

Decisions taken in the 122nd meeting of the Genetic Engineering Appraisal Committee (GEAC) held on 28.08.2014

The 122nd 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

The deliberations and decisions taken in the GEAC meeting in respect of Agenda items 5 to 6 are as follows:

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 m².

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 observed that proposal has been recommended by the IBSC and RCGM in its 115th 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.

5.1.4 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 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.

5.1.5 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 m².

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

- Multiply valINV RNAi transgenic potato event KChipInvRNAi-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

5.2.3 The Committee observed that proposal has been recommended by the IBSC and RCGM in its 115th 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.

5.2.4 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.

5.2.5 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 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.

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

5.3.4 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 observed that the proposal was recommended by IBSC in its 44th meeting and RCGM in its 130th meeting held on 27.12.2012 and 21.01.2014 respectively. 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.

5.4.5 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 was re-considered the request in its 119th meeting of GEAC held on 25.4.2014 with the revised protocol which does not include single event NK603 wherein the Committee decided 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 provided by the applicant.

5.5.3 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.

5.5.4 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 Coccinelids and spiders on the *Bt* maize and non-*Bt* plants

5.5.5 The Committee observed that the proposal was recommended by IBSC in its 42nd meeting and RCGM recommended in its 118th 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.

5.5.6 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 at six locations namely Andhra Pradesh, Karnataka, Tamil Nadu, Gujarat, Maharashtra and Bihar during dry season and eight locations during wet season namely Gujarat, Rajasthan, Haryana, Madhya Pradesh, Tamil Nadu, Andhra Pradesh, Karnataka and Uttar Pradesh 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 112th 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 116th 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 102nd 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 considered the following information submitted by the applicant:

- 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 indicate 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 118th 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 134th 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.
