

MINUTES OF THE 297th MEETING OF THE REVIEW COMMITTEE ON GENETIC MANIPULATION (RCGM) HELD ON 13.11.2024 IN HYBRID MODE AT REGIONAL CENTRE FOR BIOTECHNOLOGY (RCB), FARIDABAD

The Chairman-RCGM extended a formal welcome to the members of the RCGM for the 297th 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 296th meeting of the RCGM held on 30.10.2024.

3. On the action taken report, the Member-Secretary informed that during the 296th meeting of the RCGM, a total of 35 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 conduct preclinical toxicity studies on Nivolumab monoclonal antibody Biosimilar, Corifollitropin Alfa Biosimilar, Sacituzumab-drug-conjugate; preclinical toxicity report on Trastuzumab hyaluronidase solution Biosimilar, Insulin glargine Biosimilar; Request regarding RCGM recommendation to conduct pre-clinical toxicity studies on novel gene therapy product for Haemophilia B; request regarding the biocontainment requirement of Prions causing Scrapie disease of goat and sheep. 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 transfer seeds of GE groundnut lines; to receive seeds of GE *Brassica juncea* lines; Records of Planting and Transport, Trial site maps, and photographs of the trial sites for BRL-I 1st year trial of GE cotton hybrids; applications for the exemption of one exogenous DNA free genome edited *Oryza sativa* lines; Risk Assessment and Risk Management Plan for commercial production of ethanol using GE *Saccharomyces cerevisiae* strain and for import of GE *Saccharomyces cerevisiae* strain and its distribution for ethanol production. 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-seven IBSCs, six annual compliance reports and nil medical surveillance report, and appropriate decisions were taken by the RCGM.

6. Other items

The Committee deliberated on the draft "*Handbook for Institutional Biosafety Committees (IBSCs) - 2024*" and appropriate decisions were taken by the RCGM.

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. Neelam S. Sangwan, Professor (Biochemistry), Central University of Haryana, Mahendergarh	Member
7.	Dr. Uma Shaankar, Senior Professor, IIT-Jammu, Jammu	Member
8.	Dr. Chandish R. Ballal, Former Director, National Bureau of Agricultural Insect Resources, Bengaluru	Member
9.	Dr. K.G. Tirumurugaan, Professor, Department of Animal Biotechnology, Madras Veterinary College, TANUVAS, Chennai	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. Viswanathan Chinnusamy, Joint Director (Research), ICAR-Indian Agricultural Research Institute, New Delhi, Nominee/Representative - ICAR	Member
13.	Dr. Rubina Bose, Deputy Drugs Controller (India), CDSCO, Nominee/Representative - CDSCO	Member
14.	Sh. Rajappan Viswanathan, Astd. Drugs Controller (India), CDSCO, Nominee/Representative - CDSCO	Member
15.	Sh. Yogesh K Shelar, Astd. Drugs Controller (India), CDSCO, Nominee/Representative - CDSCO	Member
16.	Dr. Abhilasha Singh Mathuriya, Scientist D, Ministry of Environment, Forest and Climate Change, Government of India, Nominee/Representative - MoEF&CC	Member
17.	Dr. Om Prakash Meena, Assistant Director, Ministry of Home Affairs, Nominee/Representative - Ministry of Home Affairs	Member
18.	Dr. Dipti K. Thukral, Scientist-G, Science and Engineering Research Board (SERB), Department of Science and Technology, Government of India, Nominee/Representatives- DST	Member
19.	Dr. Anant Narayan Bhatt, INMAS, Nominee/Representative - Defence Research and Development Organization	Member
20.	Dr. K. C. Samal, Professor (Biotech) & Dean, College of Horticulture, Odisha University of Agriculture and Technology, Sambalpur, Representative - State Agricultural University	Special Invitee
21.	Dr. Parveen Chhuneja, Principal Molecular Geneticist, College of Agriculture, Punjab Agricultural University, Ludhiana, Representative - State Agricultural University	Special Invitee

22.	Dr. Amit P. Parikh, Scientist 'F', DBT, New Delhi	DBT officer
Biosafety Support Unit:		
23.	Dr. Govind Kumar Rai, Scientist & Coordinator	
24.	Dr. Poonam Vishwakarma, Scientist	
25.	Dr. Pranjali Vishwakarma, Scientist	
26.	Dr. Shipra Shahi, Scientist	
27.	Dr. Manpreet Kaur, Scientist	
28.	Dr. Renu Arora, Scientist	
29.	Dr. Naveen Kumar, Scientist	
30.	Ms. Surbhi Prithiani, Project Associate	
Others:		
31.	Mr. Jayachandra Ivaturi, M/s. Intas Pharmaceuticals Limited, Ahmadabad	
32.	Dr. Laxmi Adhikary, M/s. Intas Pharmaceuticals Limited, Ahmadabad	
33.	Mr. Prashant, M/s. Intas Pharmaceuticals Limited, Ahmadabad	

J. Deek