Decisions taken in the 88th meeting of the Genetic Engineering Approval Committee (GEAC) held on 13.8.2008.

The 88th meeting of the Genetically Engineering Approval Committee (GEAC) was held on 13.8.2008 in the Ministry of Environment and Forests under the Chairmanship of Shri B. S. Parsheera, Additional Secretary, MoEF and Chairman, GEAC.

The deliberations of the GEAC in respect of Agenda Item 4 to 7 are as follows:

Agenda Item No 4: Consideration of Proposals related to Pharmaceuticals

4.1 Permission for import of recombinant HIV Vaccine TBC–M4 and ADVAX for conduct of Phase-I clinical trials of preventive AIDS vaccine from M/s Therion Biologics Corporation, Cambridge, MA, USA by National AIDS Research Institute (NARI), ICMR, Pune.

4.1.1 The applicant (M/s NARI) proposes to conduct the third Phase-I clinical trials with TBC-M4 vaccine and the ADVAX (DNA) vaccine at Tuberculosis Research Centre (TRC), Chennai and NARI, Pune as per the MoU signed between NACO, ICMR and IAVI in December 2000 to facilitate the development of safe, effective and accessible AIDS vaccine and carry out clinical trials in India. The first Phase-I clinical trials with candidate vaccine tg AACO9 conducted at National Aids Research Institute (ICMR), Pune was approved by the GEAC in its meeting held on 8.12.2004. The second phase-I clinical trials with candidate vaccine TBC-M4, conducted at the Tuberculosis Research Centre (TRC, Indian Council for Medical Research), Chennai, was approved by the GEAC in its 56th meeting held on 8.6.2005.

4.1.2 The proposed clinical trials have been approved by the Scientific Advisory Committees of NARI and TRC. NARI's Institutional Ethics Committee has also approved the clinical trials of TBC-M4.

4.1.3 The Committee considered the comments received from ICMR and other experts wherein it was noted that the application lacks clarity on whether the GEAC approval is being requested for import of TBC-M4 vaccine and the ADVAX (DNA) vaccines or clinical trials. The Committee gave an opportunity to Dr. V. D. Ramanathan, Scientist F, Tuberculosis Research Centre (ICMR) for presenting his views and clarification on the matter. The following points were noted:

1. This request is for the import of the required number vials of two vaccines, ADVAX and TBC-M4 for use in a Phase I HIV Vaccine trial employing Prime Boost strategy at National AIDS Research Institute (NARI), Pune and Tuberculosis Research Centre (TRC), Chennai.
2. ADVAX has been tested in a Phase I clinical trial in USA and TBC-M4 has been tested at TRC, Chennai earlier. The trial will have two arms, one with heterologous prime boost consisting of ADVAX and TBC-M4 and the other with 3 injections of TBC M4.
3. The present application submitted to the GEAC is mainly for seeking import permission as the project has been approved by the Scientific Advisory Committee (SAC) and the Institutional Ethics Committee (IEC) of both NARI and TRC. To a query on whether the two committees were empowered to authorize the trials, Dr Ramanathan explained that while the SAC scrutinized the scientific content, the IEC which is an independent and autonomous body external to the Institute ensured that the rights of the human beings participating in the trial were protected.

4.1.5 In view of the above clarifications and taking into consideration the recommendations of ICMR and other experts, the Committee approved the request for allowing limited import of recombinant ADVAX and TBC-M4 vaccines for conduct of phase-I clinical trials in India.

4.2 **Permission for import to conduct Phase III Clinical trials with r-adenovirus p 53 (rAdp53) in the treatment for newly diagnosed unresectable squamous cell carcinoma of head and neck from China by M/s Intas Biopharmaceuticals Ltd.**

4.2.1 The company proposes to conduct prospective, randomized, multi-centric phase III studies. Total number of patients to be recruited is about 76 for a period of 3 months. The studies will be conducted at 6 centers viz: T.M.H, Mumbai, CMC Hospital, Vellore, SMS Hospital, Jaipur, Med. Sup.Dr. Ambedkar Regional , Raipur, Paterson Cancer Center, Chennai and Safderjung Hospital, New Delhi.

4.2.2 The Committee considered the recommendations of the DBT and noted that RCGM has not approved the product for conduct of phase-III clinical trials in India. Member Secretary, RCGM explained the concerns expressed by the expert members in the RCGM meeting held on 24.6.2008. Subsequently, the Committee gave an opportunity to the applicant to present their case and provide necessary clarifications. The applicant clarified some of the points raised by the experts.

However, after detailed deliberations, the Committee decided to request RCGM to reconsider the matter in light of the clarifications submitted by the applicant. RCGM was also requested to given an opportunity to the applicant to present their case.

Agenda Item No. 5: Consideration of Applications for MLRT/Strip trials and experimental seed production of transgenic crops expressing new gene/events during Rabi/Kharif, 2008 as recommended by the RCGM.

5.1 Application submitted by M/s Sungro Seeds Research Ltd., New Delhi for extension of the permission letter for conducting Multilocation Research Trial (MLRT) on Bt. Cauliflower hybrids namely SCF-8 Bt and SCF-9 Bt containing cry 1Ac gene from Rabi 2007 to Rabi, 2008.

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5.2 Application submitted by M/s. Sungro Seeds Research Ltd., New Delhi for permission to conduct Multi Location Research Trials (MLRT) of 2 transgenic Cauliflower (*Brassica oleracea var botrytis*) hybrids namely SCF-1 Bt & SCF-3 Bt containing *cry1Ac* gene during Rabi, 2008.

1.0 The Committee noted that the matter was briefly discussed in the 85th GEAC meeting held on 28.5.2008 wherein it was noted that the earlier trials have not been evaluated by the MEC which is a pre-requisite for RCGM recommendation and therefore, it was decided to await recommendations of the MEC. Subsequently, the RCGM vide their letter dated 7.7.2008 has explained that the applicant has intimated that there was very little infestation of the target pest dimond backmoth (DBM) on all locations probably due to inhospitable weather conditions for the pest which made it difficult to assess the efficacy of the Bt. gene present in the hybrids to differentiate resistance of DBM in the Bt. hybrids from the non –Bt ones. Therefore the trials during Kharif 2006 and Kharif, 2007 were not preceded further and concluded without generating sufficient data. Hence, no data was submitted to MEC.

2.0 The Committee further noted that the RCGM in its meeting held on 22.4.2008 has recommended the MLRT subject to the following condition:

"Before initiating the trials, M/s Sungro Seeds must specify that the field experiments will be terminated before flowering stage and accordingly should submit an undertaking to the RCGM. The company may then maintain an isolation distance as proposed in their application which is 200m. On the other hand for seed production, the company should ensure maintenance of isolation distance of 1.6 km and also ensure physical/biological barriers to avoid any pollen flow. This was in response to the requirement of an isolation distance of 1600 meters to be maintained as per Seed Certification Standards in case of cauliflower when the cauliflower seeds are to be produced".

It was also noted that the company has already given an undertaking that the crop will not be permitted to flower and bio efficacy data would be generated during curd formation.

3.0 The GEAC considered the above proposals in the light of the following policy decisions:

- *As the event based approval system has been adopted by the GEAC, it has been decided by both GEAC/RCGM that the primary focus of GM crop trials should be on the biosafety issues besides efficacy of the trait, rather than agronomic performance. Therefore, MLRT for hybrid by hybrid field testing may be dispensed with.*
- *Confined field trials would be permitted only to companies/organizations that are involved in the development of the technology and are responsible for conducting biosafety studies. Companies/organizations which have taken the gene/event from technology developer/provider and propose to run the trial only for agronomic performance of their germplasm will not be given permission to conduct the field trials, unless the biosafety of gene/event has been demonstrated as per the guidelines approved by the regulatory authorities.*
- *The applicant should clearly indicate the proposed biosafety studies to be conducted during the confined field trials and the protocols for the studies in their application.*
- *Timely sowing of the trials is extremely important and should be strictly adhered to by all applicants to get the correct results.*
- *The number of hybrids in each trials should be restricted to the best varies (maximum of two hybrids per trial).*
- *The trial should be conducted in the applicants' own research farm.*

4.0 After detailed deliberations, the Committee decided to advise the applicant to submit the results of the field trials conducted so far and a detailed work plan and protocols for conduct of biosafety studies. The Committee authorized RCGM to review the adequacy of the work plan submitted by the applicant before issuance of approval letter for conduct of biosafety studies at two locations within the applicants' own research farm with a maximum of two hybrids.

5.3 Application submitted by M/s. Maharashtra Hybrid Seeds Co. Ltd., Maharashtra for permission to conduct Multi Location Research Trial (MLRT) on 4 transgenic stacked cotton hybrids namely MRC-8347 BG-II RRF Roundup, MRC-8351 BG-II RRF Roundup, MRC-8301 BG-II RRF Roundup, MRC-8326 BG-II RRF Roundup containing *cry1Ac, cry2Ab and CP4EPSPS* genes (MON 15985 X MON 88913) at six locations in South zone during Kharif 2008.

5.3.1 The Committee considered the present request for repeating the trials during Kharif 2008 in light of the policy decision as mentioned under para 3.0 above.

5.3.2 After detailed deliberations, the Committee decided to advise the applicant to submit the results of the field trials conducted so far and detailed work plan and protocols for conduct of biosafety studies. The Committee authorized RCGM to review the adequacy of the work plan submitted by the applicant before issuance of the approval letter for conduct of biosafety studies at two locations within the applicants own research farms with a maximum of two hybrids.

5.4 Application submitted by M/s. J. K. Agri Genetics Ltd., Hyderabad for permission to conduct Multi-location Research Trial (MLRT) with new (HXH) transgenic cotton hybrids containing *cry1Ac* (Event-1) and *cry1EC* (Event-24) namely JKCH-1050 Bt EGII, JKCH-1947Bt EGII & JKCH-226Bt EGII at five locations in North zone, five hybrids namely JKCH-99Bt EGII, JKCH-666BT EGII, JK-Indra Bt EGII, JK-Varun Bt EGII, JK-Durga Bt EGII at five locations in Central zone and four hybrids namely JKCH-99Bt EGII, JK-Indra EGII, JK-Durga Bt EGII, JKCH-2245Bt EGII at five locations in South zone.

5.4.1 The Committee considered the present request for MLRT in light of the policy decision as mentioned at para 3.0 above.

5.4.2 Clarifications submitted by the company were examined by the RCGM. The RCGM after being satisfied with the clarifications and recommended in its 68th meeting held on 29.7.2008 that the company may generate BRL-I biosafety data. After detailed deliberations, based on the recommendations of the RCGM, the GEAC approved the application for the permission to generate BRL-I for conduct of biosafety studies at two locations within the applicants' own research farm with a maximum of two hybrids.

5.5 Application submitted by UAS, Dharwad for permission to conduct Multilocation Research Trial (MLRT) on Bt. Brinjal hybrids Bt GO 112, Bt Udupi Gulla, GO 112 and Udupi Gulla containing cry 1Ac gene at ELA Farm, Department of Agriculture, Govt of Goa during Summer- monsoon 2008 instead of at KVK Goa.

5.5.1 The Committee considered the proposal in light of the policy decision as mentioned at para 3.0 above and noted that Bt brinjal by UAS Dharwad has been developed through technology transfer from M/s Mahyco. As the biosafety assessment of Bt brinjal developed by M/s Mahyco is still under review by the regulatory agency, the request of M/s UAS, Dharwad for hybrid evaluation under MLRT was not approved by the GEAC.

5.6 Application submitted by M/s. Metahelix Life Sciences, Bangalore for permission to conduct Multi Location Research Trials (MLRT) on three cotton hybrids namely MCE101, MCE102, MCE103 containing cry1C gene (MLS9124 event) at five locations in North zone and four cotton hybrids namely MCL351, MCM352, MCM357, MCE358 containing cry1C gene (MLS9124 Event) at eight locations in Central and six locations in South zones during Kharif 2008.

5.6.1 The Committee considered the proposal in light of the policy decision mentioned at page 5 para 4.0 and noted that two Bt cotton hybrids developed by M/s. Metahelix Life Sciences is under large scale testing during Kharif, 2008. The applicant is also in the process of generating biosafety data as per the new protocols i.e. pepsin digestibility, heat/thermal stability, acute oral toxicity data generated on the purified protein and other biosafety data as recommended by the RCGM. As the biosafety assessment of Bt cotton developed by the Company is under review by the regulatory agency, the request for hybrid evaluation under MLRT was not approved by the GEAC.

5.7 Application submitted by M/s. Bayer Bioscience Pvt. Ltd., New Delhi for permission to conduct Elite Event Selection Trials on 28 Bt rice lines for research and Development purpose at their own R & D farm during Kharif 2008.

5.7.1 The Committee considered the request of M/s. Bayer Bioscience Pvt. Ltd., New Delhi for conduct of 'Elite Event Selection Trials' on 28 Bt rice lines for research and development purpose at their own R & D farm during Kharif 2008. The Committee noted that the RCGM in its 67th meeting held on 24.6.2008 has permitted the event selection trial subject to submission of protein expression data generated at green house/laboratory conditions and biosafety data on purified protein. Simultaneously, the company should generate SOPs for conducting field trials as well as level of detection (LOD) of the selected event at 0.01% level as per the directions of the Hon'ble Supreme Court.

5.7.2 After detailed deliberations, the GEAC approved the conduct of 'Elite Event Selection Trials' on 28 Bt rice at one location within the institutional research farm only subject to the conditions stipulated by the RCGM.

Agenda Item No 6: Other items

6.1 Request from M/s. Metahelix Life Sciences, Bangalore, for the permission to conduct SAU trials of Bt. cotton hybrids 5174 Bt and 5125 Bt expressing synthetic cry1 C gene (event 9124) in the central zone and South zones Kharif 2008.

6.1.1 The Committee approved the request for conduct of SAU trials with Bt Cotton hybrids 5174 Bt and 5125 Bt expressing synthetic cry1 C gene (event 9124) in central and south zones.

6.2 Application submitted by M/s. Ganga Kaveri Seeds Pvt. Ltd., Hyderabad for permission to conduct Strip Trial on eight BGII Bt cotton hybrids namely GK 230-1 BGII, GK 230-2 BGII, GK 231 BGII, GK 232 BGII, GK 233 BGII, GK 234 BGII, GK 235 BGII and GK 236 BGII, containing *cry1Ac and cry2Ab* genes (MON 15985) at GKSPL farm, Medchal , Hyderabad during Kharif 2008.

6.2.1 The Committee approved the request for conduct of strip trials on eight BG II Bt cotton hybrids expressing approved events as recommended by the RCGM in its 68th meeting held on 29.7.2008.

6.3 Application submitted by M/s. Ajeet Seeds Ltd., Maharashtra for permission to change the location of strip trial with BG I and BG II Bt cotton hybrids from their R&D Center located at Guntur in A.P. to their R&D Center in Salem district of Tamil Nadu in South zone.

6.3.1 The Committee approved the request for conduct of strip trials with BG I and BG II Bt cotton hybrids at the applicant's R&D Centre in Salem district as recommended by the RCGM in its 68th meeting held on 29.7.2008.

Agenda Item No 7: Other items with the permission of the Chair.

7.1 Representation from Greenpeace regarding illegal GM food imports.

7.1.1 The follow-up action pertaining to the complaint received from M/s Greenpeace regarding the import of Dorito's Cool Ranch Corn chips containing GM ingredients was also discussed. The Member Secretary, GEAC informed that M/s Greenpeace vide letter dated 1st August, 2008 has submitted samples of the imported chips Doritos Cool ranch containing GM corn MON 863. The complainant informed that they were not in a position to submit the old samples as the two seed samples of the same batch were damaged during the relocation of their office in Bangalore. Instead they have submitted one set of sample from a new round of sampling picked up from the market during June, 2008.

7.1.2 After detailed deliberations on the matter the GEAC opined that the complainant has not behaved very responsibly while making such an accusation. The complainant was also not available for presenting their case when given an opportunity by the GEAC in its meeting held on 25.6.2008. Since, the M/s Pepsico International clarified do not use any GM crops for manufacturing their products in India and have not authorized any agency to import any of their products from outside having GM processed foods, the Committee decided to advise the M/s Greenpeace to approach Director General of Foreign Trade for taking necessary action in the matter.

Date of next GEAC meeting: The next GEAC meeting will be held on 10.9.2008.

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