

MINUTES OF THE 293rd MEETING OF THE REVIEW COMMITTEE ON GENETIC MANIPULATION (RCGM) HELD ON 18.09.2024 BY VIDEO CONFERENCING (GO TO MEETING)

The Chairman-RCGM extended a formal welcome to the members of the RCGM for the **293rd 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 **292nd meeting** of the RCGM held on **04.09.2024**.

3. On the action taken report, the Member-Secretary informed that during the **292nd meeting** of the RCGM, a total of **48** 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 the applications to import Monkeypox virus, Drug resistant strains of *Mycobacterium tuberculosis*, *Plasmodium* parasites, and plasmids; to transfer GM *Escherichia coli*; Request to seek waiver of preclinical toxicology studies of Secukinumab monoclonal antibody Biosimilar, preclinical studies on Anti-CD-19 CAR-T cell therapy product; preclinical toxicity reports of Pembrolizumab monoclonal antibody Biosimilar, Human Papillomavirus Quadrivalent vaccine; to conduct preclinical safety studies on CRISPR edited human HSCs, Pegfilgrastim Biosimilar; Deliberation on the biocontainment requirement for handling *Mycobacterium tuberculosis* mutant strains. After deliberation on each application including information items, appropriate decisions were taken by the RCGM.

4.2 Applications in the area of Agriculture

The Committee considered the Inspection report submitted by CCC on monitoring of harvest/termination of ESTs of GE banana lines; Records of Transport, Planting, and Storage along with Trial site map and photographs of the trial site for the EST of GE Cotton lines; application to carry out R&D work involving *Drosophila*; Proforma of Confined Field Trial Inspection Report for monitoring of Harvest/Termination of Confined Field Trials by CCCs. After deliberation on each application including information items, appropriate decisions were taken by the RCGM.

5. IBSC Reports

The Committee considered minutes submitted by nineteen IBSCs, seventeen annual compliance reports and nil medical surveillance report, and appropriate decisions were taken by the RCGM.

6. Other items

The Committee discussed on comments received from public consultation of draft "*Guidance Document on Genetically Engineered Plants Containing Stacked Events*".

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

The Minutes are approved.


(Prof. Y.K. Gupta)
Chairman, RCGM

Annexure-I

| List of Participants: | | |
|--------------------------------|---|----------------------|
| 1. | Prof. Y.K. Gupta, Former Professor, AIIMS, New Delhi and President AIIMS, Jammu | Chairman |
| 2. | Dr. Ramesh Sonti, Director & Group Leader, Plant-microbe Interaction, International Centre for Genetic Engineering and Biotechnology, New Delhi | Co-Chair (Agri) |
| 3. | Dr. Arvind Sahu, Executive Director, Regional Centre for Biotechnology, Faridabad | Co-Chair (Biopharma) |
| 4. | Dr. Nitin K. Jain, Scientist 'G' & Head, Regulation, DBT, New Delhi | Member-Secretary |
| 5. | Dr. S. N. Sudhakara Babu, Former Head, Crop Production & Principal Scientist (Agronomy), ICAR-Indian Institute of Oil Seed Research, Hyderabad | Member |
| 6. | Dr. Uma Shaankar, Senior Professor, IIT-Jammu, Jammu | Member |
| 7. | Dr. Chandish R. Ballal, Former Director, National Bureau of Agricultural Insect Resources, Bengaluru | Member |
| 8. | Dr. K.G. Tirumurugaan, Professor, Department of Animal Biotechnology, Madras Veterinary College, TANUVAS, Chennai | Member |
| 9. | Dr. Ritu Aggarwal, Professor, Post Graduate Institute of Medical Education & Research, Chandigarh | Member |
| 10. | Dr. Asha Chaubey, Sr. Principal Scientist & Head of Fermentation Technology Division, CSIR-IIIM, Jammu | Member |
| 11. | Dr. A. Visala, Deputy Drugs Controller (India), CDSCO, Nominee/Representative – CDSCO | Member |
| 12. | Sh. Arvind Kukreti, Astd. Drugs Controller (India), CDSCO, Nominee/Representative – CDSCO | |
| 13. | Dr. Om Prakash Meena, Assistant Director, Ministry of Home Affairs. Nominee/Representative - Ministry of Home Affairs | Member |
| 14. | Dr. Anant Narayan Bhatt, INMAS, Nominee/Representative - Defence Research and Development Organization | Member |
| 15. | Dr. Lokesh Kumar Narnoliya, Scientist 'D', DBT, New Delhi | DBT officer |
| Biosafety Support Unit: | | |
| 16. | Dr. Govind Kumar Rai, Scientist & Coordinator | |
| 17. | Dr. Poonam Vishwakarma, Scientist | |
| 18. | Dr. Pranjali Vishwakarma, Scientist | |
| 19. | Dr. Shipra Shahi, Scientist | |
| 20. | Dr. Manpreet Kaur, Scientist | |
| Others: | | |
| 21. | Dr. Rajendra Kumar, M/s. Hetero Biopharma Limited, Hyderabad | |
| 22. | Dr. Srinivas Reddy Chilukuri, M/s. Hetero Biopharma Limited, Hyderabad | |
| 23. | Mr. Prathap Dosapati, M/s. Hetero Biopharma Limited, Hyderabad | |
| 24. | Dr. Debojyoti Chakraborty, CSIR - Institute of Genomics and Integrative Biology, Delhi | |