

MINUTES OF THE 184th MEETING OF THE REVIEW COMMITTEE ON GENETIC MANIPULATION (RCGM) HELD ON 04.06.2020 BY VIDEO CONFERENCING

The Chairman, RCGM extended a formal welcome to the members of the RCGM for the 184th 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 183rd meeting of the RCGM held on 05.05.2020.

3. On action taken report, the Member-Secretary informed that during the 183rd meeting of the RCGM, a total of 50 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 applications to import DNA constructs expressing Guselkumab/Ocrelizumab/Daratumumab/Dupilumab/Pembrolizumab, amplified regions of E and RdRP genes of SARS CoV2, HEK293 cell bank, ChAdOx1 nCoV-19 virus stock, reagents to develop influenza and SARS-COV2 vaccine, lentiviral vector having FVIII gene, live attenuated SARS CoV2 virus, wild SARS CoV2 virus and full length SARS CoV2 cDNA constructs; to receive blood samples from individuals recovered from COVID-19 infection; to transfer inactivated SARS-CoV-2 cell supernatant. Also committee considered applications permission to conduct preclinical toxicity studies on human papillomavirus vaccine, novel coronavirus 2019-nCoV vaccine, Rituximab biosimilar, recombinant Teriparatide, Bevacizumab isotype, Romiplostim biosimilar, gene therapy product for Haemophilia A or B, Tenecteplase biosimilar; pre-clinical toxicity study reports on Adalimumab biosimilar; NOC to DGFT for export of SCOMET items; 200L scale fermentation of r-Liraglutide; extension of validity to conduct preclinical toxicity studies on recombinant human albumin. After deliberation on each application including information items, appropriate decision was taken by the RCGM.

4.2 Applications in the area of Agriculture

The Committee considered applications to conduct confined field trials for event selection of GE cotton, GE brinjal; to conduct of Biosafety Research Level-I confined field trials of GE potato, and GE maize; reports on event selection trial of GE cotton lines. After deliberation on each application including information items, appropriate decision was taken by the RCGM.

5. IBSC Reports

The Committee considered minutes submitted by nine IBSCs, one annual compliance report and four medical surveillance reports, appropriate decision was taken by the RCGM.

6. Other items

The Committee considered revised Checklist and instructions for development of COVID-19 vaccines prescribing basic CMC data requirements and PCT protocols to assess animal toxicity study, revised Guidelines for the Safety Assessment of Genome Edited Plants, revised Guidance

document on Standards and specifications of BSL2 and BSL 3 facilities, regulatory requirement of a single batch production and characterization data, regulatory approvals based on one time consolidated CMC and PCT study data submission together based on pre-determined PCT protocols, approval process flow for regulatory approvals by IBSC/RCGM for import/export, increasing the frequency of RCGM meeting for reducing the timelines for regulatory approval process and appropriate decision was taken by the RCGM.

No other transaction took place and the meeting ended with vote of thanks to the chair.

The Minutes are approved.



(Dr. Rakesh Kumar Mishra)
Chairman, RCGM

List of Participants:

1.	Dr. Rakesh Kumar Mishra, Director-CCMB, Hyderabad	Chairman
2.	Dr. Amita Aggarwal, SGPIMS, Lucknow	Co-Chair (Pharma)
3.	Dr. Kuldeep Singh, Director, ICAR- NBPGR, New Delhi	Co-Chair (Agri)
4.	Dr. Gururaj Katti, Principal Scientist & Head, ICAR- IIRR, Hyderabad	Member
5.	Dr. S.K. Rath, Principal Scientist, CSIR- CDRI, Lucknow	Member
6.	Dr. P. V. Mohanan, Scientist 'G', SCTIMST, Thiruvananthapuram	Member
7.	Dr. Pradyumna Kumar Singh, CSIR-National Botanical Research Institute, Lucknow	Member
8.	Dr. Anand Kumar Kondapi, School of Life Science, University of Hyderabad, Hyderabad	Member
9.	Dr. Chandish R. Ballal, Director, National Bureau of Agricultural Insect Resources, Bangalore	Member
10.	Dr. R. Uma Shaanker, Univeristy of Agricultural Sciences, Bengaluru	Member
11.	Dr. Rajesh Gokhale, National Institute of Immunology, New Delhi	Member
12.	Dr. Guhan Jayaraman, Indian Institute of Technology, Madras	Member
13.	Dr. Neelam S. Sangwan, Head, Department of Biochemistry, Central University of Haryana, Mahendergarh	Member
14.	Dr. Rajnish Kumar Chaturvedi, CSIR-Indian Institute of Toxicology Research, Lucknow	Member
15.	Sh. Tarun Kathula, Director Biosafety, MoEFCC & Secretary-GEAC	Nominee-MoEF& CC
16.	Dr. Geeta Jotwani, Scientist F	Nominee-ICMR
17.	Dr. Shilpi Paul, Scientist E, SERB	Nominee-DST
18.	Dr. Alka Sharma, Scientist-G, & Nodal Officer (Biopharma), DBT, New Delhi	Member
19.	Dr. A.K. Rawat, Scientist- G & Nodal Officer (Agri.), DBT, New Delhi	Member
20.	Dr. Vanga Siva Reddy, CSO, BSU, New Delhi	Special Invitee
21.	Dr. Nitin K. Jain, Scientist-F, DBT	Member Secretary

DBT and Biosafety Support Unit:

22. Dr. Gandharva Nagpal, Scientist C, DBT
23. Dr. Sangeeta Agarwal, Chief (Agriculture)
24. Dr. Poonam Vishwakarma, Scientist
25. Dr. Govind Kumar Rai, Scientist
26. Dr. Manpreet Kaur, Scientist

Others:

27. Dr. T. M.Chozhavel Rajanathan, Cadila Healthcare Limited, Ahmedabad
28. Dr. Jitendra Patel, Cadila Healthcare Limited, Ahmedabad
29. Mr. Sivakesava Reddy Ankireddy, Aurobindo Pharma Limited, Hyderabad
30. Dr. Disha Dadke, Aurobindo Pharma Limited, Hyderabad
31. Dr. Narendra S. Deshmukh, Intox Pvt. Ltd., Pune
32. Dr. Vinay Bhardwaj, ICAR-CPRI, Shimla
33. Dr. Sanjeev Sharma, ICAR-CPRI, Shimla

34. Dr. Sandhya Kranthi, Rallis India Limited, Bangalore
35. Mr. Nagaraj Kampli, Rallis India Limited, Bangalore
36. Dr. Ramanathan Vairamani, Rallis India Limited, Bangalore
37. Dr. Shiva Kumar, Rallis India Limited, Bangalore
38. Mr. Anil Kumar, Rallis India Limited, Bangalore

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