

MINUTES OF THE 259th MEETING OF THE REVIEW COMMITTEE ON GENETIC MANIPULATION (RCGM) HELD ON 31.05.2023 BY VIDEO CONFERENCING (GO TO MEETING)

The Chairman-RCGM extended a formal welcome to the members of the RCGM for the 259th 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 258th meeting of the RCGM held on 17.05.2023.

3. On action taken report, the Member-Secretary informed that during the 258th meeting of the RCGM, a total of 32 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 Pembrolizumab Biosimilar; pre-clinical toxicity study report on anti-BCMA CAR-T cell therapy product, Varicella Zoster Virus gE vaccine; request for waiver of pre-clinical toxicity study for Insulin Aspart & Insulin Glargine combination drug product; requirement of RCGM review/approval for the viral vaccines developed using published cDNA sequences of the known vaccine strains; study protocols on reproductive & developmental toxicity on recombinant Human Papillomavirus Quadrivalent vaccine. After deliberation on each application including information items, appropriate decisions were taken by the RCGM.

4.2 Applications in the area of Agriculture

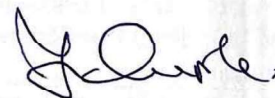
The Committee considered the applications to transfer GE rubber lines; to import transformation vector; to conduct event selection trial of GE cotton lines; request to change the trial site for event selection trial of GE rubber lines, rectification RCGM permit letters to conduct event selection trials of GE banana lines, to include an additional location to conduct event selection trial of Bt Brinjal lines; to exempt exogenous introduced DNA free SDN-1 genome edited rice 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 twenty seven IBSCs, eighteen annual compliance reports and one medical surveillance report, 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

12/6/23

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. Neelam S. Sangwan, Professor (Biochemistry), Central University of Haryana, Mahendergarh	Member
4.	Dr. Chandish R. Ballal, Former Director, National Bureau of Agricultural Insect Resources, Bengaluru	Member
5.	Dr. R. Uma Shaanker, Senior Professor, IIT, Jammu	Member
6.	Dr. S. N. Sudhakar Babu, Former Head, Crop Production & Principle Scientist (Agronomy), ICAR-Indian Institute of Oil Seed Research, Hyderabad	Member
7.	Dr. Vinay Nandicoori, Director, CSIR-CCMB, 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	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.	Smt. A. Visala, Deputy Drugs Controller (India), CDSCO. Nominee/Representative – CDSCO	Member
15.	Sh. Rajappan Viswanathan, 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.	Sh. Sunil Sharma, Ministry of Home Affairs. Nominee/Representative - Ministry of Home Affairs	Member
18.	Dr. Anant Narayan Bhatt, Institute of Nuclear Medicine and Allied Sciences (INMAS). Nominee/Representative - Defense Research and Development Organization	Member
19.	Dr. Gandharva Nagpal, Scientist 'C', DBT, New Delhi	Co-Member Secretary
Biosafety Support Unit:		
20.	Dr. Govind Kumar Rai, Scientist & Coordinator	
21.	Dr. Poonam Vishwakarma, Scientist	
22.	Dr. Pranjali Vishwakarma, Scientist	
23.	Dr. Manpreet Kaur, Scientist	
Others:		
24.	Dr. Akhil Kumar, M/s. Aurigene Oncology limited, Bangalore	

25.	Dr. Priyadarshini Chatterjee, M/s. Aurigene Oncology limited, Bangalore
26.	Ms. Bhawna Gupta, M/s. Aurigene Oncology limited, Bangalore
27.	Dr. D.M. Rao, M/s. Aurigene Oncology limited, Bangalore
28.	Dr. Satendra Kumar Mangrauthia, Senior Scientist, ICAR-Indian Institute of Rice Research (IIRR), Hyderabad



Approved

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