

MINUTES OF THE 164th MEETING OF THE REVIEW COMMITTEE ON GENETIC MANIPULATION (RCGM) HELD ON 03.04.2018 IN THE DEPARTMENT OF BIOTECHNOLOGY

The Chairman, RCGM extended a formal welcome to the members of the RCGM for the 164th meeting and initiated the process of the meeting. The list of participants is given at Annexure-I.

2. The Committee adopted the minutes and recommendations of the 163rd meeting of the RCGM held on 20.02.2018.

3. On action taken report, RCGM Secretariat informed that during the 163rd meeting of the RCGM, a total of 75 applications including information items were considered and the Secretariat is in the process of issuing the requisite permit letters based on the recommendations of the RCGM.

4. Proposals considered:

4.1 Applications in the area of Pharmaceuticals

The Committee considered applications in the area of pharmaceuticals to import transgenic *Drosophila* strains, *M. tuberculosis* strains, mammalian cell lines, and CHO cell line expressing Bevacizumab; to transfer Bevacizumab, Romiplostim, Ranibizumab, Enterokinase and Uricase genes with suitable vectors, and recombinant streptokinase; to receive Bevacizumab, and CHO cell line expressing Trastuzumab; to export CHO cell lines expressing Etanercept, Rituximab, Bevacizumab & FSH, MCB & WCB of recombinant *Pichia pastoris* expressing Insulin Glargine, Insulin Lispro & Insulin Aspart; request for amendment in the permit letter for import of MCB & WCB of Bevacizumab and WCB of Denosumab. The Committee also considered applications to conduct pre-clinical toxicity studies on Pertuzumab; pre-clinical toxicity study report on recombinant Cetuximab and Bevacizumab; Report on the physically contained cage study on *transgenic* mosquito. After deliberation on each application including information items, appropriate decision was taken by the RCGM.

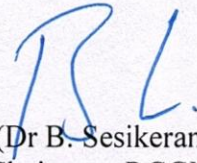
2.2 Applications in the area of Agriculture

The Committee considered applications in the area of agriculture to import dsRNA, lyophilized tissue powder of transgenic cotton expressing Bt protein; and revised protocols for soil microflora study and assessment of nutrient composition in grain and forage of transgenic maize. After deliberation on each application including information items, appropriate decision was taken by the RCGM. RCGM discussed on the draft Statement of Utilization for Import/Transfer of GMOs/LMOs & products thereof for R&D purpose, draft Guidelines on Environmental release of Genetically Engineered Microorganisms: Regulatory requirements for risk assessment and approval in India, 2018; and draft Guidelines and Protocols for analysis of effects of GE plants on soil microorganisms, 2018.

The next meeting of the RCGM was scheduled on 22.05.2018. No other transaction took place and the meeting ended with vote of thanks to the Chair.

The minutes are approved.

Date: 16.04.2018
Place: Hyderabad


(Dr B. Sesikera)
Chairman, RCGM

List of Participants:**Annexure-I**

| | | |
|--|---|------------------|
| 1. Dr. B. Sesikaran, Former Director, NIN, Hyderabad | - | Chairman |
| 2. Prof. P. Kondaiah, Chairman, IISc., Bangalore | - | Member |
| 3. Dr. Shailaja Hittalmani, UAS, Bangalore | - | Member |
| 4. Dr. Vanga Siva Reddy, CSO, BSU, New Delhi | - | Member |
| 5. Dr. Viswanathan Chinnuasamy, Principal Scientist, IARI, New Delhi | - | Member |
| 6. Dr. S. K. Rath, Principal Scientist, CSIR-CDRI, Lucknow | - | Member |
| 7. Dr. Kulbhushan Tikoo, Professor & Head, NIPER, Mohali | - | Member |
| 8. Dr. Debendra K. Sahoo, IMTECH, Chandigarh | - | Member |
| 9. Dr. A.K. Kondapi, Professor, UoH, Hyderabad | - | Member |
| 10. Dr. Gururaj Katti, Principal Scientist, IIRR, Telangana | - | Member |
| 11. Dr. Ambikanandan Mishra, MS University, Vadodra | - | Member |
| 12. Dr. P.K.Chakrabarty, ADG-ICAR, New Delhi | - | Nominee-ICAR |
| 13. Dr. Murali Krishna, Joint Director, MoEFCC, New Delhi | - | Nominee- MoEFCC |
| 14. Dr. Jayant Gangakhedkar, ADGI, CDSCO, New Delhi | - | Nominee-CDSCO |
| 15. Mr. Fahim Khan, Drug Inspector, CDSCO, New Delhi | - | Nominee-CDSCO |
| 16. Dr. Vijay Kumar, Scientist G, ICMR, New Delhi | - | Nominee- ICMR |
| 17. Dr. S.R. Rao, Scientist-H, DBT | - | Member Secretary |
| 18. Dr. Rajalakshmi Muralidharan, Scientist- F, DBT | - | Member |
| 19. Dr. Sanjay Kalia, Scientist-E, DBT | - | Member |

Biosafety Support Unit:

20. Dr. G.R. Soni, Chief (Bio-Pharma)
21. Dr. Sangeeta Agarwal, Chief (Agriculture)
22. Dr. Jyoti Batra, Scientist
23. Dr. Anuradha Gupta, Scientist
24. Dr. Prem Kumar, Scientist
25. Dr. Reema Sharma, Scientist

Other representatives:

26. Dr. Ramesh Kurli, Enzene Biosciences Limited, Pune.
27. Dr. Harish Shandilya, Enzene Biosciences Limited, Pune.
28. Dr. Chintan Patel, Cadila Pharmaceuticals Ltd., Ahmedabad
29. Dr. Nitin Joshi, Dow Agrosociences India Pvt. Ltd., Mumbai
30. Dr. T. Sarita, Pioneer (PHPL), Hyderabad
31. Dr. X.N, Paluba, Lupin Ltd., Pune
32. Dr. Sunil Trandra, Lupin Ltd., Pune
33. Sh. Arun Sachdeva, Lupin Ltd., Pune
34. Dr. Prabhakar B. Patil, Mahyco Pvt. Ltd., Mumbai
35. Dr. S.K. Dasgupta, GBIT, Jalna
36. Dr. Bharat Char, Mahyco Pvt. Ltd., New Delhi
37. Dr. Manoj Bansode, M/s. Saiseva Biotech Pvt. Ltd., Satara, Maharashtra
38. Mr. Sanjay Deshpande, Mahyco Pvt. Ltd., Mumbai