

MINUTES OF THE 303rd MEETING OF THE REVIEW COMMITTEE ON GENETIC MANIPULATION (RCGM) HELD ON 06.02.2025 BY VIDEO CONFERENCING (GO TO MEETING)

The Chairman-RCGM extended a formal welcome to the members of the RCGM for the 303rd 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 302nd meeting of the RCGM held on 22.01.2025.

3. On the action taken report, the Member-Secretary informed that during the 302nd 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 the applications to export engineered (CAR-NK, CAR-Gamma Delta T cells) and non-engineered (NK, Gamma Delta T cells) cells; to import β -globin gene LV plasmids, Dengue Tetravalent Vaccine and its Vehicle; to conduct preclinical toxicity studies on Nivolumab monoclonal antibody Biosimilar, Multiepitope Nanocage based Mpx Vaccine, novel form of human MUC1-SEA-targeted antibody conjugated to Monomethyl auristatin E; request for waiver for conduct of preclinical toxicity studies on Insulin Human Injection and seeking NOC for permission to conduct appropriate phase of human clinical trial; preclinical safety report on anti CD19 CAR T cell therapy against CD19 positive Leukaemia and Lymphoma; request seeking waiver of single dose toxicity studies and define a pathway with scientific rationale for dealing with the subsequent waiver requests regarding the non-clinical studies by Biopharma Industry stakeholders. 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 submission of Compliance Reports for action taken on recommendations of 1st CCC visits to monitor ESTs of GE Cotton lines; revised Record of Planting and Trial site map along with the photographs of the trial site for ongoing ESTs of GE rubber lines; Inspection reports submitted by CCC on monitoring of ongoing ESTs of GE cotton lines; applications seeking exemption of four exogenous DNA free GE *Oryza sativa* 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 thirty-seven IBSCs, twenty annual compliance reports and one medical surveillance report, and appropriate decisions were taken by the RCGM.

6. Other items

The Committee deliberated on Expert visit for inspection of Insect Biosafety Level-2 facility; request regarding the amendment in the name of the Company.

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

The Minutes are approved.



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. Chandish R. Ballal, Former Director, National Bureau of Agricultural Insect Resources, Bengaluru	Member
6.	Dr. R. 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. Asha Chaubey, Sr. Principal Scientist & Head of Fermentation Technology Division, CSIR-IIIM, Jammu	Member
10.	Dr. S. N. Sudhakar Babu, Former Head, Crop Production & Principal Scientist (Agronomy), ICAR-Indian Institute of Oil Seed Research, Hyderabad	Member
11.	Dr. Viswanathan Chinnusamy, Joint Director (Research), ICAR-Indian Agricultural Research Institute, New Delhi, Nominee/Representative - ICAR	Member
12.	Dr. Rubina Bose, Deputy Drugs Controller (India), CDSCO, Nominee/Representative - CDSCO	Member
13.	Sh. Arvind Kukreti, 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. Dipti K. Thukral, Scientist-G, Science and Engineering Research Board (SERB), Department of Science and Technology, Government of India, Nominee/Representative - DST	Member
17.	Dr. Abhilasha Singh Mathuriya, Scientist D, Ministry of Environment, Forest and Climate Change, Government of India, Nominee/Representative - MoEF&CC	Member
18.	Dr. Om Prakash Meena, Assistant Director, Ministry of Home Affairs, Nominee/Representative - Ministry of Home Affairs	Member
19.	Dr. Anant Narayan Bhatt, INMAS, Nominee/Representative - Defence Research and Development Organization	Member
20.	Dr. Lokesh Kumar Narnoliya, Scientist 'D', DBT, New Delhi	DBT officer
Biosafety Support Unit:		
21.	Dr. Govind Kumar Rai, Scientist & Coordinator	

22.	Dr. Poonam Vishwakarma, Scientist
23.	Dr. Pranjali Vishwakarma, Scientist
24.	Dr. Shipra Shahi, Scientist
25.	Dr. Manpreet Kaur, Scientist
Others:	
26.	Dr. M.D. Jessy, Director (Research), Rubber Research Institute of India, Kottayam
27.	Dr. Kala Gopi, Research Scientist, Rubber Research Institute of India, Kottayam



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