

**PROCEEDINGS OF THE 143rd MEETING OF THE GENETIC ENGINEERING
APPRAISAL COMMITTEE HELD ON 14.06.2021**

The 143rd meeting of the Genetic Engineering Appraisal Committee (GEAC) of the Ministry of Environment, Forest and Climate Change (MoEF&CC) was held on 14.06.2021 virtually through video conferencing. The meeting was chaired by Mrs. B.V. Umadevi, Additional Secretary, MoEF&CC. The list of participants is placed at **Annexure.**

At the outset, Mrs. B.V. Umadevi, Chairperson, GEAC welcomed all the members. Shri Tarun Kathula, Member Secretary, GEAC mentioned that GEAC meetings had moved to the virtual mode during the pandemic situation, and this is the fifth virtual meeting being organized.

Agenda Item No. 1: Leave of absence

Six Members communicated their inability to attend the 143rd meeting of GEAC, namely Prof. P. Balasubramanian, Dr. Lalitha Gowda, Dr. P. Suprasanna, Dr. A.K. Singh, Dr. N. Sathyarayanan and Dr. Madhu Dikshit.

Decision:

Leave of absence was granted to the members who could not attend the meeting.

Action: GEAC Secretariat

Agenda Item No. 2: Confirmation of minutes of the 142nd GEAC meeting

Minutes of the 142nd GEAC meeting were circulated to all the members for comments and minutes were suitably amended to incorporate the comments received from the members.

Decision:

Members confirmed the minutes of the 142nd GEAC meeting.

Action: GEAC Secretariat

Agenda Item No. 3: Action taken report on the decision taken in the 142nd GEAC meeting

Member Secretary, GEAC briefed about the action taken on the decisions at the 142nd meeting of GEAC. He informed that letters communicating GEAC decisions had been issued to applicants.

Decision:

The Committee noted the actions taken by the Secretariat.

Action: GEAC Secretariat

Agenda Item No. 4: Applications related to Commercial/ Environmental release

4.1 Application for Environmental approval of recombinant Gam-COVID Vac combined vector vaccine (Sputnik V, Russia) for grant of permission to manufacture by M/s Shilpa Biologicals Private Limited, Belur-Dharwad, Karnataka.

The application of M/s Shilpa Biologicals Private Limited, Belur-Dharwad, Karnataka seeking environmental approval for manufacturing of recombinant Gam-COVID Vac combined vector vaccine (Sputnik V, Russia) has been deliberated by the committee.

The committee observed that the RCGM has recommended the application for process development and optimization to enhance productivity of SPUTNIK V vaccine at Shilpa Biologicals Private Limited, *vide* Permit No. BT/IBKP/290/2020 dated 29.04.2021 with strict adherence to the following conditions:

- No GMOs/LMOs/Hazardous Microorganisms are allowed for experimentation for commercial production/manufacturing of the product without prior authorization from the Competent Authority.
- All rDNN Hazardous Microorganisms materials are to be destroyed and disposed of in accordance with the Regulations and Guidelines for Recombinant DNA Research and Biocontainment, 2017 of the Government of India after conclusion of the experiments.
- All experiments to be carried out are to be documented.
- The applicant is directed to submit the 'statement of utilization of the imported material to this Department.
- Any other specific instructions: National and WHO guidelines/recommendations/ advisory on R & D on COVID 19 including Interim Guidance Document on Laboratory Biosafety to Handle COVID-19 Specimens issued by DBT should be followed.

Further, the committee observed that the firm has obtained approval from CDSCO as under:

- CT-11 permission to manufacture the drug substance and drug product for examination, test and analysis *vide* Letter No. CT10/BIO/21/000066 dated 14.05.2021.
- CT-14 permission to manufacture drug product at SBPL from ready to fill unapproved bulk drug substance imported from Russia, for test or analysis *vide* Letter No. CT12/BIO/21/000041 dated 02.06.2021.

Decision:

The application of M/s Shilpa Biologicals Private Limited, Belur-Dharwad, Karnataka for manufacturing of recombinant Gam-COVID Vac combined vector vaccine (Sputnik V, Russia) was recommended with the following conditions:

- a. Submission of Environmental Risk Management and Safety Plan (ERMP) within 3 months to this Ministry.
- b. Submission of compliance report on ERMP plan every 6 months to the Regional Office of the Ministry of Environment, Forest and Climate Change;

- c. Zero Liquid Discharge shall be ensured and no waste/treated water shall be discharged outside the premises. The remnants of ZLD in the form of solids, solid waste should be treated and made chemically and biologically inert and disposed off, as per the characteristics, either at Hazardous Waste Disposal Landfill or a municipal sanitary landfill at a secure location. The records of generation, treatment, recycled/reused and disposal shall be maintained and submitted to SPCB at regular intervals of twice in a year, on 15th October (for April-September) and 15th April for October to March).
- d. The project should be implemented under the oversight of IBSC of the applicant with regular annual reports to RCGM.
- e. The Ministry may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory.
- f. The Ministry reserves the right to stipulate additional conditions if found necessary. The Company in a time bound manner shall implement these conditions.
- g. The Regional Office of this Ministry shall monitor compliance of the stipulated conditions. The project authorities should extend full cooperation to the officer (s) of the Regional Office by furnishing the requisite data/information/monitoring reports.
- h. Disposal of experimented animals as well as hazardous microbial components that should be properly defined with required SOP.
- i. Conduct RT-PCR test of biomedical waste before it is treated by the agency to ensure zero discharge of genetic material.

The Review Committee on Genetic Manipulation (RCGM) to examine and submit a Risk Assessment and Risk Management Plan to GEAC, which would be shared with applicant for compliance.

Action: GEAC Secretariat

Agenda Item No. 5: Applications related to Import/ Export

5.1 Application for import of *Bacillus amyloliquefaciens*, *Bacillus licheniformis*, *Bacillus megaterium*, *Bacillus pumilus*, *Bacillus subtilis* for the purpose of waste-water treatment by M/s Altima Technologies Pvt Ltd, Kerala.

The application of M/s Altima Technologies Pvt Ltd, Kerala for import of *Bacillus amyloliquefaciens*, *Bacillus licheniformis*, *Bacillus megaterium*, *Bacillus pumilus*, *Bacillus subtilis* for the purpose of waste-water treatment was initially considered in 139th meeting of the GEAC held on 19.05.2020 and the Committee deferred the application and sought justification from the applicant for importing *Bacillus spp* which are non-GMOs from USA, while the native Indian *Bacillus spp* species are available.

Later, this application was again considered in 140th meeting of the GEAC held on 28.07.2020, after considering the justification from the applicant, the Committee recommended the import of *Bacillus amyloliquefaciens*, *Bacillus licheniformis*, *Bacillus megaterium*, *Bacillus pumilus*, *Bacillus subtilis* Subject to compliance with the provisions of Biological Diversity Act, 2002 and clearance from Plant Quarantine Department.

Accordingly, the applicant approached the concerned Plant Quarantine Departments which is pending, therefore the applicant again approached GEAC. In this regard, after due deliberation, it was decided that GEAC would write a letter to the Additional Plant

Protection Adviser, Directorate of Plant Protection, Quarantine and Storage at the earliest. Further, Dr. S.J. Rahman would be providing a draft letter to GEAC.

Decision:

The matter has been discussed at length and it was decided to write to the Additional Plant Protection Adviser, Directorate of Plant Protection, Quarantine and Storage to seek comments on the application of M/s Altima Technologies Pvt Ltd, Kerala within 7 days.

Action: GEAC Secretariat

The meeting ended with a vote of thanks to the Chair, Co-Chair and all the members.

List of Participants

Official Members who participated			
1.	Mrs. B. V. Umadevi Chairperson, GEAC & Additional Secretary, Ministry of Environment, Forest & Climate Change, JorBagh, Aliganj, New Delhi.	3.	Shri Tarun Kathula Scientist-F, and Member Secretary (GEAC), Ministry of Environment, Forests & Climate Change, JorBagh, Aliganj, New Delhi.
2.	Dr. K. Veluthambi Co-Chairman, GEAC and Professor (retd) & Head, School of Biotechnology, Madurai Kamaraj University, Madurai	4.	Dr. Ashish Kumar Joint Director, Ministry of Environment, Forest and Climate Change, New Delhi
Officials/ Expert members			
1.	Dr. Nitin K. Jain Scientist –F and Member Secretary, RCGM Department of Biotechnology, C. G. O, Complex, Lodhi Road, New Delhi-110003.	8.	Dr. Dinesh K Agarwal, Principal Scientist, In charge, Plant Breeding & Genetics, ICAR-Indian Institute of Seed Science Mau, U. P
2.	Dr. Ashok Bhatnagar, Former Professor, Department of Botany, University of Delhi, New Delhi	9.	Dr. Yashpal Yadav Central Pollution Control Board Parviesh Bhawan, CBD cum office complex, East Arjun Nagar, New Delhi- 110032
3.	Dr. B. Venkateswarlu Former Vice-Chancellor Vasantrya Naik Marathwada Krishi Vidyapeeth, Parbani (Maharashtra).	10.	Dr. S. K. Barik Director CSIR- National Botanical Research Institute, Lucknow
4.	Dr. S. J. Rahman, Principal Scientist & Univ. Head of Entomology, AICRP on Biological Control Agricultural Research Institute (ARI), Prof. Jayashankar Telangana State Agri. University, Rajendranagar, Hyderabad.	11.	Dr. S De Principal Scientist Animal Biotechnology Centre, National Dairy Research Institute, Karnal.
5.	Dr. Sushil Gupta, Former Chairman, Central Ground Water Board, New Delhi	12.	Dr. Geeta Jotwani Scientist F Indian Council of Medical Research, New Delhi.
6.	Mr. Jayant Gangakhedkar Assistant Drugs Controller (I) Central Drugs Standard Control Organizations, FDA Bhawan Kotla Road, New Delhi-110002.	13.	Dr. Usha Rao Assistant Controller of Patents & Designs, Patent Office, New Delhi, India

7.	Shri Sunil Bakshi Food Safety and Standards Authority of India (FSSAI), FDA Bhawan, Kotla Road, New Delhi		
Member who did not participate			
1.	Prof. P. Balasubramanian Former Director, Centre for Plant Molecular Biology, TNAU, Coimbatore	4.	Dr. A.K. Singh Head, Division of Genetics, IARI, New Delhi.
2.	Dr. Lalitha Gowda, Former Chief Scientist, CSIR-CFTRI Mysore, Karnataka-570 020, India	5.	Dr. N. Sathyanarayana Joint Director Plant Protection Quarantine & storage, NH-IV, Faridabad, Haryana.
3.	Dr. P. Suprasanna Scientific Officer H (level 14) Biosciences Group, BARC, Mumbai.	6.	Dr. Madhu Dikshit Former Director CSIR-Central Drug Research Institute, Lucknow.