

MINUTES OF THE 280th MEETING OF THE REVIEW COMMITTEE ON GENETIC MANIPULATION (RCGM) HELD ON 20.03.2024 BY VIDEO CONFERENCING (GO TO MEETING)

The Chairman-RCGM extended a formal welcome to the members of the RCGM for the **280th 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 **279th meeting** of the RCGM held on **06.03.2024**.

3. On action taken report, the Member-Secretary informed that during the **279th meeting** of the RCGM, a total of **54** 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 import APC-DNA plasmid mix, Recombinant proteins and Influenza virus strains; to conduct preclinical toxicity studies on Pembrolizumab monoclonal antibody Biosimilar, Trastuzumab Hyaluronidase Biosimilar, Nivolumab Biosimilar, Semaglutide Biosimilar; preclinical toxicity report on Mepolizumab Biosimilar; request for waiver for conduct of preclinical toxicity and immunogenicity studies on indigenously developed Anti-CD-19 CAR-T cell therapy product, for seeking RCGM endorsement on the proposal on evaluation of efficacy, immunogenicity and safety of Respiratory Syncytial Virus vaccine, and for seeking advice on the regulatory pathway on development of Semaglutide 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 Records and inspection report of CCC on completion of Biosafety Research Level-I 1st Year trial, and compliance report of GE cotton Event; inspection report of CCC on termination of Event Selection Trial of GE cotton lines; compliance report and revised Record of storage for Event Selection Trials of GE banana lines; CCC inspection report for ongoing Event Selection Trial of GE cotton lines; Records on completion of post-harvest of Biosafety Research Level-I 1st Year trial of maize breeding stack; CCC inspection report for ongoing Biosafety Research Level-I 2nd Year trial of GE maize breeding stack; risk group classification of *Bidensovirus* (BmDENV2), and reclassification of *Banana bunchy top virus* (BBTV). 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, twenty-one annual compliance reports and nil medical surveillance reports, and appropriate decisions were taken by the RCGM.

6. Other items

The Committee considered Intimation regarding change of address of corporate office and request to update the same at IBKP.

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



Approved



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. P. V. Mohanan, Scientist 'G', SCTIMST, Thiruvananthapuram	Member
9.	Dr. K.G. Tirumurugaan, Professor, Department of Animal Biotechnology, Madras Veterinary College, TANUVAS, Chennai	
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.	Sh. Rajappan Viswanathan, Astt. Drugs Controller (India), CDSCO. Nominee/Representative – CDSCO	Member
14.	Dr. Dipti K. Thukral, Scientist-G, Science and Engineering Research Board (SERB), Department of Science and Technology, Government of India. Nominee/Representatives- DST	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.	Sh. Sunil Sharma, Joint Deputy Director, Ministry of Home Affairs. Nominee/Representative - Ministry of Home Affairs	Member
18.	Dr. Anant Narayan Bhatt, INMAS Nominee/Representative - Defense Research and Development Organization	Member
19.	Dr. Lokesh Kumar Narnoliya, Scientist 'D', DBT, New Delhi	DBT officer
Biosafety Support Unit:		

	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
Special Invitees and Other participants:	
25.	Dr. Celia Chalam Vasimalla, Head of Division, Division of Plant Quarantine, ICAR-NBPGR, New Delhi (Special Invitee)
26.	Dr. Supriya Chakraborty, Professor, School of Life Sciences, JNU, New Delhi (Special Invitee)
27.	Prof. Shyam Kumar, Professor in Biotechnology, Karnatak University, Dharwad (Special Invitee)
28.	Manjunath Gowda, Professor and Head, Sericulture Department, University of Agricultural Sciences, Bangalore (Special Invitee)
29.	Mr. Devesh Panwar, M/s. Intas Pharmaceuticals Limited, Ahmedabad
30.	Dr. Swagatam Ray, M/s. Intas Pharmaceuticals Limited, Ahmedabad
31.	Dr. Ravindra Pawar, M/s. Intas Pharmaceuticals Limited, Ahmedabad
32.	Dr. Samuel Solomon, M/s. Intas Pharmaceuticals Limited, Ahmedabad
33.	Dr. Amol Chouilwar, M/s. Cipla Ltd., Mumbai
34.	Mr. Darshan Aigal, M/s. Cipla Ltd., Mumbai
35.	Dr. Jeevan Ghosalkar, M/s. Cipla Ltd., Mumbai
36.	Dr. Li Shuiyan, Aurisco Pharmaceutical Co. Ltd., Shanghai, China
37.	Dr. N. Kamalakar, M/s. Nath Bio-Genes (India) Limited, Aurangabad

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