

MINUTES OF THE 289th MEETING OF THE REVIEW COMMITTEE ON GENETIC MANIPULATION (RCGM) HELD ON 24.07.2024 BY VIDEO CONFERENCING (GO TO MEETING)

The Chairman-RCGM extended a formal welcome to the members of the RCGM for the 289th 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 288th meeting of the RCGM held on 10.07.2024.
3. On the action taken report, the Member-Secretary informed that during the 288th meeting of the RCGM, a total of 42 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 TB mask/bioaerosol and reference samples; preclinical toxicity reports of VLP-based Human Papilloma Virus Vaccine, anti-BCMA CAR-T cell therapy product; request seeking waiver for conduct of preclinical toxicity and immunogenicity studies on indigenously developed Anti-CD-19 CAR-T cell therapy product; request seeking advice on the regulatory pathway on development of Semaglutide Tablets; and the revised PCT study plan with immunogenicity analysis incorporated for Daratumumab monoclonal antibody Biosimilar. 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 report of BRL-I 1st year trial of GE potato; records of Harvest/Termination on completion of BRL-I 1st year trial of GE cotton; compliance records for Event Selection Trials of GE *Brassica juncea* lines, GE cotton lines, and GE pigeon pea lines; and application seeking exemption of exogenous DNA free genome edited *Oryza sativa* lines under SDN-1 category. 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-four IBSCs, eighteen annual compliance reports and one medical surveillance reports, and appropriate decisions were taken by the RCGM.

6. Other items

The Committee discussed the draft "*National Guidelines for the Establishment and certification of Biosafety Level-3 (BSL-3) Containment Facility*"; considered the revised Risk Assessment and Risk Management Plan for Environmental approval for Ethanol production using GE *S. cerevisiae* strain; draft standard Risk Assessment and Risk Management Plans (RARMPs); intimation to RCGM regarding change in the name of the company and request to update the same on IBKP.

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

The Minutes are approved.

Approved

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

Annexure-I

List of Participants:		
1.	Prof. Y.K. Gupta, Former Professor, AIIMS, New Delhi; President AIIMS, Bhopal & 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. Neelam S. Sangwan, Professor (Biochemistry), Central University of Haryana, Mahendergarh	Member
7.	Dr. S. N. Sudhakara Babu, Former Head, Crop Production & Principal Scientist (Agronomy), ICAR-Indian Institute of Oil Seed Research, Hyderabad	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. 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. Rajappan Viswanathan, Astd. Drugs Controller (India), CDSCO, Nominee/Representative - CDSCO	Member
14.	Mr. Jayasenthil N.K., Astd. Drugs Controller (India), CDSCO, Nominee/Representative - CDSCO	Member
15.	Dr. Abhilasha Singh Mathuriya, Scientist D, Ministry of Environment, Forest and Climate Change, Government of India, Nominee/Representative - MoEF&CC	Member
16.	Dr. Geeta Jotwani, Senior Deputy Director General & Scientist G- ICMR, Nominee/Representative - ICMR	Member
17.	Dr. Omprakash 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, Delhi, Nominee/Representative - Defence Research and Development Organization	Member

20.	Dr. Santosh V. Sawardekar, Dr. Balasaheb Sawant Konkan Krishi Vidypeeth, Ratnagiri, SAU Representative	Special Invitee
21.	Dr. Lokesh Kumar Narnoliya, Scientist 'D', DBT, New Delhi	DBT officer
Biosafety Support Unit:		
22.	Dr. Govind Kumar Rai, Scientist & Coordinator	
23.	Dr. Poonam Vishwakarma, Scientist	
24.	Dr. Pranjali Vishwakarma, Scientist	
25.	Dr. Shipra Shahi, Scientist	
26.	Dr. Manpreet Kaur, Scientist	
Others:		
27.	Dr. Rajkumar Rajagopal, Dr. Reddy's Laboratories Limited, Hyderabad	
28.	Mr. Ravi Chandra Chikatimalla, Dr. Reddy's Laboratories Limited, Hyderabad	
29.	Dr. Jasvir Singh, M/s. Danisco India Pvt. Ltd., Hyderabad	
30.	Dr. Vibha Ahuja, Biotech Consortium India Limited, Delhi	
31.	Dr. Ritu Bhalla, On behalf of M/s. Oasis Ethanol Industries Private Limited, Ambala	
32.	Mr. Arun K Tomar, On behalf of M/s. Oasis Ethanol Industries Private Limited, Ambala	
33.	Ms. Mahima V, On behalf of M/s. Oasis Ethanol Industries Private Limited, Ambala	
34.	Mr. Kiran Annavarapu, On behalf of M/s. Oasis Ethanol Industries Private Limited, Ambala	

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