

MINUTES OF THE 278th MEETING OF THE REVIEW COMMITTEE ON GENETIC MANIPULATION (RCGM) HELD ON 21.02.2024 BY VIDEO CONFERENCING (GO TO MEETING)

The Chairman-RCGM extended a formal welcome to the members of the RCGM for the 278th 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 277th meeting of the RCGM held on 07.02.2024.

3. On action taken report, the Member-Secretary informed that during the 277th meeting of the RCGM, a total of 24 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 receive competent cells of *E.coli* DH5 alpha; to conduct preclinical toxicity studies on Pembrolizumab monoclonal antibody Biosimilar, Trastuzumab Hyaluronidase solution Biosimilar; preclinical toxicity report on Ranibizumab-an anti-VEGF antibody Biosimilar; to deliberate on the regulatory approval pathway for the recombinant vaccines developed outside India and involving the import of finish formulation for conducting Phase 3 clinical trial in India. 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 export recombinant plasmid vectors; submission of records on completion of the Event Selection Trial of GE Cotton lines, on termination of the Biosafety Research Level-I 1st year trial of GE potato clonal hybrid, on the harvest of the Event Selection Trial of GE pigeon pea lines; request to examine the environmental safety aspects of herbicide-tolerant GE *Medicago* spp. (alfalfa) hay. 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-four IBSCs, seventeen annual compliance reports and four medical surveillance reports, and appropriate decisions were taken by the RCGM.

6. Other items

The Committee considered the revised application recommended by the Inter-Ministerial Committee for Certification of PS2 and PS3 BSL-3 facility.

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; President AIIMS, Jammu	Chairman
2.	Dr. Ramesh Sonti, Director & Group Leader, Plant-microbe Interaction, ICGEB, 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. Chandish R. Ballal, Former Director, National Bureau of Agricultural Insect Resources, Bengaluru	Member
6.	Dr. Neelam S. Sangwan, Professor (Biochemistry), Central University of Haryana, Mahendragarh	Member
7.	Dr. Uma Shaanker, Senior Professor, IIT-Jammu, Jammu	Member
8.	Dr. S. N. Sudhakar Babu, Former Head, Crop Production, ICAR- Indian Institute of Oil Seed Research, Hyderabad	Member
9.	Dr. P. V. Mohanan, Scientist 'G', SCTIMST, Thiruvananthapuram	Member
10.	Dr. Ritu Aggarwal, Professor, Post Graduate Institute of Medical Education & Research, Chandigarh	Member
11.	Dr. Asha Chaubey, Sr. Principal Scientist & Head of Fermentation Technology Division, CSIR-IIIM, Jammu	Member
12.	Dr. Rubina Bose, Deputy Drugs Controller (India), CDSCO. Nominee/Representative – CDSCO	Member
13.	Dr. A. Visala, Deputy Drugs Controller (India), CDSCO. Nominee/Representative – CDSCO	Member
14.	Sh. Rajappan Viswanathan, Astd. Drugs Controller (India), CDSCO. Nominee/Representative – CDSCO	Member
15.	Dr. Abhilasha Singh Mathuriya, Scientist D, Ministry of Environment, Forest and Climate Change, New Delhi	Member
16.	Dr. Geeta Jotwani, Senior Deputy Director General & Scientist G- ICMR. Nominee/Representative – ICMR, New Delhi	Member
17.	Sh. Sunil Sharma, Joint Deputy Director, Ministry of Home Affairs. Nominee/Representative - Ministry of Home Affairs, New Delhi	Member
18.	Dr. Anant Narayan Bhatt, INMAS Nominee/Representative - Defense Research and Development Organization, New Delhi	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	
Others:		
25.	Mr. Prasun Guha, M/s. Intas Pharmaceuticals Limited, Ahmedabad	
26.	Dr. Laxmi Adhikary, M/s. Intas Pharmaceuticals Limited, Ahmedabad	
27.	Mr. Durgesh Sawant, M/s. Intas Pharmaceuticals Limited, Ahmedabad	
28.	Mr. Devesh Panwar, M/s. Intas Pharmaceuticals Limited, Ahmedabad	