

MINUTES OF THE 281st MEETING OF THE REVIEW COMMITTEE ON GENETIC MANIPULATION (RCGM) HELD ON 03.04.2024 BY VIDEO CONFERENCING (GO TO MEETING)

The Chairman-RCGM extended a formal welcome to the members of the RCGM for the 281st 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 280th meeting of the RCGM held on 20.03.2024.
3. On action taken report, the Member-Secretary informed that during the 280th meeting of the RCGM, a total of 53 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 *Mycobacterium tuberculosis* Clinical Strains; to import Recombinant plasmid containing *E. coli* strains, Meningococcal serogroup B isolates, purified proteins and antibody reagents; to conduct preclinical toxicity studies on Brentuximab vedotin Biosimilar and Nivolumab Biosimilar; to conduct reproductive & developmental toxicity studies on Human Papillomavirus Quadrivalent Vaccine; request seeking waiver for Preclinical toxicity studies on the development of a single dose Matrix-M Adjuvanted Rabies Vaccine, request seeking advice on the regulatory pathway on development of Semaglutide. 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 *Aedes aegypti* mutants; Revised Records of partial Harvest/Termination for the conduct of Event Selection Trial of GE pigeon pea lines, Record of Spatial isolation and Storage on completion of Event Selection Trial of GE Cotton lines; to conduct Biosafety Research Level-I 1st year trial of GE cotton hybrids. 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-nine IBSCs, eighteen annual compliance reports and three medical surveillance reports, and appropriate decisions were taken by the RCGM.

6. Other items

The Committee considered a Risk Assessment and Risk Management Plan for Environmental approval for Ethanol production using genetically engineered *Saccharomyces cerevisiae* strain; the preparation of Risk Assessment and Risk Management Plan as per 151st GEAC Recommendations; and proposal on the waiver of Non-clinical studies requirements in the process of Biosimilar development.

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, 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. Sudhakar Babu, Former Head, Crop Production & Principal Scientist (Agronomy), ICAR-Indian Institute of Oil Seed Research, Hyderabad	Member
8.	Dr. Uma Shaankar, Senior Professor, IIT-Jammu	Member
9.	Dr. P. V. Mohanan, Scientist 'G', SCTIMST, Thiruvananthapuram	Member
10.	Dr. K.G. Tirumurugaan, Professor, Department of Animal Biotechnology, Madras Veterinary College, TANUVAS, Chennai	
11.	Dr. Ritu Aggarwal, Professor, Post Graduate Institute of Medical Education & Research, Chandigarh	Member
12.	Dr. Asha Chaubey, Sr. Principal Scientist & Head of Fermentation Technology Division, CSIR-IIIM, Jammu	Member
13.	Dr. Viswanathan Chinnusamy, Joint Director (Research), ICAR-Indian Agricultural Research Institute, New Delhi, Nominee/Representative - ICAR	Member
14.	Dr. Rubina Bose, Deputy Drugs Controller (India), CDSCO. Nominee/Representative - CDSCO	Member
15.	Sh. Rajappan Viswanathan, Astt. 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. Geeta Jotwani, Senior Deputy Director General & Scientist G- ICMR. Nominee/Representative - ICMR	Member
18.	Dr. Arvind Kumar, Joint Director, Ministry of Home Affairs. Nominee/Representative - Ministry of Home Affairs	Member
19.	Sh. Sunil Sharma, Joint Deputy Director, Ministry of Home Affairs. Nominee/Representative - Ministry of Home Affairs	Member
20.	Dr. Anant Narayan Bhatt, INMAS Nominee/Representative - Defense Research and Development Organization	Member
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. Manpreet Kaur, Scientist
26.	Dr. Renu Arora, Scientist
27.	Dr. Bhawna Yadav, Scientist
28.	Dr. Subhasish Dutta, Scientist
Others:	
29.	Dr. Samir Sangitrao, M/s. Zydus Lifesciences Limited, Ahmedabad
30.	Dr. Sanjay Bandyopadhyay, M/s. Zydus Lifesciences Limited, Ahmedabad
31.	Dr. Sujata Halder, M/s. Zydus Lifesciences Limited, Ahmedabad
32.	Dr. Jitendra Patel, M/s. Zydus Lifesciences Limited, Ahmedabad
33.	Mr. Veera Pandu Sangareddy, M/s. Biological E. Limited, Telangana
34.	Mr. Shivaputhrappa Ganiger, M/s. Biological E. Limited, Telangana
35.	Dr. Suhaas Kolpe, M/s. Biological E. Limited, Telangana

Suhaas Kolpe