

MINUTES OF THE 175th MEETING OF THE REVIEW COMMITTEE ON GENETIC MANIPULATION (RCGM) HELD ON 11.09.2019 IN THE DEPARTMENT OF BIOTECHNOLOGY

The Chairman, RCGM extended a formal welcome to the members of the RCGM for the 175th meeting and initiated the process of the meeting. The list of participants is given as Annexure-I.

2. The Committee adopted the minutes and recommendations of the 174th meeting of the RCGM held on 13.08.2019.

3. On action taken report, the Member-Secretary informed that during 174th meeting of the RCGM, a total of 80 applications including information items were considered and the Secretariat is in the process of issuing permit letters based on the recommendations of the RCGM.

4. Proposals considered

4.1 Applications in the area of Pharmaceuticals

The Committee considered applications to import cGMP banks of Hepatitis A virus vaccine strain, *H. pylori* culture, Trastuzumab, Kadcyla, Linker payloads, larvae of transgenic *Drosophila melanogaster* lines, Master cell bank of recombinant CHO cell lines expressing Denosumab, Working cell bank of recombinant CHO cell lines expressing Erythropoietin, Master cell bank of recombinant CHO cell lines expressing Omalizumab, Master cell bank of recombinant CHO cell lines expressing Rituximab, Working cell bank of recombinant CHO cell lines expressing FSH, two applications for transgenic *Drosophila* lines, applications of Influenza virus strains, Hybridoma cell lines, Chikungunya monoclonal antibody, recombinant plasmids, breeding pairs of transgenic mice, wild type *Aspergillus niger* and *A. tubingensis* strains, U.V. mutated *A. tubingensis* and transgenic strains of *A. niger*; extension of the validity to import recombinant CHO cell lines expressing Rituximab; to export Master cell banks and Working cell bank of recombinant *Pichia pastoris* expressing Human Insulin, production cell bank of recombinant human insulin, Human Insulin and reference sample, recombinant BCG, diluents, Tocilizumab in-process samples, protein of *Plasmodium* species aminoacyl-tRNA synthetase; to transfer inactivated *Vibrio cholerae* Hikopjima strain expressing *E. coli* surface antigen, recombinant *E. coli* strain, wild type ETEC strain, recombinant purified protein of cholera toxin; to receive stocks of Dengue serotypes, strains of *Mycobacterium tuberculosis*; pre-clinical toxicity study reports on recombinant Denosumab and Rituximab; request for post facto extension of validity of the permission to conduct pre-clinical toxicity study on Insulin Lispro. After deliberation on each application including information items, appropriate decision was taken by the RCGM.

4.2 Applications in the area of Agriculture

The Committee considered applications to export transgenic *Nicotiana tabacum* seeds; two applications to import Rhizobium strains. After deliberation on each application including information items, appropriate decision was taken by the RCGM.

4.3 Other items

The Committee considered revised applications to import GE *Arabidopsis* lines, and recombinant *Aspergillus* strains; to conduct pre-clinical toxicity study of live attenuated Leishmania vaccine,

and recombinant live attenuated Chikungunya Vaccine, Support provided by the Biosafety Support Unit (BSU) to RCGM, inclusion of Chief Scientific Officer of BSU as Special Invitee in the RCGM and appropriate decision was taken by the RCGM.

The next meeting of the RCGM was scheduled on 11.10.2019

No other transaction took place and the meeting ended with vote of thanks to the Chair.

The minutes are approved.

(Dr. Rakesh Kumar Mishra)
Chairman, RCGM

List of Participants:

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| 1. Dr. Rakesh Kumar Mishra, Director CCMB, Hyderabad | - Chairman |
| 2. Dr. Gurinderjit Randhawa, ICAR-NBPGR, New Delhi
(on behalf of Dr. Kuldeep Singh, Director) | - Representative of
Co-Chairman |
| 3. Dr. Pradhyumna K. Singh, CSIR-NBRI, Lucknow | - Member |
| 4. Dr. Neelam S. Sangwan, CSIR-CIIMAP, Lucknow | - Member |
| 5. Dr. GururajKatti, Principal Scientist, IIRR, Hyderabad | - Member |
| 6. Dr. R. Uma Shanker, UAS Bengaluru | - Member |
| 7. Dr. S.K. Rath, Principal Scientist, CSIR-CDRI, Lucknow | - Member |
| 8. Dr. Rajnish Kumar Chaturvedi, CSIR-IITR, Lucknow | - Member |
| 9. Dr. P.V. Mohanan, Scientist G, SCTIMST, Kerala | - Member |
| 10. Dr. K.G. Tirumurugan, TANUVAS, Chennai | - Member |
| 11. Dr. GuhanJayaraman, IIT-M, Chennai | - Member |
| 12. Dr. Rajesh S Gokhale | - Member |
| 13. Dr. Shilpi Paul, DST, New Delhi | - Nominee, DST |
| 14. Dr. GeetaJotwani, Scientist F | - Nominee, ICMR |
| 15. Dr. Meenu (Representative of Dr. N.P. Singh) | - Nominee, ICAR |
| 16. Dr. Jayant Gangakhedkar, ADGI, CDSCO | - Nominee, CDSCO |
| 17. Dr. Alka Sharma Scientist-G, DBT | - Member |
| 18. Dr. A.K. Rawat, Scientist-G, DBT | - Member |
| 19. Dr. Vanga Siva Reddy, CSO, BSU, New Delhi | - Special Invitee |
| 20. Dr. Nitin Jain, Scientist-F, DBT | - Member Secretary |
| 21. Dr. GandharvaNagpal | - Scientist C, DBT |

Biosafety Support Unit:

22. Dr. Sangeeta Agarwal, Chief (Agriculture)
23. Dr. Poonam Vishwakarma, Scientist
24. Dr. AbhijitPoddar, Scientist

Other representatives:

25. P. Kumar, Hetero biopharma, Hyderabad
26. N. Rajol B, Vimta Labs
27. Vijay Nah Thota, HBL
28. O. Koaya, Virchow Biotech
29. M. Suvaram, Vipragen Biosciences