

Decisions taken in the 82nd Meeting of the Genetic Engineering Approval Committee held on 11.1.2008

The 82nd meeting of the Genetically Engineering Approval Committee (GEAC) was held on 11.1.2008 at 3.00 PM in Room No. 623 in the Ministry of Environment and Forests under the Chairmanship of Shri B. S. Parsheera, Additional Secretary, MoEF and Chairman, GEAC.

Agenda Item No 1: Consideration of new proposals

A. Pharmaceuticals

1.1 Permission for import and conduct of phase II clinical trials of MO1ZH09 Typhoid vaccine in children aged 2 to 17 years from U.K Ltd, Wokingham by M/s. Pharm –Olam International (India) Pvt. Ltd., Bangalore.

1.0 The Committee noted that the present application received from M/s. Pharm–Olam International (India) Pvt. Ltd., Bangalore on 11.7.2007 is for import of MO1ZH09 typhoid vaccine from U.K Ltd, Wokingham for conduct of phase II clinical trials in children aged 2 to 17 years who reside in the official slums of Kolkata. The company proposes to conduct a placebo-controlled, double-blind, single oral dose study to determine the safety and immunogenicity of the typhoid vaccine MO1ZH09. The study will be conducted at NICED (National Institute of Cholera & Enteric Disease), Kolkata. The study is designed to investigate the safety and immunogenicity of a new single dose live attenuated oral vaccine against typhoid fever in healthy pediatric and adolescent subjects.

2.0 After detailed deliberations and taking into consideration the recommendations received from DBT and ICGEB, the Committee approved the above proposal.

B. Transgenic Crops

1.2 Pollen flow study and experimental seed production of Bt. Brinjal by M/s. Mahyco Seeds Ltd.

1.0 The Committee considered the communication received from Director, IIVR, Varanasi and the recommendation of RCGM regarding the pollen flow study in Bt brinjal developed by M/s Mahyco.

2.0 The Committee noted that Director, IIVR has informed that pollen flow studies cannot be conducted with LST trials on technical grounds as the protocol for LST and pollen flow study are different. Further, the pollen flow study requires a large area of nearly 89 acres which is not available with the Institute. Therefore, the pollen flow study may be carried out at the company's field at Nizamabad (Andhra Pradesh) and Jalana (Maharashtra). The Committee also examined the protocol approved by Director IIVR for conducting the pollen flow study.

3.0 The Committee also took note of the views of the RCGM on the above matter. It was noted that RCGM has opined that the pollen flow study earlier carried out by the company has been carefully scrutinized by RCGM and there are apparently and scientifically no environmental concerns warranting to get the study repeated again and again. Further, adequate data on the pollen flow in brinjal is extensively available. The objective of conducting the pollen flow studies again by IIVR, Varanasi was to get the studies repeated by a third party. However, since IIVR has expressed its inability to do these studies, repeating the studies by M/s Mahyco will not give any additional benefit or data as far as evaluation of Bt brinjal pollen flow is concerned.

4.0 After extensive discussion and deliberations, the Committee opined that IIVR has not expressed inability to conduct trials. The issue is availability of land. Accordingly the Committee directed the applicant to provide the required land for conducting pollen flow studies at a minimum of two locations. The pollen flow studies will be conducted under the supervision of Director IIVR, Varanasi. The GEAC also approved the protocol recommended by IIVR for conduct of pollen flow study.

1.3 Permission for extension of the period to conduct Multi Location Research Trial (MLRT) on six Bt. brinjal hybrids containing cry1Ac gene from Kharif 2007 to Summer 2008 by University of Agriculture Sciences, Dharwad.

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1.4 Permission for extension of the period to conduct pollen flow study of marker free transgenic Bt tomato expressing cry2Ab gene from Rabi 2007 to Kharif 2008 by M/s. Mahyco, Mumbai.

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1.5 Permission for extension of the period to conduct pollen flow study of marker free transgenic Bt Rice expressing cry2Ab gene from Rabi 2007 to Kharif 2008 by M/s. Mahyco, Mumbai

1.0 The Committee noted that in respect of agenda item No. 1.3, 1.4 and 1.5 the GEAC in its earlier meeting had approved the proposals for conduct of MLRT with Bt brinjal by University of Agricultural Science, Dharwad and Pollen flow study with marker free transgenic Bt tomato and Bt rice by M/s Mahyco respectively. However, the applicants were unable to undertake the trials during Kharif/Rabi, 2007 as they were not able to comply with the requirement of Hon'ble Supreme Court direction in respect of 0.01% LOD. The applicants have now submitted the requisite information with a request that they may be permitted to conduct the trials during Summer 2008/ Kharif 2008. The GEAC conveyed it's no objection for conducting the trials in Summer/Kharif 2008 respectively.

1.6 Recommendation of RCGM relating to subchronic (90 Days) feeding study with transgenic Bt. Brinjal leaf containing cry1Ac gene (*Solanum melongena L.*) in Goats at M/s Advinus therapeutics Pvt. Ltd., Bangalore by M/s Mahyco.

1.0 The Committee noted that the GEAC in its meeting held on 8.8.2007 had approved large scale trials of Bt Brinjal containing cry 1 Ac gene in various agro-climatic zones subject to compliance of certain conditions. One of the conditions requires the applicant to undertake Subchronic (90 Days) feeding study with transgenic Bt. Brinjal leaf containing cry1Ac gene (*Solanum melongena L.*) in Goats.

2.0 The Committee considered the protocol for conducting subchronic (90 Days) feeding study in goats with transgenic Bt. Brinjal leaf proposed at M/s Advinus therapeutics Pvt. Ltd., Bangalore. The Committee noted that brinjal is not a staple food of goats and therefore, the proposed protocols involved force feeding of the animals after acute starvation. The Committee deliberated on the scientific rationale and the value addition, if any, from the additional data generated. It was pointed out by one of the members that the earlier decision to recommend the above study was on the basis of the apprehensions expressed by NGOs regarding sheep mortality at Warangal and Adilabad district of Andhra Pradesh due to grazing in Bt cotton fields. Subsequently, analytical reports received from the IVRI Izatnagar and Department of Animal Husbandry, Hyderabad has confirmed that sheep death in AP cannot be attributed to Bt cotton. This was confirmed by the representative of the State Department of Agriculture in the meeting of the Sub committee held on 11.1.2008.

3.0 The Member Secretary, RCGM further informed that purified cry1Ac protein has been tested extensively for its safety and impact of the event containing this gene on human and animal health, both in pure form as well as in plant parts across the world and in India.

4.0 After detailed deliberations the Committee concluded that there is no need to conduct Subchronic (90 Days) feeding study with transgenic Bt. Brinjal leaf containing cry1Ac gene (*Solanum melongena* L.) in Goats on the following grounds:

- The feeding protocols cannot be scientifically validated as brinjal leaves are not a part of natural diet.
- Purified cry1Ac protein has been tested extensively for its safety and impact of the event containing this gene on human and animal health, both in pure form as well as in plant parts across the world and in India.
- The expression levels of cry1Ac protein in leaves are same as in other plant parts such as seeds, with which the studies have already been conducted.

Agenda item No 2: Other item

2.1 `Presentation by Central Institute of Cotton Research on the `Monitoring the susceptibility of bollworms to Bt gene and development of insect resistance`.

1.0 Director, CICR, Nagpur informed that CICR jointly with MoEF is organizing a national consultation on IRM strategies in cotton. Therefore, recommendations of the above meeting and presentation on susceptibility of bollworms to Bt gene and development of insect resistance will be made in the next GEAC meeting

2.0 The Committee also considered the request of M/s Nath Seeds Ltd. to allow alternate agencies like Entomology Laboratories at Tamil Nadu Agriculture University (Coimbatore) and University of Agricultural Sciences (Dharwad) to monitor the baseline susceptibility studies instead of CICR Nagpur. The Committee requested Director, CICR to identify institution at the regional/ state level that have the capacity to conduct the susceptibility study expeditiously. CICR being the nodal agency was advised to coordinate the study, evaluate the data generated and submit a consolidated report to the GEAC on an annual basis.

2.2 Permission to export 2500 seeds of Bt eggplant transgenic seeds of event EE-1 containing Cry I Ac gene to American Type Culture Collection (ATCC), University Boulevard, Manassas, Virginia, USA by M/S. Mahyco.

1.0 The Committee considered the request of M/s Mahyco to export 2500 seeds of Bt eggplant transgenic seeds of event EE-1 containing Cry I Ac gene to American Type Culture Collection (ATCC), University Boulevard, Manassas, Virginia, USA for event identification pattern. It was noted that the applicant have been asked by 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 National Biodiversity Act, 2002, if any.

2.3 Nomination of GEAC representative(s) to the SAU Committees

1.0 The Member Secretary, GEAC informed that in accordance with the decision taken in the GEAC meeting held on 1.10.2007, Director Research/ Director Extension from Acharya N.G. Ranga Agriculture University, Hyderabad. Punjab Agricultural University, Ludhiana, CCS Haryana Agricultural University, Hisar, Junagarh Agricultural University, Junagarh, Mahatma Phule Krishi Vidyapeeth and Marathwada Agricultural University have forwarded names of three experts in the region who could be considered as the nominee of the GEAC in the pre/post release monitoring mechanism.

2.0 The Committee agreed with the suggestion that in view of the large number of Bt cotton field trials, all three experts may be empanelled so as to facilitate the monitoring and evaluation of field trials and depending on their availability, may be invited to participate in the field monitoring of transgenic crops. The Committee also observed that some nominations are by designation and not by name. The Committee requested the Member Secretary, GEAC to obtain the names of experts from the respective SAUs as the GEAC nominees should be by name and not designation.

Agenda No 3: Any other item with the permission of the Chair.

3.1 Discussion on the recommendations of the Sub committee constituted by the GEAC to review case by case regulation of Bt cotton expressing cry 1Ac (MON 531 event).

1.0 The Member Secretary, GEAC briefed the Committee on the progress made by the Sub committee constituted by the GEAC under the Chairmanship of Dr. B. M. Khadi, Director, CICR, Nagpur with the following terms of reference:

- a) To review the need for continued case by case regulation of Bt cotton expressing *cry 1Ac* (MON 531 event) and implication of de regulation if any.
- b) Rationalization of the Zones based on the agro climatic conditions
- c) Recommendation regarding the suitability for release of Bt cotton in other cotton growing states.

2.0 It was informed that the first meeting of the Sub committee was held on 27.11.2007 wherein the committee was of the view that the matter needs further consultation with the State Department of Agriculture and SAUs before taking a final view. As advised by the Sub Committee the State Government was also requested to submit the following information:

- a) Whether the Bt technology introduced in cotton crop has been beneficial to the farmers in the State.
- b) Total area under Bt cotton cultivation in the State during 2007 (event wise)
- c) Whether the overall productivity of cotton crop in general has increased over the period 2002 to 2007 in the State.
- d) Any other findings specific to an area / hybrid / event were observed.

3.0 The 2nd meeting of the Sub committee was held on 11.1.2008 wherein the following views were expressed by the State Governments:

1. All State Governments /SAUs have confirmed that Bt technology has been highly beneficial to the farmers and the area under Bt cotton has increased substantially. Information in this regard have also been furnished. It was also confirmed that all the four events are performing well.
2. However, in respect of the hybrids approved by the GEAC, the State Government representatives were of the view that GEAC is following the zonal approval based on political boundaries and therefore, many of the hybrids approved by the GEAC are not suitable for the entire state. Accordingly, a state wise release was recommended.
3. Representatives were also of the view once the GEAC has declared an event as bio safe, the GEAC may follow a decentralizing system empowering the State govt. and SAUs for assessing the suitability of the genotype for the region.
4. The representative of Andhra Pradesh State Department of Agriculture also informed that cotton has been exempted from the list of essential commodities and therefore the power of the State Government under the Seed Act / Seed Order to issue license for marketing has been withdrawn. It was clarified that Cabinet Note regarding the re-inclusion of the same under the list of essential commodities under consideration of the Cabinet.

4.0 The recommendations of the Sub committee regarding delegation of powers to the State Agricultural Universities and State Department of Agriculture to identify the genotypes suitable for the zones were placed before and noted by the Committee. The members were of the view that they need some more time to review the recommendations of the Sub committee and it was therefore decided that the matter may be taken up for discussion in the next GEAC meeting. Meanwhile, it was agreed, that views of the industry and the State government on the recommendations may also be obtained.

5.0 The Committee further considered the recommendations made by the Sub committee with respect to the cotton growing zones based on agro climatic factors. The GEAC adopted the revised zoning pattern recommended by the Sub committee. It was noted that the Sub Committee has recommended inclusion of Orissa in the Central zone for commercialization of Bt cotton after completion of appropriate testing and evaluation procedures.

3.2 Biosafety studies of MLS9124 of M/s Metahelix Life Science, Bangalore.

The Member Secretary, RCGM informed the Committee that biosafety studies fall under the purview of RCGM and accordingly a suitable reply has been forwarded to the applicant.

3.3 Ministry of Environment and Forests Notification No. SO 1519(E) dated 23.8.2007 exempting GM processed food from the purview of Rules, 1989.

The Committee considered the communication received from Ministry of Health and Family Welfare requesting the GEAC to continue regulation of GM processed food for some more time till the Food and Standards Authority is able to look into the matter in a scientific manner and come out with a notification. The representative of Ministry of Health suggested that this matter needs to be resolved through an inter-ministerial consultation on a priority basis. The Committee agreed with the suggestion.

3.4 Conduct of Phase-II clinical trials of Chimerivaxtm – JE in children of descending age from USA by M/s Quintiles Research (India) Pvt. Ltd.

The Committee considered the applicant's request to permit them to complete the clinical trials for all age groups subsequent to which the entire clinical trials data would be submitted to the GEAC. The Committee gave an opportunity to the applicant to present their case wherein it was clarified that they are generating only tolerability and immunogenicity data. While the tolerability data has been made available to the Committee the immunogenicity data would take some more time. During the deliberations, the applicant further explained that a double blind cohort protocol is being followed and therefore, efficacy data can be provided only after the trials have been completed in all age groups. After detailed deliberations, the Committee gave its no objection to conduct the phase-II clinical trials for all age groups for generation of tolerability and immunogenicity data in comparison with the mouse brain vaccine. The Committee further emphasized that measles vaccine will not be used in the trials.
