Decisions taken in the 41st Meeting of the Genetic Engineering Approval Committee (GEAC) held on 15th April 2004.

A Transgenic crops

1. Application for large scale trials Rasi Bt Cotton hybrids (RCH-317 Bt for North, RCH 359 Bt and RCH-118 Bt Central zone, RCH 368 Bt for South Zone) by Rasi Seeds (Selam).

1.1 M/S. Rasi Seeds P. Ltd. Salem T.N. have submitted an application on 10.3.2004 seeking approval of GEAC for conducting 150 large scale trials in all the three zones using the following hybrids containing Cry 1 Ac gene in an area of 1 acre per trial as per Protocol enclosed along with the Application:

a) RCH 317 Bt for North zone
b) RCH 118 Bt & RCH 359 Bt for Central Zone, and
c) RCH 368 Bt. for South Zone**.**

1.2 The company has also requested for seed production of the above cotton hybrids in an area of 100 ha each in the respective zones as mentioned above.

1.3 The Committee took note of the findings of MEC on the contained field trials conducted by the company during Kharif 2003 & the findings of ICAR under the AICCIP trials during Kharif 2003. The Committee noted that MEC has recommended the following hybrids for various zones:

North Zone	-	RCH 314 Bt, RCH 308 Bt, RCH 317 Bt and RCH 134 Bt
Central Zone	-	RCH 118 Bt & RCH 359 Bt
South Zone	-	RCH 111 Bt, RCH 371 Bt & RCH 368 Bt

1.4. The Committee noted that the Company vide letter dated 16th March 2004 have indicated that even though MEC has recommended the above hybrids for conducting large-scale field trials, required seeds are available only hybrids indicated in the application as per details at para 1.1:

1.5 The GEAC noted that varying number of locations are requested by various companies for conducting large scale trials. To introduce uniformity in the large scale trials conducted and to ensure that the trials conducted are adequately represented zone wise, it was decided that large scale trials in transgenic cotton should ordinarily be conducted in 80 representative locations per genotype per zone. However, wherever felt necessary, considering facts of the case the number can be increased by the GEAC.

1.6 Similarly on the issue of seed production, the GEAC decided that as a uniform policy seed production at the stage of permitting large scale trials should be allowed for an area of 100 ha per variety or as per the request made by the company whichever is lower.

1.7 The Committee further decided that these norms may as well be made applicable to the decisions taken by the GEAC in its meeting held on 31.3.2004 and to that extent the decisions may be considered suitably modified.

1.8 The Committee also agreed that while the GEAC may take note of the observations made by ICAR under the AICCIP, for large scale trials only the data generated from contained field trials under RCGM and approved by MEC and RCGM would be necessary. Two years of ICAR trial data is a requirement only for commercial release.

1.9 In view of the above stated facts the GEAC recommended large scale trials of RCH 317 Bt for North zone, RCH 118 Bt and RCH 359 Bt for Central zone, RCH 368 Bt for South zone. In accordance with the decision taken in para 1.8 & 1.9 above, the GEAC approved large scale trials of the above

hybrids at 80 representative locations per genotype per zone and seed production in an area of 100 ha for each variety.

1.10 The Committee also decided in the case of Northern zone, the Agricultural Universities would be involved in the monitoring of large scale trials with specific reference to incidence of CLCuV. This would also be applicable to the decisions taken in the GEAC meeting on 31.3.2004.

2. Permission for Seed production and large scale trials of Hybrids Ankur 651 Bt., Ankur 2534 Bt. & Ankur 2226 Bt. for North zone and Ankur 651 Bt, Ankur 2534 Bt and Ankur 09 Bt for Central zone with cry 1 Ac gene by M/s Ankur Seeds Pvt. Ltd., Nagpur

2.1 M/S. Ankur Seeds P. Ltd. Nagpur, Maharashtra have submitted an application on 19.3.2004 seeking approval of GEAC for conducting large scale trials in the North & Central zones using the following hybrids containing Cry 1 Ac gene in an area of 1 acre per trial. The company has also requested for large scale seed production of these cotton hybrids.

a) Ankur 651 Bt, Ankur 2534 Bt & Ankur 2226 Bt for North zone
b) Ankur 651 Bt, Ankur 09 Bt & Ankur 2534 Bt for Central zone

2.2. The Committee took note of the findings of MEC on the contained field trials conducted by the company during Kharif 2003 & the findings of ICAR under the AICCIP trials during Kharif 2003. The Committee noted that MEC has recommended the following hybrids for various zones:

North Zone - Ankur 651 Bt & Ankur 2534 Bt
Central Zone - Ankur 651 Bt & Ankur 09 Bt

2.3 The Committee was informed that Ankur 2226 Bt under AICCIP trials had been withdrawn by the company in the MEC meeting on 24th February 2004. It was further noted the Committee that the Ankur 651 Bt and Ankur 09 Bt is a direct derivative of the Ankur 651 non-Bt and Ankur 09 non-Bt which has been released through the AICCIP and notified by the Ministry of Agriculture in 1996 and 1998 respectively.

2.4 In view of the above stated facts, the GEAC recommended large scale trials of Ankur 651 Bt and Ankur 2534 Bt for the North zone and Ankur 651 Bt and Ankur 09 Bt for Central zone. The GEAC approved large scale trials of the above hybrids at 80 representative locations per genotype per zone and seed production in an area of 100 ha for each variety.

2.5 It was also decided that in the case of Northern zone, Agricultural Universities would be involved in monitoring of large scale trials with specific reference to CLCuV.

3. Permission for conducting large scale field trials of new Bt cotton hybrids (MRC-6301 BG-I, MRC-6160 BG-I, MRC-6304 BG-I, MRC-6703 BG-I, MRC-6322 BG-I, MRC-6918 BG-I, MRC-6928 BG-I) containing cry1Ac gene in Kharif 2004 season by Mahyco.

3.1 M/S. Mahyco have submitted an application on 26.2.2004 seeking approval of GEAC for conducting 420 large scale field trials in the central and south zones using the following hybrids containing Cry 1 Ac gene.

MRC 6160 BGI	-	60 ha	and seed production in an area of 50 ha.
MRC 6301 BGI	-	90 ha	and seed production in an area of 160 ha
MRC 6304 BGI	-	90 ha	and seed production in an area of 80 ha
MRC 6322 BGI	-	60 ha	and seed production in an area of 50 ha
MRC 6703 BGI	-	60 ha	and seed production in an area of 50 ha

MRC 6918 BGI - 30 ha and seed production in an area of 30 ha
MRC 6928 BGI - 30 ha and seed production in an area of 30 ha

3.2 The Committee took note of the findings of MEC on the contained field trials conducted by the company during Kharif 2003 & the findings of ICAR under the AICCIP trials during Kharif 2003. The Committee noted that MRC 6304, MRC 6322, MRC 6703, MRC 6918 & MRC 6928 are not among the hybrids recommended by MEC.

3.3 In view of the above stated facts the GEAC recommended the following:

a) Large scale trials of MRC 6301 Bt and MRC 6160 Bt for Central zone and MRC 6160 Bt and MRC 6322 Bt for South zone at 80 locations per genotype per zone.

b) In accordance with the decision taken at 4.1 para 13, the GEAC approved seed production as follows:

MRC 6160 BGI - 50 ha
MRC 6301 BGI - 100 ha
MRC 6322 BGI - 50 ha

B Pharmaceuticals cases

4. Permission for import and marketing or r-Human Interlukin-2 (rhuIL-2) from Laboratories Pablo Cassara Argentina by Glenmark Laboratories Pvt. Ltd.

4.1 The Committee noted that the above proposal was approved by the GEAC in the meeting held on 27th November 2003 for conducting Phase-III clinical trials. The company has requested the GEAC to waive the requirement for Phase-III clinical trials and instead grant them approval for PMS.

4.2 The Committee observed that the following information along with supporting documents may be sought before the proposal is considered:

a. Whether it is approved and marketed in the country of origin.
b. Whether the product has been approved for marketing in other countries; if so their names.
c. Whether the product has been rejected by any country. If so the reasons, thereof.

5. Permission for import and marketing of r-human Erythropoietin (rhEPO) manufactured by Shenzhen SPEC- Bio- Pharmaceuticals Industry Co. Ltd. China by M/s V.H. Bhagat Co, Mumbai.

5.1 The Committee noted that the above proposal was approved by the GEAC in the meeting held on 27th November 2003 for conducting Phase-III clinical trials. The company has requested the GEAC to waive the requirement for Phase-III clinical trials and instead grant them approval for PMS.

5.2 The Committee observed that the following information along with supporting documents may be sought before the request is considered:

i. Whether it is approved and marketed in the country of origin.
ii. Whether the product has been approved for marketing in other countries; if so their names.
iii. Whether the product has been rejected by any country. If so the reasons, thereof and Certificate thereto.

6. Permission for import of rhu-Epidermal Growth Factor for manufacturing and marketing in India a fixed dose combination of 10 ug/GM and silver Suphadiazine 1% as a cream for topical application in Burn cases from Centre for Genetic Engineering & Biotechnology Cuba by M/s Glenmark Laboratories Pvt. Ltd., Mumbai.

6.1 The Member Secretary informed the Committee that the proposal was submitted by M/s Glenmark on 31.5.2002 for approval of GEAC to manufacture a fixed dose combination of Silver Suphadiazine and rhu-epidermal growth factor (EGF) as a tropical cream imported from Centre for Genetic Engineering and Biotechnology, Cuba. Simultaneously the company submitted another application on 5.7.2002 requesting approval of GEAC to import small quantity (2 gm) of rhu-epidermal growth factor (EGF) for making a test batch from the same source. The second request was sent to DBT and DCGI for comments on 25th July 2002.

6.2 The Committee noted that the GEAC had earlier approved the similar product to M/s CIMMCO, New Delhi for conducting Phase-III clinical trials. In view of the above, both DBT and DCGI have conveyed their no objection to the above proposal.

6.3 The DCGI has directed the company to conduct Phase-III clinical trials vide DCGI letter No. 4-99/02-DC dated 6.8.2003. However information submitted by the company indicate that they had earlier approached DCGI for waiver of Phase-III clinical trials stipulated by DCGI. The matter was referred by DCGI to some experts who gave a favorable opinion and advised for PMS. However, the company does not have any document to substantiate the opinion of the experts or formal communication from DCGI regarding waiver of Phase-III clinical trials.

6.4 In view of the facts of the case, GEAC requested DCGI to clarify whether they had initially communicated their approval for conducting Phase –III trials and also subsequently if Phase-III clinical trials have been exempted by the Directorate. Decision on the above project was deferred until receipt of clarification from DCGI.

7. Permission for manufacture and marketing of r-Streptokinase by M/s Shantha Biotechnics Pvt. Ltd., Hyderabad.

7.1 The company vide their letter dated 5th April 2004 has appealed to the Committee to grant them personal hearing to present details of the clinical trials conducted by the company using r-Streptokinase.

7.2 The summary of Streptokinase clinical trial data as submitted by the company was circulated to the members. The Committee invited representative of Shantha Biotechnics for a personal hearing.

7.3 After discussions the following decisions were taken:

a. Protocols approved by DCGI for conducting Phase-III human clinical trials and data generated therein would form the benchmark for taking decision by the GEAC.

b. The Company would submit a copy of the report submitted vide letter dated 5th April 2004 and other clarification to issues raised by GEAC at para 7 (point a-d) to DCGI. The DCGI in turn would forward the same to GEAC along with their comment.

c. The RCGM would give their report regarding the adequacy of the containment facilities at Shantha Biotechnics to meet the environmental safety regulations.

d. The GEAC requested both the representatives of DCGI and DBT to forward their reports expeditiously for reconsideration of the matter in the next meeting.

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