Decisions taken in the 93rd meeting of the Genetic Engineering Approval Committee (GEAC) held on 13.5.2009.

The 93rd meeting of the GEAC was held on 13.5.2009 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 5: Consideration of applications for commercial release of Bt cotton hybrids expressing new genes

5.1 **Permission for commercial release of MH 5125 Bt and MH 5174 Bt cotton hybrids expressing synthetic *cry 1C* gene (event 9124) for central and south zones by M/s Metahelix Life Sciences Pvt. Ltd, Bangalore .**

5.1.1 The Committee considered the application of M/s Metahelix Life Science Pvt. Ltd for commercial release of Bt cotton hybrids namely 5174 Bt and 5125 Bt expressing synthetic *cry 1C* gene (event 9124) in central and south zones. The following points were noted:

1. The indigenously developed Bt cotton developed by the applicant is in due compliance with the regulatory process.
2. This event expresses a truncated, synthetic *cry 1C* gene designed by the Company and obtained by protocols developed for cotton transformation in-house. The synthetic gene is designed based on the *cry 1C* protein made by *Bacillus thuringiensis*.
3. The Bt cotton hybrids 5174 Bt and 5125 Bt have completed multi locational field trials during Kharif, 2006 at seven locations in the central and south zones.
4. In the 86th GEAC meeting held on 25.6.2008, the applicant was given permission to conduct large scale field trials, ICAR trials and seed production. The applicant has now completed the large scale trials. However, in place of ICAR trials, the applicant has conducted SAU trials. The ICAR trials could not be taken up due to late approval.

5.1.2 The applicant has completed the following biosafety studies:

- Acute Oral Toxicity in Rats
- Sub chronic oral toxicity in rats (90 days)
- Primary Skin Irritation tests in rabbits
- Irritation of mucus membrane in rabbits
- Skin sensitization study in guinea pigs
- Allergenicity studies – Passive Cutaneous Analhylaxis test.
- Feeding studies with laying hens
- Feeding studies with catfish
- Feeding studies in goats
- Feeding studies in lactating crossbred cows
- Pollen flow studies
- Weediness, Aggressiveness and Germination
- Effect of Bt cotton event MLS 9124 on beneficial fauna
- Study of soil micro flora of Bt and Non Bt soils
- Effect of Bt cotton on soil fauna
- Estimation of Cry 1C in soils of Bt cotton fields
- Baseline susceptibility studies for Spodoptera litura to Bt
- Biochemical equivalence
- Limit of Detection at 0.01% and event specific PCR.

5.1.3 It was informed that the LST / SAU trials of M/s Metahelix Life Sciences Ltd., could not be evaluated by the MEC as the term of the Committee expired on 12.2.2009. The Committee requested Dr. P. Ananda Kumar, former Chairman, MEC who was invited to the GEAC meeting as a special invitee, to give his views on the LST/SAU data. Dr. Kumar informed the Committee that the

performance of both the hybrids namely MH-5125 Bt and MH-5174 Bt was superior to the RCH-2 Bt (the conventional RCH-2 hybrid is a centrally notified variety and very popular among farmers).

5.1.4 Member Secretary, RCGM informed that the above proposal was considered by the RCGM in its meeting held on 2.5.2009 wherein the Committee sought comments of Dr. P. Ananda Kumar and two other experts on the performance of the hybrids under LST. The Committee also requested Director, NIN to review the acute toxicity studies using purified protein recently submitted by the applicant. Comments have been received from the experts wherein it has been concluded that the studies conducted by the applicant are in order. The Committee also noted that the acute toxicity studies using purified protein is a requirement under the new procedures for food safety assessment recently adopted by the GEAC/RCGM.

5.1.5 During the deliberations, the need for conducting acute toxicity studies using purified protein was discussed. It was opined that the above study was prescribed with a view to assess the toxicity/allergencity of a gene, if any, during the laboratory testing stage and such studies are necessary especially in food crops. It was also clarified that this is not a substitute to the acute toxicity studies using protein expressed from plant material. After detailed deliberations, it was agreed that the need for acute toxicity studies using purified protein should be case/gene/crop specific and may not be necessary in cases where the gene from one edible crop is transferred to another crop.

5.1.6 After detailed deliberations and taking into consideration the above facts, the Committee approved commercial release of MH 5125 Bt and MH 5174 Bt cotton hybrids expressing synthetic *cry 1C* gene (event 9124) for central and south zones developed by M/s Metahelix Life Sciences Pvt. Ltd, Bangalore .

5.2 Permission for commercial release of NHH-44 Bt cotton hybrid BN Bt event (BNLA 601) for central and south zones by M/s Central Institute for Cotton Research (CICR), Nagpur.

5.2.1 The Committee considered the application of M/s CICR, Nagpur for commercial release of NHH-44 Bt cotton hybrid BN Bt event (BNLA 601) expressing Bt *cry 1Ac* protein. The following points were noted:

1. The indigenously developed Bt cotton developed by the applicant is in due compliance with the regulatory process.
2. The transgenic *cry 1Ac* and amino acid sequence present in the BN Bt event is 99.99% similar to *cry 1Ac* expressing in the Event-1 of JK Seeds.
3. The Bt cotton NHH 44 Bt have completed multi locational field trials during Kharif, 2006 at four locations each in the central and south Zones.
4. In the 84th GEAC meeting held on 2.5.2008, the applicant was given permission to conduct large scale field trials, ICAR trials and seed production with NHH 44 Bt. The applicant has now completed the large scale trials and ICAR trials.
5. GEAC approved the commercial release of BN Bt (variety) developed by CICR in the north, central and south zones on the grounds that Bt technology has been introduced for the first time in a popular and well established varietal background.
6. There would be no cost to the trait value which would provide cheaper options to the farmers.

5.2.2 The applicant has also completed the following biosafety studies:

- Protocols to carry out Biosafety experiments on acute oral toxicity/allergenicity study of transgenic Bt cotton (Gossypium species) containing cry 1Ac gene in small laboratory animals (rat, rabbit, guinea pigs), live stock animals (cow, goat), birds, (chicken), fish.

- Toxicology study report by M/s Sriram Industrial Research, Delhi on small laboratory animals (rat, rabbit, guinea pigs).
- Pollen flow studies with Bt. cotton conduct as per guidelines of RCGM, DBT.
- Pollen flow studies with wild species of cotton with Bt cotton.
- Estimation of Bt-Cry protein expression at various stages of plant growth in the transgenic cotton plants.
- Transgenic Cotton expressing Bt-Cry protein and its effect on soil microflora and soil fauna (earthworm).
- Report -Studies on Boiler chicken performance as influenced by feeding diets containing Bt. cottonseed meal differences.
- Report- Evaluation of Bt and non- Bt meal as a feed ingredient for fish Common Carp and comparing the differences.
- Report- Effect of feeding cottonseed produced from Bt cotton cultivar on feed intake, production and composition of milk dairy cows.
- Animal feeding trials on Bio-safety studies with biotechnologically transformed Bt. cotton crop using seed meal.
- Identification and sequencing of the T-DNA insertion Region in the Genomic DNA of transgenic Bt-cotton (CV. Bikaner, Nerma) using Genome Walking Method.
- Limit of Detection at 0.01% and event specific PCR.

5.2.3 It was informed that the LST / ICAR of M/s CICR, Nagpur could not be evaluated by the MEC as the tenure of the Committee has expired 12.2.2009. The Committee requested Dr. P. Ananda Kumar, former Chairman, MEC who was invited to the GEAC as a special invitee, to give his views on the LST/ICAR data. Dr. Kumar informed the Committee that the performance of the hybrid NHH-44 Bt was superior to RCH-2 Bt.

5.2.4 The Committee also noted that the acute toxicity studies using purified protein is a requirement under the new procedures for food safety assessment recently adopted by the GEAC/RCGM whereas the BN Bt variety expressing *cry 1Ac* gene (BNLA 601 event) was approved for commercial release during Kharif, 2008.

5.2.5 To a query as to why the proposal was referred to the GEAC when the CICR developed Bt cotton event has been approved for commercial cultivation, it was clarified that the new event based approval procedure is applicable only for events that have completed three seasons of commercial cultivation.

5.2.6 After detailed deliberations and taking into consideration the fact that NHH-44 Bt was developed by using BN Bt as female parent which contains the same *cry 1Ac* gene & event that has already been approved for commercial cultivation, the Committee approved commercial release of NHH-44 Bt cotton hybrid developed by M/s CICR, Nagpur.

Agenda item No.6: Consideration of application for confined field trials of BRL-1 of transgenic crops expressing new genes/events as recommended by the RCGM.

6.1 Permission to conduct confined field trial of BRL- 1 on Bt. Brinjal containing *cry1Fa1* (Event 142) in their own farm land at three locations during summer 2009 by M/s Bejo Sheetal Seeds Pvt. Ltd., Jalna.

6.1.1 The present request of M/s Bejo Sheetal Seeds Pvt. Ltd., is for conduct of confined field trials of BRL- 1 on Bt. Brinjal containing *cry1Fa1* (Event 142) in their own research farm land at three locations during summer 2009. It was noted that the applicant has obtained the gene construct from IARI, New Delhi.

The Committee noted that the RCGM in its meeting held on 27.1.2009 has recommended the proposal subject to (i) confirmation on the *identify of the gene by NRCPB in view of the difference in*

terminology used in section F.1 and section F.10 i.e. cry1Fa1 and cry1Fa1 (Event 142) of the application; and (ii) the applicant should generate and submit the data on pepsin digestibility, thermal stability and acute oral toxicity of the purified protein. It was noted NRCPB has clarified that NRCPB/IARI has filed a patent application in India Patent Office New Delhi (No. 2048/Del/2006) on non codon-modified *cry 1Fa1* gene sequence. The gene *cry1Fa1* is expressed in brinjal (Pusa Purple Long) and the name of the event is 'Event 142'.

6.1.3 During the deliberations, the Member Secretary, GEAC informed that the GEAC in its meeting held on 12.11.2008 had constituted a Sub committee under the Chairmanship of Dr. K. R. Kranthi, Director, CICR to finalize the document pertaining to the list of studies to be undertaken under BRL-I trials and BRL-II trials of GM crops. However, the Sub-committee was unable to meet due to non-availability of the Chairman and some of the members. The document has now been posted on the DBT website and some comments have been received. Member Secretary, RCGM informed that the document has also been circulated to the members of the RCGM for their comments. The Committee advised that a Sub-committee under the Chairmanship of Prof. Arjula R. Reddy, Co-Chair, GEAC may examine the document and submit its recommendations to the GEAC.

6.1.4 To a query on the availability of information on site details such as location, size of trial plot, area under control of the applicant, type and distance from the nearest cultivated crop of the same species, etc., it was clarified that information is available in the application form. It was further clarified that information regarding field trials is available in the public domain.

6.1.5 After detailed deliberations and based on recommendations of the RCGM, the Committee approved the request for conduct of confined field trial of BRL- 1 on Bt. Brinjal containing *cry1Fa1* (Event 142) within the company's research farm at three locations namely; Jalna, Guntur and Varanasi during 2009.

Agenda Item No 7: Other Items.

7.1 Permission to export 2500 seeds of Bt okra transgenic seeds of event OE-17A expressing *cry 1Ac* gene to National Collections of Industrial, Food and Marine Bacterial (NCIMB) Ltd., U.K. by M/s Mahyco.

7.1.1 The Committee considered the request of M/s Mahyco to export 2500 seeds of Bt okra transgenic seeds of event OE-17A expressing *cry I Ac* gene to National Collections of Industrial, Food and Marine Bacterial (NCIMB) Ltd., U.K. for event identification pattern. It was noted that the applicant has been asked by the International Search Authority under Patent Co-operation Treaty to deposit the biological material to satisfy the requirement of Article 5 of the PCT (Patent Co-operation Treaty) for sufficiency of disclosure, i.e. the invention cannot be said to be disclosed adequately until the deposit of biological material. The Committee approved the above request subject to compliance with the provisions of the Biological Diversity Act, 2002.

7.1.2 The Committee further opined that there is an urgent need to create an Intellectual Depository Authority (IDA) for depositing biological materials in India. The feasibility of establishing such a facility at NBPGR may be explored. The Committee advised the Ministry to take up the matter with the concerned agencies such as Ministry of Agriculture/ Ministry of Commerce.

7.2 Permission to export 2500 seeds of Bt rice transgenic seeds of 3 events PE-2, PE-4 and PE-7 expressing cry 1Ac gene to National Collections of Industrial, Food and Marine Bacterial (NCIMB) Ltd., U.K. by M/s Mahyco.

7.2.1 The Committee considered the request of M/s Mahyco to export 2500 seeds of Bt rice transgenic seeds of 3 events PE-2, PE-4 and PE-7 expressing *cry 1Ac* gene to National Collections of Industrial, Food and Marine Bacterial (NCIMB) Ltd., U.K. for event identification pattern. It was noted

that the applicant has been asked by the International Search Authority under Patent Co-operation Treaty to deposit the biological material to satisfy the requirement of Article 5 of the PCT (Patent Co-operation Treaty) for sufficiency of disclosure, i.e. the invention cannot be said to be disclosed adequately until the deposit of biological material. The Committee approved the above request subject to compliance with the provision of the Biological Diversity Act, 2002.

7.3 Request from CICR, Nagpur for permission of the GEAC for cultivation of pigeon-pea as refugia border crop around BN Bt variety.

7.3.1 The Committee considered the request of M/s CICR, Nagpur to allow cultivation of pigeon-pea as refugia border crop around BN Bt variety on the grounds that; (i) There shall be no cross pollination which can dilute the BN Bt variety; (ii) Use of pigeon-pea as refugia has significance to farmers as they can preserve the BN Bt seed variety, which could be used for 5-6 years without any dilution; and (iii) For an acre, 200 gm of pigeon-pea (refugia) packet can be added to 2 kgs of BN Bt seeds which can be sold at Rs 200/- to Rs. 260/- per bag.

7.3.2 The Committee noted that cultivation of pigeon-pea along with cotton is a common practice in the Central and South zones. It was also noted that the above request is in line with the recommendations that emerged from the IRM strategy workshop organized by MoEF jointly with CICR, Nagpur in February, 2008.

7.3.3 After detailed deliberations, the Committee approved the cultivation of pigeon-pea as refugia border crop around BN Bt variety. The Committee was also of the view that pigeon-pea may be used as an alternate host in place of non Bt cotton refugia while growing Bt cotton.

7.4 Request for waiver of pollen flow studies on transgenic cotton containing genes *cry 1Ac* Event -1 and *cry 1EC* (Event -24) at JKAL R&D Farm Hyderabad by M/s J. K. Agri Genetics Ltd.

7.4.1 The Committee noted that the above request was rejected by the GEAC in its meeting held on 12.11.2008. Member Secretary, RCGM informed that the RCGM in its 73rd meeting held on 30.12.2008 was of the view that there is no scientific rationale in repeating the pollen flow studies just because of change of event in the cotton background as it is not going to change the biology of crop. The RCGM further advised that the regulatory system should also look into the economics of biosafety and avoid repetitive tests which may not be warranted.

7.4.2 After detailed deliberations, the Committee was of the opinion that the Sub committee constituted under Prof. Arjula R. Reddy, Vice Chancellor, Yogi Vemana University and Co-Chairman, GEAC to review the list of biosafety studies under BRL-I and BRL-II trials may give its considered opinion on the matter based on which a final view would be taken by the GEAC. It was therefore decided to defer decision on the above matter.

Agenda item No. 8: Pharmaceuticals

8.1 Permission for manufacture and marketing of FMD (Foot and Mouth Disease) vaccine by M/s Intervet India Ltd. Pune.

8.1.1. The Committee considered the request of M/s Intervet India Ltd. Pune for manufacture and marketing of FMD (Foot and Mouth disease) vaccine. The FMD vaccine is an inactivated vaccine prepared from vaccine strains of FMD virus which are produced in bulk on the living substrate BHK cells. The cells are grown in the industrial scale fermentors by using the tissue culture medium formulated by using dehydrated tissue culture medium powder. This tissue culture growth medium is supplemented by bovine serum. The vaccine is inactivated by the binary ethylenemine and formulated with suitable adjuvant.

8.1.2 After detailed deliberations and taking into consideration the recommendations received from NIN and other experts, the Committee approved the above proposal.

Agenda Item No 9: Any other matter with the permission of the Chair.

9.1 Request for issuing 'No Objection' to M/s K. K. Enterprise, Mumbai for import of Doritos Chips and the flavors such as 'NACHO', 'TACO' and 'BBQ' made from corn, indigenously produced in Taiwan from M/s Brilliant Market Pvt. Ltd., Singapore.

9.1.1 The Committee considered the request of M/s K. K. Enterprise, Mumbai for import of Doritos Chips of three flavors namely 'NACHO', 'TACO' and 'BBQ' from M/s Brilliant Market Pvt. Ltd. Singapore. However, the consignment has been detained at Nhava Sheva Customs in light of the communication dated 10.10.2008 issued by this Ministry and communication dated 12.11.2009 by DGFT regarding the illegal entry of Doritos Chip "Cool Ranch' flavor from USA based on a representation earlier received from M/s Greenpeace.

9.1.2 The Committee noted that the Doritos chips being imported from Singapore are produced in Taiwan. As per the declaration given by the importer, the product is made from corn indigenously produced in Taiwan and not genetically modified corn. It was also noted that Taiwan does not produce any GM food crop. However, Taiwan does import GM soybean and corn from USA. Taiwan also has a labeling policy which stipulates a threshold of 5% of GM content.

9.1.3 It was clarified that the matter has been referred to the GEAC in light of the following regulations:

1. The DGFT notification dated 7th April, 2006 pertains to import of GMO and requires:

   (i) All applications for import of GMOs/LMOs for research, bulk import of GM food, feed, raw or processed or any ingredient of food, food additives or any food product that contains GM materials will require prior approval by GEAC;
   (ii) At the time of import, all consignments containing products which have been subjected to genetic modification will carry a declaration stating that the product is 'Genetically Modified'.
   (iii) In case a consignment does not carry such a declaration and is later found to contain genetically modified material, the importer is liable to penal action under the Foreign Trade (Development and Regulation) Act, 1992.

2. Rule 11 of Rules, 1989 requires prior approval of the GEAC for import of GM food including processed food, ingredients, additives, etc.

9.1.4 After detailed deliberations and taking into consideration that the applicant has submitted a declaration confirming that the 'Doritos Corn Chips' being imported from Singapore have been produced in Taiwan from non GM corn, it was decided to convey 'no objection' for release of the consignment subject to the condition that if it is later found to contain genetically modified material, the importer is liable for prosecution under the relevant law. The Committee further advised that the customs officials at Nhava Sheva port may be directed to retain two packets of each flavor on a random sampling basis for further verification, if necessary.

9.2 Export of Bt cotton hybrid seed to Pakistan by M/s Bayer Bio Sciences Pvt. Ltd. Hyderabad.

9.2.1 The Committee considered the request of M/s Bayer Bio Sciences Pvt. Ltd. to export Bt cotton BG II hybrid seeds expressing *cry 1Ac and cry 2Ab* (MON 15985) event to M/s Bayer Crop Science

Pvt. Ltd., Karachi. The intended purpose of the export is for conducting multi locational field trials in different agro climatic zone in Pakistan. The shipment will contain 3250 gm (650 gm per hybrid). It was noted that the applicant has submitted the copy of the license agreement with M/s Monsanto and import permit from Ministry of Food, Agriculture and Livestock, Department of Plant Protection (Plant Quarantine Division), Government of Pakistan.

9.2.2 After detailed deliberations, the Committee conveyed it's 'no objection' for export of Bt cotton seeds expressing *cry 1Ac and cry 2Ab* (MON 15985) event to Pakistan subject to the following conditions:

1. Approval of the Pakistan National Biosafety Committee in accordance with the Pakistan Biosafety Rules, 2005 and National Biosafety Guidelines, 2005;
2. Approval from the National Biodiversity Authority, Chennai.

9.3 Export of Bt cotton hybrid seed to Pakistan by M/s Monsanto Holdings Pvt. Ltd., New Delhi.

9.3.1 The Committee considered the request of M/s Monsanto to export Bt cotton BG II hybrid seeds expressing *cry 1Ac and cry 2Ab* (MON 15985) event to M/s Monsanto Pakistan Agritech. Pvt. Ltd, Lahore. The intended purpose of the export is for conducting multi locational field trials in different agro climatic zone in Pakistan. The proposed shipment will be total 33.5 Kg. (300 g x 14 + 4 Kg X 8) of different twenty two BG II cotton hybrid seeds. It was noted that the applicant has submitted the copy of the license agreement with M/s Monsanto and import permit from Ministry of Food, Agriculture and Livestock, Department of Plant Protection (Plant Quarantine Division), Government of Pakistan.

9.3.2 After detailed deliberations, the Committee conveyed it's 'no objection' for export of Bt cotton seeds *cry 1Ac and cry 2Ab* (MON 15985) event to Pakistan subject to the following conditions:

1. Approval of the Pakistan National Biosafety Committee in accordance with the Pakistan Biosafety Rules, 2005 and National Biosafety Guidelines, 2005;
2. Approval from the National Biodiversity Authority, Chennai.

9.4 Permission to conduct confined field trials for event selection on transgenic dwarf potato containing GA20 Oxidase 1 gene (Events HP-600, HP-608, HP-609, HP-502, HP-504, HP-508, HP-401, HP-425, HP-431 and HP-433) by M/s Central Potato Research Institute (CPRI), Shimla.

9.4.1 The Committee considered the request of M/s CPRI to conduct confined field trials for event selection on transgenic dwarf potato containing GA20 Oxidase 1 gene (Events HP-600, HP-608, HP-609, HP-502, HP-504, HP-508, HP-401, HP-425, HP-431 and HP-433) by M/s Central Potato Research Institute (CPRI), Shimla. The trials will be conducted within the institutional research farm located at Shimla. The Committee further noted that the RCGM in its meeting held on 9.4.2009 has recommended the above proposal.

9.4.3 After detailed deliberations, the Committee approved the proposal of M/s CPRI to conduct event selection trials with transgenic potato containing GA20 Oxidase 1 gene within the institutional research farm at CPRI, Shimla.

9.5. Permission to conduct strip trials for event selection with RB-transgenic potato clones at R&D Farm, located at CPRI Campus, Shimla instead of Modipuram for evaluation of late blight resistance by M/s Central Potato Research Institute, Shimla.

9.5.1 The Committee noted that the above proposal was approved by the GEAC in its meeting held on 12.11.2008. The present request of the applicant is for change in location from CPRI, Modipuram to CPRI, Shimla to conduct event selection trials.

9.5.2 The Committee reiterating its earlier decision approved the event selection trials during 2009 within the institutional research farm at CPRI, Shimla.

9.6 Permission to conduct biosafety research level – I trials (BRL-I) on transgenic cotton hybrids namely JKCH-1050 Bt EGII, JKCH-1947Bt EGII expressing cry 1Ac (event 1) and cry 1Ec (event 24) by M/s. JK Agri Genetics Ltd., Hyderabad in the North Zone.

9.6.1 The Committee noted that the above proposal was approved by the GEAC in its meeting held on 9.7.2008. The present request is for revalidation of the earlier permission as the applicant could not undertake the field trials during 2008 due to delay in planting.

9.6.2 The Committee reiterating its earlier decision approved the conduct of BRL-I during Kharif, 2009 in the north zone.

The next meeting of the GEAC is scheduled for 10.6.2009.

****