**Decisions taken in the 44th Meeting of the Genetic Engineering Approval Committee (GEAC) held on 14th July 2004.**

## Opening Remarks of the Chairperson

The Chairperson explained that as per the guidelines for "Good Practices in Environmental Regulations" adopted by the Ministry, the Committee would be required to consider all the items listed in the Agenda and if required the meeting would continue the following day. Thus none of the proposals were to be postponed for the next GEAC meeting. She further added that the "Good Practices" also recommended provision of personal hearing by the applicants before the Committee. Accordingly a notice had been put on the MoEF website and those present were to be given the opportunity for personal hearing.

## Decisions

### 1. Permission for conducting large-scale trials of Bt. Cotton hybrids containing cry1Ac gene (MON 531) and seed production in Kharif 2004 by M/s Mahyco.

1.1 The company vide their letter dated 8.6.2004 has requested the GEAC to reconsider its earlier decision and permit large scale trials and seed production of MRC 6304 Bt, MRC 6928 Bt and MRC 6918 Bt containing Cry 1Ac gene (MON 531).

1.2 The GEAC gave an opportunity to the applicant for presenting their case before the Committee. Regarding the request of the company for conducting large-scale trials and seed production of MRC 6304 Bt, MRC 6918 Bt and MRC 6928 Bt the Committee concluded that as per the current practice the company has fulfilled the following requirements for large-scale trials:

- Completion of Multi-locational field trials under RCGM.
- Monitoring & evaluation of the multi-locational trials by MEC.
- Recommendation of MEC & RCGM on suitability of the hybrids for respective zones.

1.3 In view of the above stated facts and noting the recommendation made by MEC/ RCGM, which is based on detailed evaluation of results of the contained trials, the GEAC recommended large-scale trials of MRC 6304 Bt for the Central zone and MRC 6918 Bt and MRC 6928 Bt for the South zone. In accordance with the decisions taken in the GEAC meeting on 15.4.2004 the Committee permitted large-scale trials of above hybrids in the 80 representative locations per genotype per zone. Similarly on the issue of seed production, a decision was taken by GEAC that 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. Accordingly the Committee permitted seed production of MRC 6304 Bt in an area of 90 ha and MRC 6918 Bt and MRC 6928 Bt in an area of 30 ha for each hybrid.

### 2.0 Permission for conducting large-scale trials of new Bt. Cotton hybrids Bunny and Mallika containing cry1Ac gene (MON 531) and seed production in Kharif 2004 by M/s Nuziveedu Seeds Ltd.

2.1 The Committee noted that M/s Nuziveedu Seeds Limited has transferred the Cry 1 AC Gene (MON 531) through traditional back crossing method into the parental lines of the hybrids NCS-145 ("Bunny") and NCS – 207 (Mallika). Both these non-Bt hybrids are "centrally notified hybrids".

2.2 In the meeting held on 9.6.2004, the GEAC had broadly agreed with the recommendation of RCGM but had taken the view that this should be on the basis of case-to-case verification and recommendation by RCGM. As regards the specific case of M/s Nuziveedu Seeds Ltd. the view taken

was that, before the request of the Applicant for conducting large-scale trials is considered, the Committee desired to know about details of their seed production and regulatory approvals obtained for development and production of seed. The Member Secretary, RCGM briefed the Committee about the details asked for by the GEAC in its last meeting. The following facts were noted:

a) Seed production has been done in greenhouse in contained conditions, with the approval of IBSC and under intimation to the RCGM as per DBT Guidelines of 1998.
b) Complying with the directions of RCGM, the company has signed a license agreement with the original developer and obtained 'no objection certificate' for the use of Cry 1Ac gene (MON 531 event) in their hybrids.
c) After thorough consideration the RCGM gave its approval for conduct of ICAR trials, multi-locational trials and seed production during Kharif 2004 in its meeting held on 25.3.2004.
d) On the request of the company for conduct of large-scale trials during Kharif 2004 itself, the RCGM directed the company to approach GEAC on this matter in the meeting held on 13.5.2004.

2.3 The Committee was of the view that production of transgenic seeds in contained conditions should be restricted for experimental purposes only. Hence, the need for evolving clear guidelines for the guidance of the applicant was reiterated. On the issue of scientific evidence regarding confirmation of the claims that the Bt hybrids developed by company containing Cry 1 Ac gene (MON 531) and its morphological equivalence to the corresponding non Bt hybrids, the members of RCGM present in the meeting informed the Committee that RCGM takes into account relevant scientific facts before taking a final view on any proposal. The view taken by the Committee was that, in future, RCGM in its recommendations may give specific findings on these issues among others.

2.4 Based on the recommendation and view taken by RCGM regarding approved event (MON 531 in Cry 1Ac gene) in Bt cotton hybrids/varieties and other facts of the case, the GEAC recommended large scale trials of NCS 145 Bt (Bunny) and NCS 207 (Mallika) at 80 representative locations per genotype per zone and seed production in an area of 100 ha for each hybrids.

**3.0 Large-scale field trials and seed production of Bt. Cotton hybrids containing Cry 1Ac gene (new event) developed by M/s J.K. Agri Genetics Ltd.**

3.1 M/s J. K. Agri Genetics has developed indigenous Bt Cotton technology in collaboration with IIT BREF BIOTECH, Kharagpur and University of Delhi, South Campus. In this Programme, Cry IAC Gene was incorporated in some of J. K. Cotton parental lines (J K Durga, JK 666, JK Vanur and JK99) in a new event.

3.2 The Committee gave an opportunity to the applicant to present their case before the GEAC. On the request of the company for reconsideration the Committee noted the following facts:

a) RCGM has permitted conduct of multi locational field trial at two locations each in three states (T.N, A.P and Karnataka) during Kharif 2004 and experimental seed increase in 4 Bt hybrids (J.KC 666 BT, JKC 555 BT/JK VARUN, JK DURGA and JKC 99BT) in an area of half acre. The area permitted for seed production should be adequate for generation of seeds for large-scale trials.
b) No specific recommendation for conduct of large-scale trials at this stage has been received from RCGM.

3.3 It was finally decided that after evaluation of results of the contained field trials by the MEC and the RCGM, the matter may be considered at an appropriate stage.

**4.0 Permission for conducting large-scale trials of new Bt. Cotton hybrids containing cry1Ac gene and seed production in Kharif 2004 by M/s. Ajeet Seeds Ltd.**

4.1 M/s Ajeet Seeds Ltd. has developed a new Bt cotton hybrid ACH-33-I (Ajeet-33-I) containing Cry 1Ac gene (MON 531). The present request from the company is for conducting large-scale trials at 80 locations and seed production in an area of 40 acres during kharif 2004.

4.2 Taking into consideration its earlier decision that there should be case-to-case verification and recommendation by the RCGM in such matters; the Committee noted that in the instant case no specific recommendation from the RCGM has been received. Further, the Committee noted that the non-Bt hybrids ACH-33 I is not a centrally notified variety. Hence the GEAC did not approve the request of the company.

**5.0 Permission for Phase III clinical trials OF R-human Epidermal growth factor manufactured by M/s Bharat Biotech International Ltd. Hyderabad.**

5.1 Taking note of the recommendations made by RCGM and DCGI, the committee accorded approval for conducting Phase III clinical trials using r-human Epidermal growth factor developed by the company.

**6.0 Permission for Phase III clinical trials of r-human Insulin manufactured by M/s Bharat Biotech International Ltd. Hyderabad.**

6.1 Taking note of the recommendations made by RCGM and DCGI and taking into consideration that it is an approved drug, the committee accorded approval for conducting Phase III clinical trials using r-human Insulin developed by the company.

**7.0 Permission for Phase III clinical trials of r-human Hepatitis vaccine manufactured by M/s Indian Immunologicals Ltd. Hyderabad.**

7.1 Taking note of the recommendations made by RCGM and DCGI and taking into consideration that it is an approved drug, the committee accorded approval for conducting Phase III clinical trials using r-human Hepatitis B vaccine developed by the company.

**8.0 Permission for Phase III clinical trials of G-CSF indigenously manufactured by M/s Zenotech Hyderabad.**

8.1 Taking note of the recommendations made by RCGM, DCGI and taking into consideration that it is an approved drug, the committee accorded approval for conducting Phase III clinical trials using r-human G-CSF indigenously developed by the company.

**9.0 Permission for Phase III clinical trials of GM-CSF indigenously manufactured by M/s Zenotech Hyderabad.**

9.1 Taking note of the recommendations made by RCGM, DCGI and taking into consideration that it is an approved drug, the committee accorded approval for conducting Phase III clinical trials using r-human GM-CSF indigenously developed by the company.

**10.0 Permission for Phase III clinical trials of G-CSF indigenously manufactured by M/s Shantha Biotechnics, Hyderabad.**

10.1 Taking note of the recommendations made by RCGM, DCGI and taking into consideration that it is an approved drug, the committee accorded approval for conducting Phase III clinical trials using r-human G-CSF indigenously developed by the company.

**11.0 Permission for Phase III clinical trials of r-Hepatitis B Combination vaccine (DTPw) indigenously manufactured by M/s Shantha Biotechnics, Hyderabad.**

11.1 M/s Shantha Biotechnics Ltd has developed DTPw a trivalent vaccine to make a combination of DTPw with r-Hepatitis B. The present request of the company is for conduct of Phase –III clinical trials of the combination vaccine ( DTPw + r-Hepatitis B vaccine).

11.2 Taking into consideration that the comments of RCGM, DCGI, DBT and other Experts, the committee accorded approval for conducting Phase III clinical trials using combination vaccine ( DTPw + r-Hepatitis B vaccine) developed by the company.

**12.0 Ex post facto approval for conducting phase III clinical trials and permission for manufacture and marketing of r-Hu-G-CSF by M/s Intas Pharmaceuticals Ahmedabad.**

12.1 The Committee noted the observations of RCGM regarding the biosafety aspects including the adequacy of the containment facilities. Based on the recommendations of RCGM and views of experts, the GEAC accorded approval for manufacture and marketing of r-Hu-G-CSF by the company.

**13.0 Ex post facto approval for conducting phase III clinical trials and permission for manufacture and marketing of r-Erythropoetin by M/s Shantha Biotechnics, Hyderabad.**

13.1 The Committee noted the observations of RCGM regarding the biosafety aspects including the adequacy of the containment facilities. Based on the recommendations of RCGM, DCGI, DBT and other Experts, the GEAC accorded approval for manufacture and marketing of r-Erythropoetin by the company.

**14.0 Ex post facto approval for conducting phase III clinical trials and permission for manufacture and marketing of r-Insulin by M/s Biocon India Ltd. Bangalore.**

14.1 The Committee noted the observations of RCGM regarding the biosafety aspects including the adequacy of the containment facilities. On the procedural issue, the Committee noted that this matter has figured earlier in some other cases and is essentially linked up with the different procedures stipulated as a result of certain streamlining initiatives by the DBT.

14.2 Based on the recommendations of RCGM, DBT, DCGI and other experts, the GEAC accorded approval for manufacture and marketing of r-Insulin by the company.

**15.0 Import and marketing of r-human interferon alpha–2b by M/s Kee Pharma Ltd. New Delhi from Tianjin Hualida Biotechnology Co. Ltd. China.**

15.1 The above proposal was considered in the 40th meeting of GEAC held on 31.3.2004 wherein it was decided to await the specific comments of DCGI and DBT on the safety and efficacy of the product.

15.2 Based on the comments received from the DCGI, DBT and CDRI, the GEAC accorded approval for limited import of the product for conducting Phase III clinical trials.

**16.0 Request for waiver of Phase-III clinical trials of r-interlukin 2 (rlL-2) by M/s Kee Pharma Ltd. New Delhi.**

16.1 The Committee noted that the grounds on which waiver is being sought by the company is similar to the request made by M/s Glenmark Laboratories Pvt. Ltd. In the case of M/s Glenmark Laboratories Pvt. Ltd. the following view was taken by the GEAC in the meeting held on 9.6.2004.

- The contention about difficulties in availability of sufficient number of patients for conducting phase III clinical trials on the grounds of rarity of disease, in a country like India, was not found tenable.

- Duration of the treatment and high cost cannot be a consideration as a basis for exemption from clinical trials.

- Phase III clinical trials conducted under the Drugs and Cosmetic Act. No recommendation for waiver of Phase III has been received from DCGI.

16.2 In the light of above decision, the Committee rejected the request of the company for waiver of Phase III clinical trials.

**17.0 Revalidation of GEAC approval for Import and marketing of Somatropin Injection (r-DNA) by M/s Eli Lilly (India) Pvt. Ltd. Gurgaon.**

17.1 The Committee noted that the approval granted by the GEAC was revalidated for a period of two years in its 33rd meeting held on 5.7.2002. The present request is for extension of the approval for two more years. The Committee conveyed their 'no objection' for revalidation of the GEAC approval.

**18.0 Permission for conducting Large-scale trials and seed production of newly developed transgenic bollgard –II Cotton hybrids containing the staked Cry 2A(b) and Cry 1A(c) genes in kharif 2004 by MAHYCO.**

18.1 M/s Mahyco has developed a new transgenic Bt cotton hybrids (Bollgard II) containing two stacked Cry 2A(b) and Cry 1 A(c) genes (MRC 7201 BG-II, MRC 7160 BG-II, MRC 7301 BG-II, MRC 7322 BG-II, MRC 7326 BG-II and MRC 7703 BG-II).

18.2 The Committee gave an opportunity to the applicant for presenting their case. The Committee also discussed at length the recommendation of RCGM. The Committee also noted that as per the current practice the company has fulfilled the following requirements for large-scale trials:

- Completion of Multi-locational field trials under RCGM.
- Monitoring & evaluation of the multi-locational trials by MEC.
- Recommendation of MEC & RCGM on suitability of the hybrids for the respective zones.

18.3 In view of the above stated facts and noting the recommendation made by MEC/ RCGM, which is based on the detailed evaluation of the results of the contained trials and biosafety studies, the GEAC recommended large scale trials of MRC 7201 BG II, MRC 7160 BG II, MRC 7301 BG II and MRC 7326 BG II for large-scale trials in the Central and South zone at 80 representative locations per genotype per zone and seed production in an area of 40 ha for MRC 7201 BG II and for the remaining hybrids in an area of 5 ha subject to the following conditions.

a) While conducting large-scale trials the development of resistance in lepidopteron pests with reference to the stacked genes (Cry 1Ac and Cry 2Ab genes) as well as Cry 1Ac gene should be assessed.

b) Impact of cultivation of Bt Cotton in crops cultivated in neighboring fields in terms of lepidopteron pests should be assessed.

**19.0 Commercial release of Bt cotton hybrids namely RCH 20 Bt for south zone and RCH 138 Bt and RCH 144 Bt in central zone developed by M/s Rasi Seeds (P) Ltd.**

19.1 On the request of the company, the Committee noted that there is no new information meriting reconsideration of the earlier decision for conducting large-scale trials for another season during Kharif 2004. Hence the Committee rejected the request of the company.

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