

MINUTES OF THE 177th MEETING OF THE REVIEW COMMITTEE ON GENETIC MANIPULATION (RCGM) HELD ON 11.11.2019 IN THE DEPARTMENT OF BIOTECHNOLOGY

The Chairman, RCGM extended a formal welcome to the members of the RCGM for the 177th 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 176th meeting of the RCGM held on 11.10.2019.

3. On action taken report, the Member-Secretary informed that during the 176th meeting of the RCGM, a total of 26 applications including information items were considered and the Secretariat is in the process of issuing 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 to import CHO cells containing Null vector, reassortant influenza strain, influenza strain; to export bivalent Typhoid Conjugate Vaccine drug substance, intermediates and finished formulation, mastercell bank of recombinant *E.coli* expressing Pegfilgrastim, mastercell bank and working cell bank of recombinant *Pichia pastoris* expressing Human Insulin; to receive working cell bank of recombinant *E.coli* expressing Pegfilgrastim, working cell bank of recombinant *Pichia pastoris* expressing Insulin glargine and Human Insulin; to transfer cell lysate derived from CHO cell line expressing Infliximab, working cell bank of recombinant *E.coli* expressing Pegfilgrastim, working cell bank of recombinant *Pichia pastoris* expressing Insulin glargine and Human Insulin; to conduct preclinical toxicity studies on live Respiratory Syncytial Virus vaccine; preclinical study report on Autologous Haematopoietic stem cells with high expression factor VIII, recombinant Darbepoetin; and addendum/notification on recombinant Infliximab. 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 conduct confined field trial forevent selection of transgenic pigeon pea. After deliberation on each application including information items, appropriate decision was taken by the RCGM.

4.3. Other items

The committee considered the Expert Committee on “Regulatory framework & Data requirement for biosafety assessment of genome edited organisms”, Regulatory Reforms to Improve Drug Development Process in India, representation from the Drosophila Research Community on the process of import of *Drosophila* and other living modified model organisms and appropriate decision was taken by the RCGM.

The next meeting of the RCGM was scheduled on 11.12.2019

RBMD

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:

- | | | |
|-----|------------------------------------------------------------------------------------------|--------------------|
| 1. | Dr. Rakesh Kumar Mishra, Director, CCMB, Hyderabad | - Chairman |
| 2. | Dr. Gurinderjit Randhawa, (on behalf of Dr Kuldeep Singh, Director ICAR-NBPGR New Delhi) | - Co-Chairman |
| 3. | Dr. Neelam S. Sangwan, Senior Principal Scientist CIMAP, Lucknow | - Member |
| 4. | Dr.GururajKatti, Principal Scientist, IIRR, Hyderabad | - Member |
| 5. | Dr. R. Uma Shanker, UAS Bengaluru | - Member |
| 6. | Dr. S.K. Rath, Principal Scientist, CSIR-CDRI, Lucknow | - Member |
| 7. | Dr. P.V. Mohanan, Scientist G, SCTIMST, Kerala | - Member |
| 8. | Dr. GuhanJayaraman, IIT-M, Chennai | - Member |
| 9. | Dr.N.P.Singh, IIPR, Kanpur | - Nominee, ICAR |
| 10. | Dr.Jayant Gangakhedkar,ADGI- CDSCO | - Nominee, CDSCO |
| 11. | Dr.Alka Sharma Scientist-G, DBT | - Member |
| 12. | Dr.Vanga Siva Reddy, CSO, BSU, New Delhi | - Special Invitee |
| 13. | Dr. Nitin Jain, Scientist-F, DBT | - Member Secretary |
| 14. | Dr.GandharvaNagpal | - Scientist C, DBT |

Biosafety Support Unit:

16. Dr. Sangeeta Agarwal, Chief (Agriculture)
17. Dr. Poonam Vishwakarma, Scientist
18. Dr.Reema Sharma, Scientist

Other representatives:

- 19.Dr. Alok Srivastava, CMC, Vellore
- 20.Dr. LeenaYeolkar, Serum Institute of India, Pune
20. Dr.DhananjayKapse, Serum Institute of India, Pune
- 21.Dr. Ramnath R L, Reliance Life Sciences, Navi Mumbai
- 22.Dr.RohiniSreevathsa, ICAR-NIPB, New Delhi
- 23.Dr.Sandeep, ICAR-NIPB, New Delhi
- 24.Dr.Gururaj, ICAR-IARI, New Delhi