MINUTES OF THE 157th MEETING OF THE REVIEW COMMITTEE ON GENETIC MANIPULATION (RCGM) HELD ON 9.5.2017 IN THE DEPARTMENT OF BIOTECHNOLOGY

The Chairman, RCGM extended a formal welcome to the members of the RCGM for the 157th meeting and initiated the process of the meeting. The list of participants is given at Annexure-I.

2. Proposals considered

2.1 Applications in the area of Pharmaceuticals

The Committee considered applications in the area of pharmaceuticals to transfer the Edmonston- Zagreb strain of Measles virus; to import the frozen monoclonal antibody against receptor activator of nuclear factor kappa-B ligand WCB1 of stably transfected CHO cells; to conduct pre-clinical toxicity studies on SIPL Dengue Monoclonal antibody, recombinant Human Insulin Lispro, recombinant Ramucirumab, and Liraglutide; pre-clinical study report on recombinant Panitumumab; and request for extension of validity of the permission to conduct PCT studies on recombinant Darbepoetin, and TERIZENE. 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 receive seeds of transgenic mustard & cotton; to import gene constructs in transformed E. coli cell; to transfer transgenic rice seeds; to conduct event selection trials of transgenic cotton, wheat and rice; inspection reports of Central Compliance Committee on its visit to multi-localational trials in contained conditions on RNAi based Nuclear Polyhedrosis Virus resistant genetically engineered silkworm lines at CSTRI, Berhampore & Mysore, and ASSRDI, Hindupur; request for extension of validity of the permission to conduct biosafety studies with purified EPSPS protein of glyphosate tolerant maize; approval of protocols for assessment of nutrition composition of transgenic maize and the effect of transgenic maize on soil microflora. After deliberation on each application including information items, appropriate decision was taken by the RCGM.

3. Other items

The Committee considered Draft guidelines for Bio-containment, and also deliberated on data requirement on application seeking RCGM permission to conduct pre-clinical toxicity studies on Biopharmaceuticals produced through continuous batch culture.

The next meeting of the RCGM was scheduled on 20.06.2017. No other transaction took place and the meeting ended with vote of thanks to the Chair.

The minutes are approved.

Date: 19.05.2017
Place: Hyderabad

(Dr. B. Sesikeran)
Chairman, RCGM
### List of Participants:

1. Dr. B. Sesikeran, Former Director, NIN, Hyderabad  - Chairman
2. Dr. S.R. Bhat, Emeritus Scientist, NRCPB, New Delhi  - Co-Chairman (Agri.)
3. Dr. Vanga Siva Reddy, New Delhi  - Member
4. Dr. S.N. Sudhakar Babu, DOR, Hyderabad  - Member
5. Dr. Natarajan Sakthivel, Pondicherry University  - Member
6. Dr. Vishwanthan Chinnasamy, IARI, New Delhi  - Member
7. Dr. G. Dhinakar Raj, TRPVB, TANUVAS, Chennai  - Special Invitee
8. Dr. Kulbhushan Tikoo, NIPER, Mohali  - Member
9. Dr. P. K. Chakrabarty, (Nominee-ICAR)  - Member
10. Dr. Sanjeev Galande, II SER, Pune  - Member
11. Dr. S.K. Rath, Principal Scientist, CSIR-CDRI, Lucknow  - Member
12. Dr. Debendra K. Sahoo, IMT, Chandigarh  - Member
13. Dr. Ambikanandan Misra, MSU, Vadodara  - Member
14. Dr. Murali Krishna, MoEF&CC, New Delhi  - GEAC representative
15. Dr. S.R. Rao, Scientist-G, DBT  - Member Secretary
16. Dr. Rajalakshmi Muralidharan, Scientist-E, DBT  - Member
17. Dr. Amit Parikh, Scientist-D, DBT  - Member

### Biosafety Support Unit:

18. Dr. G.R. Soni, Chief Bio-Pharma
19. Dr. Pranjali Vishwakarma, Scientist
20. Dr. Abhijit Poddar, Scientist
21. Dr. Sandeep Soni, Scientist
22. Dr. Poonam Vishwakarma, Scientist

### Other representatives:

23. Dr. S.H. Rao Reliance Life Sciences, Navi Mumbai
24. Dr. Girish Makand, Reliance Life Sciences, Navi Mumbai
25. Dr. Pitesh Mishra, M/s. Mahyco Ltd., New Delhi
26. Dr. Bharat, M/s. Mahyco Ltd., New Delhi
27. Dr. Pankaj Bihari, M/s. Mahyco Ltd., New Delhi
28. Sh. Sanjay Deshpande, M/s. Mahyco Ltd., New Delhi
29. Sh. Pramod Kumar, M/s. Serum Institute of India, Pune
30. Dr. Peddi S. Reddy, M/s. Serum Institute of India, Pune
31. Dr. S.S. Pimal, M/s. Serum Institute of India, Pune
32. Dr. R. Jayachandran, M/s. Serum Institute of India, Pune
33. Dr. Ramnath R.L., Reliance Life Sciences, Navi Mumbai
34. Dr. Ramesh, Dr. Reddy’s Lab, Hyderabad
35. Dr. J. Sreenivasaha, Senior Scientist, Dr. Reddy’s Laboratories Ltd., Hyderabad
36. Dr. Bhavna Gupta (Associate Director), Dr. Reddy’s Laboratories Ltd., Hyderabad
37. Dr. Prasad Shivardraiah, M/s. Anthem Biosciences Ltd., Bangalore
38. Dr. VivekKushwaha, M/s. Anthem Biosciences Ltd., Bangalore
39. Dr. Sangamesh Purania, M/s. Anthem Biosciences Ltd., Bangalore
40. Dr. Prasad Shivardraiah, M/s. Anthem Biosciences Ltd., Bangalore
41. Dr. Pushpadhary Mall, M/s. Anthem Biosciences Ltd., Bangalore
42. Dr. Swarkesh Parihar, M/s. Anthem Biosciences Ltd., Bangalore