Decisions taken in the 69th Meeting of the Genetic Engineering Approval Committee held on 30.6.2006.

The 69th Meeting of the Genetic Engineering Approval Committee (GEAC) was held on 30.6.2006 in the Ministry of Environment and Forests under the Chairmanship of Shri B S Parsheera Additional Secretary, MoEF and Chairman GEAC.

1.0 Consideration of Proposals

1.1 Discussion on the Report of the sub-Committee on Bt Cotton and Related issues.

1.1.1 The Ministry of Environment & Forests, Government of India, vide their OM No. 10/13/2005–CS – GEAC dated 28.4.2006 constituted a sub-Committee on Bt Cotton and related issues under the Chairmanship of Dr C D Mahyee, Chairman ASRB, and Co-Chair GEAC, to look into the existing processes, protocols and other related issues and give recommendation for rationalization of the same. The Committee considered the recommendations made by the Sub- Committee in respect of the following issues:

a. Measures to streamline the evaluation of Bt cotton hybrids under RCGM/GEAC/ICAR systems and seed production for transgenic cotton in CVRC notified and non-notified varieties in both released gene/event and new gene/event.
b. The period of Large Scale and ICAR Trials and seed production for new genes in new crops.
c. Mechanism to monitor the performance of Bt cotton.
d. Recommendations to implement the Alternate Monitoring Mechanism.
e. Review of GEAC compliance conditions in respect of refugia, IRM practice, IPM strategy, appropriate packaging practice etc.
f. Parameters and benchmarks for deciding the superiority of the hybrids evaluated under RCGM / ICAR system.
g. Applicability of the new procedure in respect of *cry1Ac* gene (Mon 531 event).
h. Strengthening the enforcement mechanism to to address various issues reported by the NGOs.
i. Permission for LST/Commercial release based on agro-climatic conditions rather than the zonal concept of Central/ South / North zone based on political boundaries recommended by ICAR.
j. Rationalization of Biosafety Studies

1.1.2 Dr Mayee, Co-Chair GEAC and Chairman of the sub-Committee explained the rationale behind the proposed recommendations. The Committee further discussed the following recommendations made by the sub-Committee:

a. Extensive biosafety and agronomic testing is not necessary for approved event. Once an event has been tested for its biosafety and approved for environmental release, it should be treated on par with the non-Bt hybrids.

b. An "event based approval system" instead of the case by case approval process presently adopted by the GEAC under Rules 1989, would speed up the introduction of new and diverse products for the Indian farmer, stimulate competition and offer a wider choice, without compromising bio-safety and environmental safety.

c. What is important for assessing the efficacy of Bt technology are (i) confirmation of the gene/event, (ii) level of protein expression and (iii) morphological characterization based on DUS parameters.

d. While due consideration for agronomic aspects of the transgenic seeds should be given, the technology in no way increases the yield potential of a hybrid but because of the inherent protection to bollworms there is saving of bolls, and also significant reduction in number of sprays, which results in increase in yield. Therefore Parameters such as level of protein expression, susceptibility to diseases, staple length, staple strength, etc need to be given due consideration while selecting promising hybrids as these parameters also contribute to the economic gain.

e. Bt cotton hybrids expressing *cry1Ac gene* (MON 531 event) which has been tested since 2002 may be permitted for multi-location trials (MLT) by RCGM based on the following case verification data:

- Confirmation of gene event through DNA fingerprinting
- Level of Protein expression in greenhouse/station strip trials
- Morphological characterization using DUS descriptors
- Bio-efficacy data generated in laboratory conditions.
- Authorization/NOC from the technology provider to use the technology.

Based on the MLT data the RCGM may recommend the suitability of the hybrid for commercial release to the GEAC.

f. In view of the constraints expressed by ICAR in handling large number of field trials due to limited resources and infrastructure, the Committee has recommended that ICAR trials in respect of Bt cotton with *cry1Ac* (Mon 531 event) may be optional. Alternatively the Companies may opt for SAU trials.

g. In case of Bt cotton hybrids expressing new gene events or new transgenic crops, the prevailing system of two year LST in tandem with two year ICAR trials after multi-location trials under RCGM would continue. The liberalized procedure recommended for Bt cotton hybrids expressing cry1Ac gene (Mon 531 EVENT) would be applicable to new events after its performance have been monitored post release for a period of three years and GEAC has renewed it approval for commercial release.

h. Since agriculture is a State subject, involvement of the State Agriculture Universities (SAUs) and State Agriculture Departments has been enhanced by designating Director Research of SAUs as the nodal point for pre-release field monitoring and Director Extension of SAUs as the nodal point for post release monitoring mechanism, with representatives of State Agriculture Departments/ District Agriculture officers in the committee.

i. The cost of monitoring would be borne by the applicant. The fee of Rs. 5000/- per trial (per hybrid/location) under monitoring in MLT would be deposited with the Registrar/Controller of the University who in turn will make available funds to the Director of Research to meet the expenses for organizing and conducting the monitoring and report preparation as per the prescribed norms. If there are any LSTs conducted in the jurisdiction of a SAU, Rs. 500/- per hybrid/per location would be deposited by the applicant with the University for monitoring.

1.1.3 While there was a general consensus on the recommendation of the sub-Committee, the representative of ICAR expressed his reservations about the revised procedure, though he also agreed that existing procedure is not entirely satisfactory.

1.1.4 After detailed discussions the **Committee adopted the recommendations** of the sub-Committee report subject to the following amendments:

a. Page 8 para i, first point "Confirmation of gene event through DNA finger printing" may be amended as "Confirmation of gene event through molecular characterization (DNA finger

printing/ Southern Blot etc)". Similar correction to be incorporated at page 10 para B (iii) first point.

b. Page 8 para i, last point "in case of sub licensee" to be added at the end of the sentence. Similar correction to be incorporated at page 10 para B (iii) last point.

c. Page 9 point viii which refers to permission for 100 ha seed production during MLT stands deleted. The Committee was of the view that once MLT is permitted based on the case verification documents prescribed by the sub-Committee, the Bt cotton hybrids expressing *cry1Ac* (Mon 531 event) may be treated on par with the non-Bt hybrids and therefore no specific approval for seed production is necessary. RCGM may obtain a declaration from the applicant along with the application that no seed production for commercial sale shall be undertaken till the hybrid is approved for commercial release.

d. Page 11 para C, the word "Bt Cotton" to be replaced by "transgene"

e. Page 11 and 12 para C (a) the following changes were proposed in the composition of the pre-release monitoring team:
- Point (2) and (3) to be merged as "Plant Breeder (concerned crop)"
- Point (7) to be amended as "One subject matter specialist relevant to the transgene (Biotechnologist).
- Point (9) to be amended as Agriculture officer of the concerned district
- Point 10 "nominee of GEAC/RCGM to be indicated as nominee of GEAC and RCGM separately.

Similar editorial corrections, where applicable, to be incorporated in the composition of the post release monitoring teams at page 14 and 15.

f. Page 13 in point 4 the words "nature of gene expression in transgene and" to be incorporated in the second line after "based on the ----------".

g. Point 8 regarding the time frame of the Monitoring Teams stands deleted.

h. Page 14 point iv related to financial mechanism for pre and post release monitoring, the Committee was of the view that there is also a need to strengthen the functioning. of the regulatory bodies. The Committee recommended the creation of a "Biosafety Fund", details of whose the operation may be worked out. The applicants for approval of GEAC would be required to pay application fee.

i. On the monitoring mechanism recommended by the sub-Committee, the GEAC was of the view that the recommendations are limited to short term measures to evaluate the performance of Bt cotton hybrid. However, there is a need to undertake long term studies such as impact of the transgene on the biodiversity, acceptability of the Bt cotton fibre quality and strength, socio-economic benefits etc. The Committee opined that Chairman NBRA, Director CIRCOT and an expert with socio-economic background be invited to submit a concept paper for consideration of the GEAC based on which proposal for long term impact studies may be undertaken through the relevant scientific/academic institutions.

j. Page 17 para E (1) the last sentence to be amended as "However the yield comparison should be with a recently released and related Bt check".

k. Page 18 para F (a) on the applicability of the new procedure recommended by the sub-Committee in respect of Bt cotton hybrids expressing *cry1Ac gene* (MON 531 event), the Committee was of the view that the same may be applicable from the current season as the sowing season in some parts of Central and South zones is yet to begin due to delayed monsoons.

1.1.5 While adopting the recommendations of the sub-Committee, the GEAC took note of the reservation expressed by the representative of ICAR.

1.1.6 In light of the decision taken by the GEAC to adopt the recommendations of the sub-Committee with immediate effect, the Member Secretary placed before the Committee the request for reconsideration of the GEAC decision for commercial release and large scale trials of several Bt cotton hybrids expressing *cry1Ac gene* (MON 531 event). A list of such cases would be prepared by Member Secretary. After a brief discussion on the applicability of the new procedure for different scenarios, it was decided that a sub-Committee comprising of the following Members be constituted to look into the eligibility of the new procedure in respect of individual cases:

a) Dr C D Mayee, Chairman ASRB, and Co-Chair GEAC, **Chairman**
b) Dr P Anand Kumar, Principal Scientist, National Research Centre on Plant Biotechnology, (NRCPB), IARI, New Delhi-110012. **Member**
c) Dr T V Ramanaiah, Director, DBT, New Delhi. **Member**
d) Dr R Warrier, Additional Director, MoEF. **Member Secretary**

The GEAC authorized the Chairman & co-Chairman to take final decision on the recommendation of this Committee.

1.2 Discussion on the mechanism for review of Bt Brinjal proposal in light of comments received.

1.2.1 The Member Secretary informed the Committee that, in accordance with the decision taken in the GEAC meeting on 1.6.2006, the biosafety data on Bt Brinjal has been posted on website on 21.6.2006 for inviting public comments. The deadline for submitting the comments is 5.7.2006.

1.2.2 Taking into consideration the comments received from several NGOs and others, the Committee decided to extend the time period of submitting their comments upto 15th July 2006. Regarding the request of some NGOS for detailed biosafety package and statistical analysis of biosafety data, the Committee was of the view that the NGOS /Public may be permitted to examine the report in the MoEF in the presence of a GEAC representative.

1.2.3 The GEAC also decided to constitute an Expert Committee comprising of senior experts in Plant Breeding and Toxicologists to look into the comments received from the NGOS/ public and submit its recommendation to the GEAC.

1.3 Permission for LST and Seed Production of ACH 33-2 Expressing *cry1Ac + cry2Ab* (Event 15985) in the Central Zone by M/s Ajeet Seeds.

1.3.1 In accordance with the decision taken at para 4.1.7 of agenda item 4.1, the Committee decided to refer the case to the sub-Committee under Dr C D Mayee, Chairman ASRB and Co-Chair GEAC.

1.4 Permission for Seed Production of JKCH 1050 BT in North zone and JKCH 666Bt and JKCH 226Bt in the central zone Expressing *cry1Ac* (Event 1) by M/s J. K Agri-genetics.

1.4.1 In accordance with the decision taken at para 4.1.7 of agenda item 4.1, the Committee decided to refer the case to the sub-Committee under Dr C D Mayee, Chairman ASRB and Co-Chair GEAC.

1.5 Consideration of proposal for multi-locational trials recommended by RCGM in its meeting held on 23.5.2006.

1.5.1 In compliance with the Hon'ble Supreme Court Order dated 1.5.2006 in respect of WP NO 260/2005 – Aruna Rodrigues & Others vs Union of India, the Committee considered the recommendations made by RCGM in its meeting held on 27th June 2006 in respect of eleven proposals for conduct of multi-location field trials of transgenic crops

1.5.2 After careful and in-depth consideration of the proposals and the recommendations of RCGM, the GEAC approved the proposals recommended by RCGM in the meeting held on 27.6.2006 and authorized Member Secretary, RCGM to issue the requisite communications in this regard.

2.0 Consideration of proposals related to Pharmaceuticals.

2.1 Permission for revalidation of GEAC approval for import and marketing of Drotrecogin alpha (activated) – Xigris by M/s Eli Lilly and Company (India) Pvt Ltd.

2.1.1 The Committee noted that the GEAC in its 33rd Meeting held on 5.7.2002 had approved import and marketing of Drotrecogin alpha (activated) – Xigris for a period of four years. As per Rule 13(2) of the 1989 Rules approvals of GEAC are valid for a period of four years at the first juncture and renewable for two years at a time.

2.1.2 The GEAC Conveyed its 'No Objection' for revalidation of GEAC permission for two more years.

2.2 Permission for revalidation of GEAC approval for import and marketing of Humatrope (Somatropin) - DNA origin by M/s Eli Lilly and Company (India) Pvt Ltd.

2.2.1 The Committee noted that the GEAC had approved the import and marketing of Somatropin Injection (r-DNA) for a period of four years in its 13th meeting held on 14.11.96. Subsequently in accordance with the provisions of Rule 13(2) of the 1989 Rules, the approval was revalidated for a period of two years in the 33rd GEAC meeting held on 5.7.2002 and 44th meeting held on 14.7.2004.

2.2.2 The GEAC conveyed its 'No Objection' for revalidation of GEAC permission for two more years.

2.3 Permission for revalidation of GEAC approval for import and marketing of human Insulin (DNA origin) and its formulations by M/s Novo Nordisk.

2.3.1 The Committee noted that the GEAC in its 33rd Meeting held on 5.7.2002 had approved import and marketing of human Insulin (DNA origin) and its formulations by M/s Novo Nordisk for a period of four years.

2.3.2 In accordance with the provisions of Rule 13(2) of the 1989 Rules, the GEAC Conveyed its 'No Objection' for revalidation of GEAC permission for two more years.

2.3.3 The Committee also considered the need for continued renewal of GEAC permission for r-Pharma proposals in light of the recommendations of the Task Force on r-Pharma which has been adopted by the GEAC. The Committee was of the view that renewal of GEAC permission is not necessary in respect of r-Pharma proposals which do not require the approval of GEAC as per the new procedure.

3.0 Any Other Item with the permission of the Chair.

3.1 Import of GM Soybean Oil.

3.1.1 The Committee noted that, on an interim basis, the GEAC in its meeting held on 2.5.2006 had approved the import of refined Soybean oil and crude degummed soybean oil subject to certification confirming that it has been derived from Round up Ready Soybean. The importer was also directed to submit the analytical report from either CFTRI/NIN/Shri Ram Laboratories on the composition of crude-degummed Soybean oil both pre and post processing stage. The test results should also include the pre and post refining levels of glyphosate in the oil as well as in the residue. Subsequently in the GEAC meeting held on 22.5.2006, it was further clarified that oil trade industry association on behalf of all importers may seek one time approval of GEAC for import of GM soy bean oil derived from Round up Ready Soybean. The samples may be drawn as per the procedure prescribed under PFA. The GEAC clearance does not obviate the requirement under PFA.

3.1.2 The Member Secretary informed that the analytical report in respect of all parameters except levels of glyphosate in the oil/residue has been received on 29.6.2006. The Committee advised the Member Secretary to obtain views of the experts on the results of the analysis of oil/residue. Also, comments from other laboratories were also to be obtained. The Committee further authorized the Chairman GEAC to take a final view based on the comments received from the experts and laboratories.

Date of the next GEAC Meeting: 9th August 2006

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