Decisions taken in the 94th meeting of the Genetic Engineering Approval Committee (GEAC) held on 10.6.2009.

The 94th meeting of the GEAC was held on 10.6.2009 in the Ministry of Environment and Forests (MoEF) under the Chairmanship of Shri B S Parsheera, Special Secretary, MoEF and Chairman GEAC.

Agenda item No. 4: Consideration of application for confined field trials of BRL-1/event selection of transgenic crops expressing new genes/events as recommended by the RCGM.

4.1 Permission for repeating the biosafety research trials (BRL-1) during the second year trials on Bollgard-II RRF hybrids namely MRC-8017 BG-II, MRC-8031 BG-II in the north zone and MRC-8347 BG-II & MRC-8351 BG II expressing stacked *cry1Ac & cry2Ab* and *CP4EPSPS* genes at two locations each in the central and south zones during Kharif 2009 by M/s Maharashtra Hybrid Seeds Co. Ltd., Mumbai.

4.1.1 The Committee noted that the GEAC in its meetings held on 28.5.2008, 9.7.2008 and 13.8.2008 had approved the conduct of BRL-I of the above hybrids expressing *cry1Ac & cry2Ab and CP4EPSPS* genes (MON 15985 X MON 88913) at two locations each in the north, central and south zones, respectively for generating the biosafety and bio-efficacy data.

4.1.2 It was noted that the present request of the applicant is to conduct the BRL – I trials during the second year with the same transgenic cotton hybrids at the same locations. During the deliberations one of the members opined that in view of the post harvest restriction which has been imposed on the applicant, it may be advisable to conduct the trials at new locations. The Committee was of the view that the trials may be permitted at the same site provided there is a gap of minimum three months before the next trial is initiated.

4.1.3 The RCGM in its 76th meeting held on 2.5.2009 has recommended the conduct of second year BRL-1 on Bollgard –II RRF hybrids namely MRC-8017 BG-II, MRC-8031 BG-II in the north zone, MRC-8347 BG-II & MRC-8351 BG II in the central and south zones expressing the *stacked cry1Ac & cry2Ab and CP4EPSPS* genes at two locations each zone during Kharif 2009 for generating biosafety data.

4.1.4 After detailed deliberations and based on the recommendations of the RCGM, the Committee approved the request for conduct of confined field trials of BRL- 1 during the second year with Bollgard-II RRF hybrids namely MRC-8017 BG-II, MRC-8031 BG-II in the north zone and MRC-8347 BG-II & MRC-8351 BG II expressing stacked *cry1Ac & cry2Ab* and *CP4EPSPS* genes at two locations each in the central and south zone.

4.2 Permission to conduct evaluation of bio-efficacy, residue, phytotoxicity and carryover of potassium salt of glyphosate formulation of herbicide on transgenic stack cotton hybrids *(MON 15985XMON 88913)* at PAU, Ludhiana instead of MPKV, Rahuri by M/s Maharashtra Hybrid Seeds Company Ltd., Mumbai.

4.2.1 The Committee noted that the above proposal was approved by the GEAC in its meeting held on 12.11.2008 at two locations at Mahatama Phule Krishi Vidyapeeth, Rahuri in Maharashtra and Anand Agriculture University in Gujarat. However, the study could not be undertaken due to late approval. The present request of the applicant is for change in one location from MPKV, Rahuri (Maharashtra) to PAU, Ludhiana.

4.2.2 The RCGM in its 76th meeting held on 2.5.2009 has recommended the evaluation of bioefficacy, residue, phytotoxicity and carryover of potassium salt of glyphosate formulation of herbicide on transgenic stack cotton hybrids (MON 15985 X MON 88913) at PAU, Ludhiana.

4.2.3 After detailed deliberations and based on the recommendations of the RCGM, the GEAC approved the request for change in location by the applicant.

4.3 Permission to conduct biosafety research trials (BRL-1) on two transgenic corn hybrids namely 30V92HR and 30B11HR containing *cry1F* and *CP4EPSPS* genes (stacked event of TC1507 X NK603) during Kharif 2009 by M/s Pioneer Overseas Corporation, Hyderabad.

4.3.1 The Committee considered the request of M/s Pioneer Overseas Corporation, Hyderabad for conducting BRL-1 trials on two transgenic corn hybrids namely 30V92HR and 30B11HR containing *cry1F* and *CP4EPSPS* genes (stacked event of TC1507 X NK603) at four State Agricultural Universities (SAUs) namely; University of Agricultural Science (UAS), GKVK Campus, Bangalore; University of Agricultural Science (UAS), Dharwad; Maharana Pratap University of Agriculture and Technology, Udaipur and Acharya N.G Ranga Agricultural University (ANGRAU), Hyderabad during Kharif 2009.

4.3.2 Transgenic corn hybrids with stacked event of TC 1507 x NK603 has been developed for preventing yield losses of corn crop and improve crop productivity. The corn hybrids with stacked event TC 1507 X NK 603 express novel proteins: the insecticidal protein c*ry1F* which confers resistance to lepidopteron insect pests and the CP4 EPSPS protein which confers tolerance to the herbicide glyphosate (from NK 603 event).

4.3.3 M/s Dow Agro Sciences (DAS), USA and Pioneer Hi- Bred International, USA have jointly developed TC-1507 event in corn and holds equal rights on the said event. A declaration has been signed whereby DAS has authorized M/s Pioneer Overseas Corporation, Hyderabad to file a joint application before the regulatory authorities for obtaining regulatory approvals for transgenic corn expressing TC-1507+NK 603 event in India.

4.3.4 The applicant has also submitted a validated event specific LOD protocol of 0.01% from SGS India Pvt. Ltd, Ahmedabad. The RCGM in its 77th meeting held on 25.5.2009 has recommended the proposal of M/s. Pioneer Overseas Corporation, Hyderabad to conduct BRL-1 trials on two transgenic corn hybrids namely 30V92HR and 30B11HR containing *cry1F* and *CP4EPSPS* genes (stacked event of TC1507XNK603) at four SAUs.

4.3.5 During the deliberations, the Committee also considered the following three protocols to conduct BRL-1 trials with transgenic corn:

Protocol-I: (Guard rows):

- H.4 Reproductive Isolation:
- Sowing of **13 rows** of African Tall Maize plants covering a distance of **7.8** meters all around the experimental plot area.
- Keeping an isolation distance of **50 meters** (including 7.8 meters) all around the experimental field. {This is as per the Indian Minimum Seeds Certifications Standards- Maize Hybrids (page No. 37-41) where maximum distance prescribed is **300** meters and also reducing the distance by planting border rows. By planting 13 border rows, the distance can be reduced to 50 meters,}

Protocol-II (Detasseling/removal of male floral parts):

- H.4 Reproductive Isolation:
- Detasseling/removal of male floral parts in all transgenic and non-transgenic maize entries.
- Sowing of **13 rows** of African Tall Maize plants covering a distance of 7.8 meters all around the experimental plot area.
- Keeping an isolation distance of **10** meters (including 7.8 meters)

Protocol-III (Spatial isolation):

- H.4 Reproductive Isolation:
- Sowing of **10** or **13 rows** of African Tall Maize plants covering a distance of **6** to **7.8** meters all around the experimental plot area.
- Keeping an isolation distance of **300 meters** (including 6 to 7.8 meters) all around the experimental field. (This protocol would be implemented, provided sufficient land is available with the SAUs).

4.3.6 The Committee also noted that IBSC has approved Protocol-II (Detasseling/removal of male floral parts) on the following grounds:

1. This protocol addresses the issue of pollen dispersal effectively as detasseling of corn plants in treatments as indicated.
2. As total plants in the treatment are very small in number, the detasseling activity could be done timely and effectively.
3. This protocol also takes care of accidental transfer of target genes into other corn species.
4. As this protocol takes minimum land requirement it would be convenient and easy to conduct at State Agricultural Universities (SAU) research Station, Directorate of Maize Research Stations (DMR) and in applicant fields.

4.3.7 The Committee was of the view that detasselling/removal of male floral parts can cause disturbances in the metabolic and reproductive behaviors of the plant and therefore the plant should be grown under normal conditions and trials be conducted with an isolation distance of 300 m and physical barrier of 10 or 13 rows of African Tall Maize plants covering a distance of 6 to 7.8 meters all around the experimental plot area as suggested in Protocol III.

4.3.8 The Committee also sought clarification from the representative of M/s Pioneer Overseas Corporation, on whether the hybrids 30V92HR and 30B11HR are imported materials or Indian germplasm. It was clarified that both the hybrids and four parental lines were imported from USA with the approval of the RCGM for field testing and seed multiplication respectively. The conventional counterparts are popular hybrids which are extensively cultivated in India for the past 15 years. The company has completed the introgression/ transformation process with the two gene events in the USA and has imported the seeds for field testing in India.

4.3.9 After detailed deliberations and based on the recommendations of the RCGM, the Committee approved the request for conduct of confined field trial of BRL- 1 on two transgenic corn hybrids namely 30V92HR and 30B11HR containing *cry1F* and *CP4EPSPS* genes (stacked event of TC1507 X NK603) at four SAUs during Kharif 2009

4.4 Permission to conduct biosafety research trial level-1 (BRL-1) with 2 transgenic corn hybrids containing c*ry1F* (event TC 1507) under confined conditions during Kharif 2009 for biosafety, bio-efficacy and agronomic evaluation by M/s Dow Agro sciences, Mumbai.

4.4.1 The Committee considered the request of M/s Dow Agro sciences, Mumbai for conducting BRL-I on two transgenic corn hybrids containing *cry1F* (event TC-1507) at three SAUs namely; Tamil Nadu Agricultural University, Coimbatore; University of Agricultural Sciences (UAS), Bangalore and University of Agricultural Science (UAS), Davangere during Kharif 2009 for generating biosafety, bio-efficacy and agronomic data.

4.4.2 Transgenic corn (event TC-1507) hybrids expressing Cry 1F protein was developed to prevent lepidopteron insect damage and subsequent yield losses of corn crop and improve crop productivity. M/s Dow Agro Sciences, USA and Pioneer Hi- Bred International, USA have jointly developed TC-1507 event in corn and holds equal rights on the said event. A declaration has been signed that M/s Dow Agro Sciences (DAS), USA would act as the nodal agency for providing all

information and submitting applications for obtaining regulatory approvals. IBSC in its meeting held on 3.3.2009 and 6.5.09 has approved the proposal for conducting BRL-1 trials with TC 1507 maize at two locations with two hybrids in the south zone.

4.4.3 The applicant has also submitted a validated event specific LOD protocol of 0.01% from SGS India Pvt. Ltd, Ahmedabad. The RCGM in its 77th meeting held on 25.5.2009 has recommended the proposal to conduct BRL-1 trials with TC-1 and TC-2 transgenic corn hybrids containing *cry1F* event (TC-1507) under confined conditions at three SAUs for generation of biosafety and bio-efficacy data.

4.4.4 After detailed deliberations and based on the recommendations of the RCGM, the Committee approved the request for conduct of BRL- 1 trials with 2 transgenic corn hybrids containing c*ry1F* (event TC 1507) at three SAUs during Kharif 2009 for generating biosafety, bio-efficacy and agronomic data. The BRL-1 trials will be conducted as per Protocol III indicated under agenda item 4.3.

4.5 Permission to conduct biosafety research trials level 1 (BRL-1) during the second year with two transgenic cotton hybrids namely WS 103 and WS 106 expressing *cry 1 Ac & cry 1F* (Widestrike =Event 3006-210-23 and Event 281-24-236) at two locations in south zone for generating biosafety, bio-efficacy and agronomic data by M/s Dow Agro Sciences, Mumbai.

4.5.1 The Committee noted that the GEAC in its meeting held on 28.5.2008 had approved the conduct of BRL-I trials with two transgenic cotton hybrids namely WS 103 and WS 106 expressing *cry 1Ac & cry 1F* (Widestrike=Event 3006-210-23 and Event 281-24-236 at two locations in south zone for generating biosafety data. The applicant has submitted the following data generated during the first year BRL-1 trials:

i. Quantification of Cry1F and Cry1Ac protein expression by WS hybrids using ELISA;
ii. DNA fingerprinting of WS cotton hybrids
iii Generation of baseline susceptibility data and detectable proteins on target petss and bio-efficacy studies
iv Bio-efficacy experiments with Widestrike
v Studies on soil micro-flora, earthworms and estimation of *Cry1F and cry 1Ac* protein concentration in soils from BRL-1 trials of WideStrike hybrids
vi Study of pollen flow from WS 106 hybrid at one location in south zone during Kharif, 2008 season
vii Study on germination, aggressiveness and weediness of WS hybrids in Kharif, 2008 in south zone.

4.5.2 The present request of the applicant is to conduct the BRL-1 trials during the second year with the same two transgenic cotton hybrids at the same location.

4.5.3 The RCGM in its 77th meeting held on 25.5.2009 has recommended the conduct of BRL-1 trials during the second year with two transgenic Widestrike cotton hybrids namely WS 103 and WS 106 expressing *cry 1Ac & cry 1F (*Widestrike= Event 3006-210-23 and event 281-24-236) under confined condition at two locations in south zone during kharif -2009 as per new SOPs and protocols.

4.5.4 After detailed deliberations and based on the recommendations of the RCGM, the Committee approved the request for conduct of BRL-1 during the second year with two transgenic cotton hybrids namely WS 103 and WS 106 expressing *cry 1 Ac & cry 1F* (Widestrike =Event 3006-210-23 and Event 281-24-236) at two locations in south zone for generating biosafety, bio-efficacy and agronomic data.

4.6 Permission to conduct biosafety research trials level 1 (BRL-1) with two transgenic cotton hybrids namely WS 103 and WS 106 expressing *cry 1Ac & cry1F* (Widestrike=Event 3006-210-23 and Event 281-24-236) for under confined condition at two locations in central zone for biosafety, bio-efficacy and agronomic evaluation by M/s. Dow AgroSciences, Mumbai.

4.6.1 The Committee noted that the present request of M/s Dow AgroSciences, Mumbai is for conduct of BRL-1 trials with two transgenic cotton hybrids namely WS 103 and WS 106 expressing *cry 1 Ac & cry 1F* (Widestrike=Event 3006-210-23 and Event 281-24-236) at two locations namely Aurangabad (Maharashtra) and Vadodara (Gujarat) in the central zone for generating biosafety, bio-efficacy and agronomic data.

4.6.2 The RCGM in its 77th meeting held on 25.5.2009 has recommended the conduct of BRL-1 trials with two transgenic Widestrike cotton hybrids namely WS 103 and WS 106 expressing *cry 1Ac & cry 1F* (Widestrike= Event 3006-210-23 and event 281-24-236) at two locations in the central zone during kharif -2009.

4.6.3 After detailed deliberations and based on the recommendations of the RCGM, the Committee approved the request for conduct of BRL-1 trials with two transgenic cotton hybrids namely WS 103 and WS 106 expressing *cry 1 Ac & cry 1F* (Widestrike =Event 3006-210-23 and Event 281-24-236) at two locations in central zone for generating biosafety, bio-efficacy and agronomic data.

4.7 Permission to conduct biosafety research trials level 1 (BRL-1) second year trials and F1 seed production in an area of 0.5 hectare on two transgenic cotton hybrids namely JKCH-99 Bt EGII and JK-Indra Bt EGII containing *cry1Ac & cry1EC* (Event1 and Event 24) under confined condition at two locations in Central and South zones during 2009 by M/s J. K. Agri Genetics Ltd., Hyderabad.

4.7.1 The Committee noted that the GEAC in its meeting held on 13.8.2008 had approved the conduct of BRL-I with JKCH-99 Bt EGII and JK-Indra Bt EGII hybrids expressing containing *cry1Ac & cry1EC* (Event1 and Event 24) at two locations each in the central and south zones respectively for generating biosafety, bio-efficacy and agronomic data.

4.7.2 The present request of the applicant is to conduct the BRL-1 trials during the second year. The applicant has also requested for permission to produce F1 seed of the above hybrids at one location in an area of 0.5 ha.

4.7.3 The RCGM in its 77th meeting held on 25.5.2009 has recommended the conduct of BRL-1 trials during the second year and F1 seed production in an area of 0.5 acre on two transgenic cotton hybrids namely JKCH-99 Bt EGII and JK-Indra Bt EGII expressing *cry1Ac & cry1EC* (Event1 and Event 24) at two locations each in central and south zones respectively during Kharif -2009. The Committee noted that the request for seed production by the applicant and the recommendations of RCGM are at variance. The Committee opined that the seed production may be permitted in an area of 0.5 acre at one location as recommended by the RCGM.

4.7.4 After detailed deliberations and based on the recommendations of the RCGM, the Committee approved the request for conduct of BRL-1 trials during the second year on two transgenic cotton hybrids namely JKCH-99 Bt EGII and JK-Indra Bt EGII containing *cry1Ac & cry1EC* (Event1 and Event 24) at two locations each in the central and south zones during 2009.

4.8 Permission to conduct confined field trial for Event Selection of 88 Bt Rice containing *cry1Ab, cry1Ca* and *bar* genes for research and development purpose at company owned land during Kharif 2009 by M/s. Bayer Biosciences Pvt. Ltd., Hyderabad.

4.8.1 The Committee considered the request of M/s. Bayer Bioscience Pvt. Ltd., New Delhi to conduct 'Elite Event Selection Trials' on 88 Bt rice lines expressing *cry 1 Ab, cry 1 Ca* and bar genes for research and development purpose within their own R & D farm during Kharif 2009.

4.8.2 RCGM in its 77th meeting held on 25.5.2009 has recommended the conduct of 'Elite Event Selection Trials' on 88 Bt rice lines for research and development purpose at their own R & D farm at Hyderabad.

4.8.3 The Committee conveyed its no objection to the above proposal.

4.9 Permission to conduct biosafety research trials (BRL-1) during Kharif, 2009 on two transgenic corn hybrids namely Hishell and 900M Gold expressing MON 89034 and NK603 events at six State Agricultural Universities (SAUs) by M/s Monsanto India Ltd., New Delhi.

4.9.1 The Committee noted that the GEAC in its meetings held on 12.11.2008 had approved the conduct of BRL-I of the above mentioned two corn hybrids expressing stacked events MON 89034 and NK603 at three SAUs namely; Mahatama Phule Krishi Vidyapeeth (MPKV), Rahuri, Maharashtra; Tamil Nadu Agricultural university (TNAU), Coimbatore, Tamil Nadu and Rajendra Agricultural university(RAU), Samastipur, Bihar during Rabi, 2008 for generating the bioefficacy and biosafety data.

4.9.2 The present request of the applicant is to conduct BRL-1 trials with the same two transgenic corn hybrids Hishell and 900M Gold expressing MON 89034 and NK603 events at six locations in the following SAUs during Kharif, 2009:

1. Punjab Agricultural Unviersity, Ludhiana;
2. Regional Research Station, Uchani, Karnal (CCS HAU, Hisar), Haryana
3. Directorate of Weed Science Research, Jabalpur, Madhya Pradesh;
4. MPUA & Tech., Udaipur, Rajasthan;
5. University of Agricultural Science, Dharwad, Karnataka; and
6. Tamil Nadu Agricultural Unversity, Coimbatore, Tamil Nadu.

4.9.3 The applicant vide their communication dated 9.6.2009 to the GEAC has informed that the BRL-1 trials during Rabi season at three SAUs has recently been completed and the data compilation is under progress. However, corn is grown in Rabi and Kharif season with spread in 5 varied agro climatic zones resulting in varied appearance of insect pests, non target organisms, weeds and soil micro-flora. This necessitates the generation of biosafety data during Kharif season also.

4.9.4 The RCGM in its 76th meeting held on 2.5.2009 has recommended the conduct of BRL-1 at eight locations subject to the submission of report of BRL-1 trials conducted during Rabi-2008. The RCGM subsequently modified its recommendations in the 77th RCGM meeting held on 25.5.2009 and has conveyed that M/s Monsanto India Limited, New Delhi may be permitted to conduct BRL-I trials of corn hybrids Hishell and 900 M Gold containing events MON 89034 and NK603 under confined conditions at 20 locations, as requested instead of restricting them to 8 locations, as the guidelines for the conduct of confined field trials have provision for conducting a maximum of 20 BRL-I trials. It was clarified that the new guidelines and SOPs for conducting confined field trials is not specific to BRL-1 trials only and is applicable to BRL-II trials as well. It is in this context that a maximum of 20 locations has been indicated in the guidelines. Further for generation of biosafety data a policy decision has been taken by the GEAC to permit trials only in one or two locations with one of two hybrids.

4.9.5 After detailed deliberations and based on the recommendations of the RCGM, the Committee approved the request for conduct of BRL-1 trials during Kharif, 2009 on two transgenic corn hybrids namely Hishell and 900M Gold expressing MON 89034 and NK603 events at six SAUs.

Agenda Item No 5 : Pharmaceuticals (reconsideration case)

5.1 Permission for import and marketing of live vaccine Innovax- ND-SB vaccine, a preventive vaccine in poultry from USA by M/s Intervet India Pvt.Ltd.

5.1.1 The Committee noted that the above proposal was deferred in the 92nd meeting of the GEAC held on 11.2.2009 as some of the experts opined that the live vaccines are banned in India. It was decided to obtain the requisite clarifications from the Department of Animal Husbandry, Ministry of Agriculture.

5.1.2 The Department of Animal Husbandry vide their letter No. 102-69/2007-Trade dated 28.4.2009 has informed that the import of live poultry vaccine such as Marek's Disease, Infectious Bursal Disease, Infectious Bronchitis and Salmonella, New Castle Disease and Avian Encephalomyelitis are allowed in India as per Director General of Health Services order No. X-11026/1/04-D dated 3.5.2005 and No. X-11026/1/2004-DC dated 20.6.2007.

5.1.3 The Committee conveyed its no objection to the proposal.

Agenda Item No 6: Any other matter with the permission of the Chair.

6.1 Monitoring for changes in bollworm susceptibility to Bt toxins deployed in pest resistant transgenic cotton.

6.1.1 The Committee noted that in accordance with the decision taken in the GEAC meeting held on 11.1.2008 and recommendations from the 'National Consultation on IRM Strategy' held on 21-22 January, 2008 at New Delhi, CICR, Nagpur has submitted a proposal for monitoring the baseline susceptibility of bollworm to Bt gene through the CICR/ICAR regional stations. The proposal has been recommended by the RCGM and other experts. The proposal would be funded jointly by DBT and MoEF. Additional centers would be taken up by CICR under the technology mission project.

6.1.2 Some of the members were of the view that the post release surveillance should be carried out at the expense of the technology provider and should not be subsidized by the Government. Member Secretary, GEAC informed that CICR, Nagpur was notified as a nodal agency for monitoring the changes in bollworm susceptibility to Bt toxin in transgenic cotton in 2002 and till date the monitoring was being carried out at the expense of the technology provider. Each technology provider was required to pay Rs. 10/- lakhs per annum for conducting the study. However, the present initiative was taken up since the area of Bt cotton cultivation has increased exponentially and taking into consideration the views expressed by members of the GEAC and other stakeholders in the National Consultation on IRM strategy that such studies should be independent of the involvement of the applicant.

6.1.3 The Committee after detailed deliberation opined that in view of the new scenario (increased area under cotton cultivation and release of new events in cotton crop) there is a need to review the above matter to decide on the amount to be charged from the applicants and modalities for payment. The Committee approved the conduct of the above study and during the interim period, it was agreed that the above study may be jointly supported by the MoEF, DBT and CICR. The Committee was also of the view that equal emphasis should be placed on Pectinophora gossypiella (Pink bollworm; PBW) while monitoring the changes in baseline susceptibility in bollworm for which CICR may involve experts from other institutions as necessary.

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