NK603) and single event NK-603. The Committee considered the chronology of events and status of approval in respect of each event as given in the agenda notes.

5.5.4 The Committee further noted that the company is conducting BRL-II trials on transgenic maize (Event MON 89034 x NK603) and collected data on efficacy of the insecticidal proteins Cry1A.105 and Cry2Ab2 towards target pests and its safety towards non-target pests. They have also conducted studies to monitor the baseline susceptibility levels and insect behavioral studies across the country and the data generated will be helpful in ascertaining refuge requirements for the sustenance of the technology.

5.5.5 The Committee took note that the objectives of the trials are to:

- a) Study abundance/productivity of the Pink stem borer (*Sesamia inferens*), maize stalk borer (*Chilo partellus*) and cob borer, *Helicoverpa armigera*, from non-Bt plants (serving as refuge) interspersed (termed as built-in-refuge, BIR) within the Bt maize crop at levels of 0% (no BIR), 5% and 10% in a main crop of Bt maize (event MON 89034 x NK603). For comparison, block refuges (in which non-Bt plants would be grown at one end of the plot) at 5 and 10% levels would be grown.
- b) Study movement of larvae of *C. partellus*, *S. inferens* and *H. armigera* from Non-Bt BIR refuge plants to the surrounding Bt maize plants.
- c) Evaluate the concept of BIR for long term sustainability of Bt maize (event MON 89034 x NK603).
- d) Evaluate abundance of beneficial arthropods including Coccinellids and spiders on the Bt maize and non-Bt plants

5.5.6 The Committee also took note of the field experiment and proposed isolation measures as given below:

- Replicated complete block design with 6 treatments
- 12 rows/treatment with 40 plants/row
- Row – row distance: 60 cm; plant-plant distance: 20 cm
- 13 perimeter rows of West African tall maize.

5.5.7 The Committee considered the following information on the gene construct and transformation:

- (i) Transformation method: Agrobacterium mediated transformation

(ii) Detailed information regarding the genes and vectors:

Detail of Plasmid	Events
source of gene	Event MON 89034 Chimeric protein derived from <i>Bacillus thuringiensis</i>  Event NK603 <i>Agrobacterium tumefaciens</i> strain CP4
The name of the plasmid vector used for transformation	Event MON 89034 PV-ZMIR245  Event NK603 PV-ZMGT32
What are the promoter and the terminator used for expressing the gene of interest/s?	Event MON 89034 Promoters- e35S and FMV; Termination sequences- Hsp17 and NOS for Cry1A.105 and Cry2Ab2 resp.  Event NK603 P: e35S and Ract1; T: NOS
The antibiotic resistance marker used in transformation (inclusive of promoter and terminator).	Event MON 89034  NPT-II (P-35S, T-NOS).
Are additional antibiotic resistance markers present in the transgenic plant?	Event NK603 No
Is any reporter gene such as GUS or GFP present in the transgenic plant	Event MON 89034 No.  Event NK603 No
Is the plant a marker free transgenic?	Event MON 89034 Yes  Event NK603 No

5.5.8 The Committee observed that the proposal was recommended by IBSC in its 42<sup>nd</sup> meeting and RCGM recommended in its 118<sup>th</sup> meeting held on June 28, 2012 and 20.11.2012 respectively with the directions (i) select hotspots or locations with abundant insect populations for the trial and (ii) to use split plot design with main plot and subplots to stop inter-plot movements of the insects:

5.5.9 In view of the above, and taking in to consideration the recommendations of the RCGM, the Committee approved the request for conduct of confined field trials with transgenic maize (Event MON 89034 x NK603) to evolve a refuge strategy for transgenic maize hybrids during any appropriate seasons subject to submission of NOC from the State Government where the trials will be conducted.

**5.6 Request for extension of the validity period for conduct of Biosafety Research (BRL-I) trials and inclusion of trial location to Telangana with transgenic rice events namely; MHR03, MHR05, MHR32, MHR174, MHR256, MHR83, MHR90, MHR95, MHR489 and MHR509 containing *cry1Ac* and *cry1Ab* gene by Metahelix Life Sciences.**

5.6.1 The Committee considered the request of M/s Metahelix Life Sciences for extension of the validity period for conduct of BRL-I trials with Bt rice events namely; MHR03, MHR05, MHR32, MHR174, MHR256, MHR83, MHR90, MHR95, MHR489 and MHR509 expressing *Cry 1Ac* and *Cry 1Ab* genes. This proposal was considered as an additional agenda item with the permission of the Chair.

5.6.2 The Committee noted that the GEAC in its 112<sup>th</sup> meeting held on 21.9.2012 had approved the request for conduct of BRL-1 on rice (*Oryza sativa*) events namely MHR03, MHR05, MHR32, MHR174, MHR256, MHR83, MHR90, MHR95, MHR489 and MHR509 containing *cry1Ac* and *cry1Ab* gene in long leased land at Vattinagulapalli Village, Ranga Reddy District in Andhra Pradesh during appropriate season in 2011-2012. The GEAC had extended the validity for conduct of BRL-I trials in its 116<sup>th</sup> meeting held on 11.4.2012

5.6.3 The Committee further noted that the applicant has requested for inclusion of Telangana State in the permission letter approved for BRL-I trials instead of Andhra Pradesh as the proposed location is now part of the newly formed state of Telangana.

5.6.4 In view of the above, the Committee approved the request for extension of the validity period to conduct BRL-I trials with Bt rice events expressing *Cry 1Ac* and *Cry 1Ab* at Vattinagulapalli Village, Ranga Reddy, Telangana during any appropriate seasons subject to submission of NOC from the State Government where the trials will be conducted.

**Agenda Item No 6: Application related to Pharmaceuticals:**

**6.1 Request for revalidation of GEAC permission for manufacture and marketing of Brucella abortus (strain 19) Vaccine, live, IP by M/s Intervet India Pvt. Ltd, Pune.**

6.1.1 The Committee considered the request of M/s Intervet India Pvt. Ltd for revalidation of GEAC permission letter dated 11.8.2010 for manufacture and marketing of Brucella abortus (strain 19) Vaccine, live, IP in India.

6.1.2 The Committee noted that the GEAC had approved the manufacture and marketing of Brucella abortus (strain 19) Vaccine, live, IP in its 102<sup>nd</sup> meeting held on 30.7.2010 for a period of four years. In accordance with the provisions of Rules 1989 13 (2), approval of the

GEAC shall be valid for a period not exceeding four years at the first instance and subsequent renewable for 2 years at a time.

6.1.3 The Committee noted that M/s Intervet India Pvt Ltd vide their letter No IIP/LRA/GEAC-renewal/ Brucella abortus /2014/39 dated 22.07.2014 has submitted following information :

- For the last 3 years Brucella abortus S19 vaccine is being manufactured and supplied to Department of Animal Husbandry and Dairying under the Ministry of Agriculture as per tender conditions set on yearly basis:
- Number of Brucella S19 vaccine doses supplied to the Government from 2012 to 2014 till date (June) are 0.84 Million doses.
- Number of Brucella S19 vaccine doses supplied to the commercial dairy farms from 2012 to 2014 till date (June) are 0.15 Million doses.
- Post marketing surveillance data: is maintained by Department of Animal Husbandry and respective State Governments (Like Punjab, Karnataka etc). Post – vaccination disease surveillance amongst few dairy farms in Maharashtra do indicates that economic losses due to brucellosis disease are minimized in the farm conditions.
- Regarding marketing feedback it was noted that Departments of Animal husbandry, Government of India and State Governments are the main customers for Brucella S19 vaccine and vaccine is used by them to the farmer. Same dairy farmer is using the vaccine repeatedly to their young calves on annual basis. Technical advice is extended to all dairy farmers through specialized cell called "Veterinary Services Department".
- Regarding the Incidence of disease it was noted that Brucellosis is part of control program by Government of India; the disease situation is monitored by the Government directly. Overall, Brucellosis disease situation is under control in all dairy farms and villages where strict bio-containment practices are followed along with vaccination of female calves.

6.1.4 After detailed deliberations, and taking in to the consideration the information provided by the applicant, the Committee decided to revalidate the GEAC permission for manufacture and marketing of Brucella abortus (strain 19) Vaccine, live, IP, for a period of two years.

## **6.2 Permission to carryout non-commercial trials to scale up yeast biotransformation process using GMO yeast Category I yeast (*Saccharomyces cerevisiae*) with volume upto 4000L by M/s Embio Ltd. Mumbai.**

6.2.1 The Committee noted that the request of M/s Embio Ltd, Mumbai was considered by the GEAC in its 118<sup>th</sup> meeting held on 21.03.2014 wherein Committee decided in the first instance to obtain information on (i) details of gene construct of enzyme and their function and (ii) details of transformation. The Committee also requested RCGM to reconsider the application on the basis of the above information and if required the applicant may be requested to make a presentation before the RCGM. Accordingly decision on the proposal was deferred.

6.2.2 The Committee also noted that the proposal was reconsidered by the RCGM in its 134<sup>th</sup> meeting held on 26.5.2014. RCGM also informed that applicant made a presentation before the Committee. RCGM recommended the same to GEAC for further consideration and requested the applicant to submit details of effluent treatment protocol and a copy of the approval received from Central Pollution Control Board.

6.2.3 The Committee noted that the applicant has subsequently, submitted effluent treatment protocol and copy of the Consent to Operate under Air/Water Acts received from State Pollution Control Board. The Consent is valid up to 30.7.2015.

6.2.4 After detailed deliberations, and taking in to the consideration the recommendations of the RCGM, the Committee approved the request to carryout non-commercial trials to scale up yeast biotransformation process using GMO yeast Category I yeast (*Saccharomyces cerevisiae*) with volume upto 4000L.

**Agenda Item No 7: With the permission of Chair**

7.1 One of the Members opined that the following information regarding monitoring of BRL-I and BRL-II trials may be considered by the GEAC in the next meeting:

- How many NOCs have been received?
- How many field trials are being conducted in our country this Kharif (June to November) season
- What is the status of the monitoring?

7.2 Member Secretary informed that only one BRL-II trials on transgenic maize of M/s Monsanto are going on at MPKV, Rahuri. The GEAC issued permission letter after receipt of NOC on 8.7.2014. The trials were planted on 5<sup>th</sup> August 2014. The monitoring dates are 18-19<sup>th</sup> September 2014.

7.3 The Committee decided to obtain BRL-I information from DBT/RCGM.

**The meeting ended with a vote of thanks to the Chair and Members.**

**Next date of GEAC meeting is tentatively scheduled for 29<sup>th</sup> Oct'2014**

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## Annexure -1

List of the Members who attended the 122<sup>nd</sup> GEAC meeting held on 28.08.2014

S.No.	Name and address
1.	Shri Hem Pande, Additional Secretary, MoEF& CC and Chairman ,GEAC.
2.	Shri. Bishwanath Sinha, Joint Secretary, MoEF& CC and Co-Chairman ,GEAC
3.	Dr. B. Sesikeran, Former Director, National Institute of Nutrition, Hyderabad.
4.	Dr. Swapan Kumar Datta, DDG (Crop Science), Indian Council of Agricultural Research, Krishi Bhawan, New Delhi.
5.	Dr. Ramesh Sonti, Chief Scientist, CSIR, Centre for cellular & Molecular Biology (CSI-CCMB) Uppal Road, Hyderabad
6.	Dr. V V Ramamurthy, Principal Scientist, Entomology Division, IARI, New Delhi.
7.	Dr. Luther Rangreji, Associate Professor, Faculty of Legal Studies, South Asian University,233, Akbar Bhavan, Chankyapuri
8.	Shri R.K. Mishra, ADC(Seeds) Department of Agriculture & Cooperation Ministry of Agriculture, Krishi Bhawan, New Delhi
9.	Dr. S.S. Banga, Plant Breeder, Punjab Agriculture University, Ludhiana
10.	Prof. O. P. Govila, Former Prof. of Genetics, Indian Agricultural Research Institute, "MANAS" House No. BU-58, Pitampura, Delhi
11.	Shri. R. Murali, Dy Director (E) , Directorate of Plant Protection, Quarantine & Storage NH IV, Faridabad-121001. New Delhi
12.	Dr. Ranjini Warriar, Director, Ministry of Environment, Forests & Climate Change and Member Secretary, GEAC.
13.	Smt. Madhu Gupta, Research Officer, MoEF& CC.

## Representative from Companies

14.	Dr. Raja Rajagopal , M/s Dupont India Pvt. Ltd
15.	Dr. Manish Deshpande, M/s Dupont India Pvt. Ltd
16.	Dr. A. K. Mohanty, Principal Scientist , NDRI , Kamal
17.	Dr. Shiv Prasad , Principal Scientist & Head , NDRI ,Karnal
18.	Dr. Deepak Prem , Regulatory Affairs Team leader;
19.	Mr. Dhiraj parit, Regulatory Affairs Lead, M/s Monsanto India Pvt . Ltd.
20.	Dr. David Sa/miras , Science Fellow, M/s Monsanto St. Louis ,USA
21.	Dr. Amrish Tyagi , Principal Scientist , NDRI , Kamal
22.	Nitin Ahire , National TD Manager , M/s Bayer BioSciences India Pvt. Ltd
23.	Tim Dennely , M/s Bayer BioScience Pvt Ltd.
24.	Mr. Yogesh Kumar, Regulatory Affairs, M/s Bayer BioScience Pvt Ltd