

MINUTES OF THE 292nd MEETING OF THE REVIEW COMMITTEE ON GENETIC MANIPULATION (RCGM) HELD ON 04.09.2024 BY VIDEO CONFERENCING (GO TO MEETING)

The Chairman-RCGM extended a formal welcome to the members of the RCGM for the 292nd 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 291st meeting of the RCGM held on 21.08.2024.

3. On the action taken report, the Member-Secretary informed that during the 291st meeting of the RCGM, a total of 38 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 Research cell banks for recombinant Hepatitis-B Surface antigen, transgenic *Drosophila* lines; to conduct preclinical toxicity studies on gene therapy product for Haemophilia B, Semaglutide Injection Biosimilar, tetravalent Human Polyomavirus Vaccine, Pembrolizumab monoclonal antibody Biosimilar; preclinical toxicity reports of Aflibercept Biosimilar; Request submitted regarding the biocontainment requirement of Monkeypox virus; RCGM to deliberate on the letter received from O/o of DCG(I)-CDSCO regarding the Proposal for waiver on Non clinical study requirements for Biosimilar development; Intimation to RCGM regarding the Constitution of Committee for revision of Existing Guidelines on Similar Biologics, 2016. 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 applications to import GE *Medicago truncatula* Tnt1 mutant lines; to export GE maize seeds; inspection report by CCC on completion of Harvest/Termination of BRL-I 1st year trial of GE cotton Event; Records of Transport and Storage with Trial site map and photographs of the trial site for the EST of GE cotton lines; Compliance Report along with Records of Harvest, updated Records of Transport, Storage and Storage Inspection for ESTs of GE banana lines; application for the exemption of exogenous DNA free GE *Brassica juncea* lines. After deliberation on each application including information items, appropriate decisions were taken by the RCGM.

5. IBSC Reports

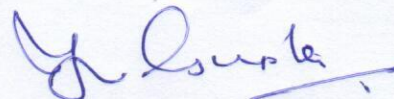
The Committee considered minutes submitted by twenty-two IBSCs, thirteen annual compliance reports and nil medical surveillance report, and appropriate decisions were taken by the RCGM.

6. Other items

The Committee discussed on public consultation of draft "Guidance Document on Genetically Engineered Plants Containing Stacked Events", and making the list of all registered IBSCs available to the public at IBKP.

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. Neelam S. Sangwan, Professor (Biochemistry), Central University of Haryana, Mahendergarh | 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. | Sh. Rajappan Viswanathan, Astd. Drugs Controller (India), CDSCO, Nominee/Representative - CDSCO | Member |
| 12. | Dr. Viswanathan Chinnusamy, Joint Director (Research), ICAR-Indian Agricultural Research Institute, New Delhi, Nominee/Representative - ICAR | Member |
| 13. | Dr. Abhilasha Singh Mathuriya, Scientist D, Ministry of Environment, Forest and Climate Change, Government of India, Nominee/Representative - MoEF&CC | Member |
| 14. | Dr. Geeta Jotwani, Senior Deputy Director General & Scientist G- ICMR, Nominee/Representative - ICMR | Member |
| 15. | Dr. Arvind Kumar, Joint Director, Ministry of Home Affairs, Nominee/Representative - Ministry of Home Affairs | Member |
| 16. | Dr. Om Prakash Meena, Assistant Director, Ministry of Home Affairs. Nominee/Representative - Ministry of Home Affairs | Member |
| 17. | Dr. Dipti K. Thukral, Scientist-G, Science and Engineering Research Board (SERB), Department of Science and Technology, Government of India, Nominee/Representatives- DST | Member |
| 18. | Dr. Anant Narayan Bhatt, INMAS, Nominee/Representative - Defence Research and Development Organization | Member |
| 19. | Dr. Lokesh Kumar Narnoliya, Scientist 'D', DBT, New Delhi | DBT officer |
| Biosafety Support Unit: | | |
| 20. | Dr. Govind Kumar Rai, Scientist & Coordinator | |
| 21. | Dr. Poonam Vishwakarma, Scientist | |
| 22. | Dr. Pranjali Vishwakarma, Scientist | |
| 23. | Dr. Shipra Shahi, Scientist | |
| 24. | Dr. Manpreet Kaur, Scientist | |