PROCEEDINGS OF THE 142nd MEETING OF THE GENETIC ENGINEERING APPRAISAL COMMITTEE HELD ON 11.05.2021

The 142nd meeting of the Genetic Engineering Appraisal Committee (GEAC) of the Ministry of Environment, Forest and Climate Change (MoEF&CC) was held on 11.05.2021 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 fourth virtual meeting being organized.

Agenda Item No. 1: Leave of absence

Four Members communicated their inability to attend the 142nd meeting of GEAC, namely Prof. P. Balasubramanian, Dr. A.K. Singh, Dr. N. Sathyanarayana, and Dr. Usha Rao.

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 141st GEAC meeting

Minutes of the 141st 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 141st GEAC meeting.

Action: GEAC Secretariat

Agenda Item No. 3: Action taken report on the decision taken in the 141st GEAC meeting

Member Secretary, GEAC briefed about the action taken on the decisions at the 141st 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 Clinical Trials for Biopharmaceutical Drugs (Insulin Lispro) derived from Living Modified Organism (Recombinant *Escherichia. Coli*) by M/s GeneSys Biologics Pvt. Ltd., Hyderabad.

The proposal of M/s GeneSys Biologics Pvt. Ltd., Hyderabad seeking environmental approval of large scale production of Biopharmaceutical drugs (Insulin Lispro) from Recombinant *Eschericia coli* (LMO) was deliberated by the committee. The applicant has also obtained the clearance of RCGM.

Decision:

The application of M/s GeneSys Biologics Pvt. Ltd., Hyderabad for environmental approval for manufacturing of Biopharmaceutical Drugs (Insulin Lispro) derived from Living Modified Organisms (Recombinant *Escherichia coli*) was recommended by the committee 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 six months to the concerned Regional Office of this Ministry;
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.

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

4.2 Application for commercial production of Recombinant *Sus scrofa* (Porcine) Pepsinogen (protein zero) using genetically modified *Pichia pastoris* by M/s Richcore Lifesciences Pvt. Ltd., Bengaluru.

The proposal of M/s Richcore Lifesciences Pvt. Ltd., Bengaluru seeking environmental approval for commercial production of Recombinant *Sus scrofa* (Porcine) Pepsinogen (protein zero) using genetically modified *Pichia pastoris* was deliberated by the committee. The applicant has also made a presentation before the committee.

Decision:

The application of M/s Richcore Lifesciences Pvt. Ltd., Bengaluru for environmental approval for commercial production of Recombinant *Sus scrofa* (Porcine) Pepsinogen (protein zero) using genetically modified *Pichia pastoris* was recommended by the committee subject to 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 six months to the concerned Regional Office of this Ministry
c. Zero Liquid Discharge shall be ensured and no waste/treated water shall be discharged outside the premises. Waste water from the unit should not be mixed with the general public sewage system. 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. The material produced at commercial level would be shipped back to the client's facility or their recommended analytical facility for testing purpose and would not be utilized in India.
i. Approval from FSSAI may be sought if used for human consumption or any other purpose in India.

Necessary approvals may be obtained for import of *Pichia pastoris* strain from the client (Clara foods, South San Francisco, California, USA) for commercial production of Recombinant Sus scrofa (Porcine) Pepsinogen (protein zero) using genetically modified *Pichia pastoris.*

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

4.3 Application for commercial production of Recombinant *Gallus gallus* (Chicken) Ovomucoid (Protein one) using genetically modified *Pichia pastoris* by M/s Richcore Lifesciences Pvt. Ltd., Bengaluru.

The proposal of M/s Richcore Lifesciences Pvt. Ltd., Bengaluru seeking environmental approval for commercial production of Recombinant *Gallus gallus* (Chicken) Ovomucoid (Protein one) using genetically modified *Pichia pastoris* was deliberated and the committee. The applicant has also made a presentation before the committee.

Decision:

The application of M/s Richcore Lifesciences Pvt. Ltd., Bengaluru for environmental approval for commercial production of Recombinant *Gallus gallus* (Chicken) Ovomucoid (Protein one) using genetically modified *Pichia pastoris* was recommended by the committee subject to 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 six months to the concerned Regional Office of this Ministry;
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. The material produced at commercial level would be shipped back to the client's facility or their recommended analytical facility for testing purpose and would not be utilized in India.
i. Approval from FSSAI may be sought if used for human consumption or any other purpose in India.

Necessary approvals may be obtained for import of *Pichia pastoris* strain from the client (Clara foods, South San Francisco, California, (USA) for commercial production of Recombinant *Gallus gallus* (Chicken) Ovomucoid (Protein one) using genetically modified *Pichia pastoris.*

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

4.4 Application for environmental approval of Cellulosic Ethanol Production using CelluX™ 4 YEAST by M/s Indian Oil Corporation Limited, New Delhi.

The proposal of M/s. Indian Oil Corporation Limited, New Delhi seeking environmental approval of Cellulosic Ethanol Production using CelluX™ 4 YEAST was deliberated by the committee. The applicant has also made a detailed presentation before the committee.

Decision:

The application of M/s. Indian Oil Corporation Limited, New Delhi for environmental approval Cellulosic Ethanol Production using CelluX™ 4 YEAST was recommended by the committee 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 six months to the concerned Regional Office of this Ministry
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. The applicant would be sharing a note with GEAC Secretariat on how it will reduce stubble burning and benefit farmers

The applicant is also requested to obtain separate permissions while importing the genetically modified CelluXTM 4 YEAST.

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

4.5 Request for approval to manufacture the Risk Group 1 category CHO cells lines expressing Bevacizumab (BP01) by M/s CuraTeQ Biologics Private Limited, Hyderabad.

The proposal of M/s CuraTeQ Biologics Private Limited, Hyderabad seeking environmental approval to manufacture the Risk Group 1 category CHO cells lines expressing Bevacizumab (BP01) was deliberated by the committee. The application was considered by the Review Committee on Genetic Manipulation (RCGM) in its 179th and 186th meetings held on 09.01.2020 and 23.07.2020 and the applicant received a conditional approval from RCGM subject to condition of submission of data and GEAC approval. During the RCGM meeting discussing the Form C3 application, CuraTeQ was asked to perform a risk assessment of the CHO cell line expressing BP01 and submit it to RCGM and GEAC.

Accordingly, a detailed risk assessment was performed to understand the impact of the genetically modified CHOK1SV cell line expressing genes of heavy and light chains of BP01, on humans and environment as per the approach specified in Annexure 2 of the

"Regulation and guidelines on biosafety of Recombinant DNA Research and Biocontainment, 2017" has been shared by the applicant with RCGM and GEAC.

Decision:

The application of M/s CuraTeQ Biologics Private Limited, Hyderabad for environmental approval to manufacture the Risk Group 1 category CHO cells lines expressing Bevacizumab (BP01) 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 six months to the concerned Regional Office of this Ministry;
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.

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

4.6 Application for Environmental approval of recombinant Gam-COVID-Vac combined vector vaccine (Sputnik V, Russia) for grant of permission to manufacture by M/s Stelis Biopharma Private Limited, Bengaluru.

The application of M/s Stelis Biopharma Private Limited, Bengaluru 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 in its 201st meeting held on 04.03.2021 has recommended the application to carry out research and development work and also for scale up of Gam-COVID-Vac combined vector vaccine against SAARS-CoV2R&D, *vide* reference No. BT/BS/17/316/2009-PID dated 10.03.2021 with strict adherence to the following conditions:

- The applicant should follow the "Interim guidance document on laboratory biosafety to handle COVID – 19 specimens" issued by DBT.
- The applicant is required to comply; with the Regulations and Guidelines for Recombinant DNA Research and Biocontainment, 2017.

- Any other specific instruction: National and WHO guidelines/recommendations/advisory for research and development work on COVID-19 should be followed.

The committee observed that the firm has obtained approval from CDSCO for their facility (Stelis Unit-III) located at 68/A Bommasandra, Bengaluru. The applicant has also made a detailed presentation before the committee and the requested the committee to extend the production of the vaccine to another facility of M/s Stelis Unit-II facility located at 21-D, Obadenahalli, Doddaballapura Bengaluru, which is yet to obtain from CDSCO.

Decision:

The application of M/s Stelis Biopharma Private Limited, Bengaluru for manufacture 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. Submission of complete report on monthly basis as sought by RCGM;
e. The project should be implemented under the oversight of IBSC of the applicant with regular annual reports to RCGM.
f. The Ministry may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory.
g. The Ministry reserves the right to stipulate additional conditions if found necessary. The Company in a time bound manner shall implement these conditions.
h. 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.
i. Disposal of experimented animals as well as hazardous microbial components that should be properly defined with required SOP.
j. Manufacturing at additional facility of firm M/s Stelis Unit-II facility located at 21-D, Obadenahalli, Doddaballapura Bengaluru shall be allowed subject to the approval of CDSCO.

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

4.7 Application for No Objection Certificate (NOC) for therapeutic and non-therapeutic protein products for manufacture, storage and transfer of genetically engineered *Escherichia coli cells* (Insulin Aspart Soluble) by M/s. BioGenomics Limited, Maharashtra.

The proposal of M/s. BioGenomics Limited, Maharashtra for No Objection Certificate (NOC) therapeutic and non-therapeutic protein products for manufacture, storage and transfer of genetically engineered *Escherichia coli cells* (Insulin Aspart Soluble) was deliberated and committee. The applicant has also obtained the clearance of RCGM.

Decision:

The application of M/s. BioGenomics Limited, Maharashtra for No Objection Certificate (NOC) for therapeutic and non-therapeutic protein products for manufacture, storage and transfer of genetically engineered *Escherichia coli cells* (Insulin Aspart Soluble) was recommended by the committee 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.

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

4.8 Application for No Objection Certificate (NOC) for therapeutic and non-therapeutic protein products for manufacture, storage and transfer of genetically engineered *Escherichia coli* cells (Insulin Aspart Mix 30) by M/s. BioGenomics Limited, Maharashtra.

The proposal of M/s. BioGenomics Limited, Maharashtra for No Objection Certificate (NOC) therapeutic and non-therapeutic protein products for manufacture, storage and transfer of genetically engineered *Escherichia coli cells* (Insulin Aspart Mix 30) was deliberated by the committee. The applicant has also obtained the clearance of RCGM.

Decision:

The application of M/s. BioGenomics Limited, Maharashtra for No Objection Certificate (NOC) for therapeutic and non-therapeutic protein products for manufacture, storage and transfer of genetically engineered *Escherichia coli cells* (Insulin Aspart Mix 30) was recommended by the committee 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.

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

4.9 Application for No Objection Certificate (NOC) for therapeutic and non-therapeutic protein products for manufacture, storage and transfer of genetically engineered *Escherichia coli* cells (Insulin Glargine) by M/s. BioGenomics Limited, Maharashtra.

The proposal of M/s. BioGenomics Limited, Maharashtra for No Objection Certificate (NOC) therapeutic and non-therapeutic protein products for manufacture, storage and transfer of genetically engineered *Escherichia coli cells* (Insulin Glargine) was deliberated by the committee. The applicant has also obtained the clearance of RCGM.

Decision:

The application of M/s. BioGenomics Limited, Maharashtra for No Objection Certificate (NOC) for therapeutic and non-therapeutic protein products for manufacture, storage and transfer of genetically engineered *Escherichia coli cells* (Insulin Glargine) was recommended by the committee 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.

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

4.10 Application for No Objection Certificate (NOC) for therapeutic and non-therapeutic protein products for manufacture, storage and transfer of genetically engineered *Escherichia coli* cells (r-met G-CSF) by M/s. BioGenomics Limited, Maharashtra.

The proposal of M/s. BioGenomics Limited, Maharashtra for No Objection Certificate (NOC) therapeutic and non-therapeutic protein products for manufacture, storage and transfer of genetically engineered *Escherichia coli cells* (r-met G-CSF) was deliberated by the committee. The applicant has also obtained the clearance of RCGM.

Decision:

The application of M/s. BioGenomics Limited, Maharashtra for No Objection Certificate (NOC) for therapeutic and non-therapeutic protein products for manufacture, storage and transfer of genetically engineered *Escherichia coli cells* (r-met G-CSF) was recommended by the committee 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.

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 movement of transgenic cotton seeds within India by M/s BASF India Limited, New Delhi.

The proposal of M/s BASF India Limited, New Delhi for movement of transgenic cotton seeds within India was initially considered in 139th meeting of the GEAC held on 19.05.2020. However, it was learnt by GEAC secretariat that the transgenic cotton seeds were already transported from M/s Bayer Bioscience Pvt Ltd, Patancheru site to M/s Bayer Bioscience Pvt. Ltd Multi-crop testing facility at Chandippa Village, Shankarpally Mandal, Ranga Reddy District, Telangana and sought correction in the NOC letter of GEAC.

In this regard, GEAC has requested the RCGM to check the facts. Accordingly, the application was considered in the 193rd meeting of the RCGM held on 12.11.2020 and opined that the storage does not entail for R&D purposes contains large amount of transgenic seeds (i.e., 530 kg in total) and RCGM recommended the secretariat to refer the request to GEAC for consideration of storage of transgenic cotton seeds.

Decision:

Based on the recommendation of RCGM, the application of M/s BASF India Limited, New Delhi for movement of transgenic cotton seeds (i.e., 530 kg in total) from M/s Bayer BioScience Pvt Ltd, Chandippa Village, Shankarpally Mandal, Rangareddi District, Telangana to Gubba Cold Storage, Hyderabad has been recommended by the committee.

Action: GEAC Secretariat

5.2 Application for import and use of GMO *Clostridium autoethanogenum* strain for commercial ethanol production by DBT-IOC Centre for Advanced Bio-Energy Research, Indian Oil Corporation Limited, Faridabad.

The proposal of DBT-IOC Centre for Advanced Bio-Energy Research, Indian Oil Corporation Limited, Faridabad for import and use of GMO *Clostridium autoethanogenum* strain for commercial ethanol production was deliberated by the committee.

Decision:

The application of DBT-IOC Centre for Advanced Bio-Energy Research, Indian Oil Corporation Limited, Faridabad for import and use of GMO approximately 1.5 kg per year of *Clostridium autoethanogenum* strain S213755 from LanzaTech, USA for commercial ethanol production has been recommended by the committee. The committee also suggested the applicant to obtain separate approval from GEAC for large scale manufacturing in future.

Action: GEAC Secretariat

5.3 Application for No Objection Certificate (NOC) to import "Bursal Disease-Marek's Disease Vaccine, Serotype 3, Live Marek's Disease Vector (Brand Name: POULVAC PROCERTA HVT-IBD from USA for Veterinary use by M/s Zoetis India Limited, Mumbai.

The proposal of M/s. Zoetis India Limited, Mumbai for import of "Bursal Disease-Marek's Disease Vaccine, Serotype 3, Live Marek's Disease Vector (Brand Name: POULVAC PROCERTA HVT-IBD) from USA for Veterinary use was deliberated by the committee. The committee noted that the product was already approved in USA.

Decision:

The committee recommended the proposal of M/s. Zoetis India Limited, Mumbai for import of "Bursal Disease-Marek's Disease Vaccine, Serotype 3, Live Marek's Disease Vector (Brand Name: POULVAC PROCERTA HVT-IBD) from USA for Veterinary use subject to the following conditions:

i) *"initial 3 batches of the subject vaccine to be certified in ICAR-Indian Veterinary Research Institute (ICAR-IVRI)*

ii) obtain relevant approvals from Department of Animal Husbandry and Dairying, Drug Controller General of India etc. as per existing Indian laws applicable for import of vaccines.

iii) The final data certified by IVRI to be presented before the GEAC for final approval, before it is marketed in the country.

Action: GEAC Secretariat

5.4 Application for No Objection Certificate (NOC) for a veterinary vaccine derived from Living Modified Organism (Ranikhet Disease Vaccine Live (Lentogenic Strain), IP, KBNP –C4152R2L Strain) by M/s Virbac Animal Health India Pvt. Ltd., Mumbai.

The proposal of M/s Virbac Animal Health India Pvt. Ltd., Mumbai for No Objection Certificate (NOC) for a veterinary vaccine derived from Living Modified Organism (Ranikhet Disease Vaccine Live (Lentogenic Strain), IP, KBNP –C4152R2L Strain) was deliberated by the committee. The committee noted that the product was already approved in Korea.

Decision:

The committee has recommended the proposal of M/s Virbac Animal Health India Pvt. Ltd., Mumbai for import of veterinary vaccine derived from Living Modified Organism (Ranikhet Disease Vaccine Live (Lentogenic Strain), IP, KBNP –C4152R2L Strain) subject to the following conditions:

i. *"initial 3 batches of the subject vaccine to be certified in ICAR-Indian Veterinary Research Institute (ICAR-IVRI)*
ii. obtain relevant approvals from Department of Animal Husbandry and Dairying, Drug Controller General of India etc. as per existing Indian laws applicable for import of vaccines.
iii. The final data certified by IVRI to be presented before the GEAC for final approval, before it is marketed in the country.

Action: GEAC Secretariat

5.5 Submission of IVRI report for the products (Recombitek C3, Recombitek C4, Recombitek C6 & Recombitek C6/CV vaccines) by M/s Boehringer Ingelheim India Private Ltd., Mumbai.

The proposal of M/s Boehringer Ingelheim India Private Ltd., Mumbai for importing Recombitek C3, Recombitek C4, Recombitek C6, Recombitek C6/CV, Vaxxitek HVT IBD and Prevexxion RN was initially considered in the 140th meeting of the GEAC and the committee has directed the firm to get "initial 3 batches of the subject vaccine to be certified in IVRI before it is marketed in the country" and the final data certified by IVRI to be presented before the GEAC for final approval, before it is marketed in the country.

Accordingly, M/s Boehringer Ingelheim India Private Ltd., Mumbai has submitted the test reports of 3 batches issued by IVRI for the products namely, Recombitek C4, Recombitek C6 and Recombitek C6/CV while submitted only one batch for Recombitek C3. The applicant stated that the composition of Recombitek C3 is also present in the Recombitk C4, C6 and C6CV, where IVRI has already provided test reports.

Decision:

After considering the IVRI report by the committee, the application of M/s Boehringer Ingelheim India Private Ltd., Mumbai for import of products (Recombitek C3, Recombitek C4, Recombitek C6 & Recombitek C6/CV vaccines) was recommended by the committee for marketing in the country.

Action: GEAC Secretariat

5.6 Submission of IVRI report for Bursal diseases- Marek's disease vaccine, Serotype 3 Live Marek's Disease vector (Vaxxitek HVT+IBD) vaccine by M/s Boehringer Ingelheim India Private Ltd., Mumbai.

The proposal of M/s Boehringer Ingelheim India Private Ltd., Mumbai for importing Bursal diseases- Marek's disease vaccine, Serotype 3 Live Marek's Disease vector (Vaxxitek HVT+IBD) vaccine was initially considered in the 140th meeting of the GEAC and the committee has directed the firm to get "initial 3 batches of the subject vaccine to be certified in IVRI before it is marketed in the country" and the final data certified by IVRI to be presented before the GEAC for final approval, before it is marketed in the country.

In this regard, M/s Boehringer Ingelheim India Private Ltd., Mumbai has submitted the test reports of 3 batches issued by IVRI for Bursal diseases- Marek's disease vaccine, Serotype 3 Live Marek's Disease vector (Vaxxitek HVT+IBD) vaccine. As per IVRI report the HVT titre and safety, sterility tests are in order (IP 2018, 9CFR) and regarding the effectiveness of the vaccine against IBD, these batches are being certified based on protection of birds against IBD challenge after vaccination with Master-Seeds lot.

Decision:

After considering the IVRI report by the committee, the application of M/s Boehringer Ingelheim India Private Ltd., Mumbai for import of Bursal diseases-Marek's disease vaccine, Serotype 3 Live Marek's Disease vector (Vaxxitek HVT+IBD) vaccine was recommended by the committee for marketing in the country.

Action: GEAC Secretariat

5.7 Submission of IVRI report of three batches samples of "Cell Associated Live recombinant Herpes Virus of Turkey (strain HPV360) Innovax ND-IBD" by M/s Intervet India Pvt. Ltd., Pune.

The proposal of M/s Intervet India Pvt. Ltd., Pune for importing the cell Associated Live Recombinant Herpes Virus of Turkey Strain HPV360 (Innovax ND IBD) was initially considered in the 140th meeting of the GEAC and the committee has directed the firm to get "initial 3 batches of the subject vaccine to be certified in IVRI before it is marketed in the country" and the final data certified by IVRI to be presented before the GEAC for final approval, before it is marketed in the country.

Accordingly, M/s Intervet India Pvt. Ltd., Pune has submitted final data of IVRI Certification of 3 batches of Cell Associated Live recombinant Herpes Virus of Turkey strain HPV360 (Innovax ND-IBD) for consideration of GEAC.

Decision:

After considering the IVRI report, the application of M/s Intervet India Pvt. Ltd., Pune for import of Cell Associated Live recombinant Herpes Virus of Turkey (strain HPV360) Innovax ND-IBD was recommended by the committee for import and marketing in the country.

Action: GEAC Secretariat

Agenda Item No. 6: Additional Items for consideration/ information

6.1 Application for extension of permission to store the TC1507 transgenic maize seeds as per inventory for one more year till November 2021 by M/s Dow AgroSciences India Private Limited (DAS), Hyderabad.

The proposal of M/s Dow AgroSciences India Private Limited (DAS), Hyderabad for for extension of permission to store the TC1507 transgenic maize seeds as per inventory for one more year till November 2021 was deliberated by the committee.

It was also observed that the RCGM in its 194th meeting held on 26.11.2020 has considered the request of M/s Dow AgroSciences India Private Limited (DAS), Hyderabad and recommended for storage of seed material for one more year till November, 2021. Further, RCGM recommended that the secretariat to refer the request to GEAC for consideration of storage of GE maize seeds in the proposed facility.

Decision:

Based on the recommendation of RCGM, the committee has recommended the extension of permission to store the TC1507 transgenic maize seeds as per inventory for one more year till November 2021 by the firm M/s Dow AgroSciences India Private Limited (DAS), Hyderabad.

Action: GEAC Secretariat

6.2 Application for extension of permission to store the TC1507×MON810 and MON810 transgenic maize seeds as per inventory for one more year till November 2021 by M/s Pioneer Hi-Bred Private Limited, Telangana.

The proposal of by M/s Pioneer Hi-Bred Private Limited, Telangana for extension of permission to store the TC1507×MON810 and MON810 transgenic maize seeds as per inventory for one more year till November 2021 was deliberated by the committee.

The committee has also observed that RCGM in its 194th meeting held on 26.11.2020 has considered the request and recommended for the storage to the seed material for one more year till November, 2021. Further, RCGM recommended that the secretariat to refer the request to GEAC for consideration of storage of GE maize seeds in the proposed facility.

Decision:

Based on the recommendation of RCGM, the committee recommended the extension of permission to store the TC1507×MON810 and MON810 transgenic maize seeds as per inventory for one more year till November 2021 by the firm M/s Pioneer Hi-Bred Private Limited, Telangana.

Action: GEAC Secretariat

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

Annexure

List of Participants

Official Members who participated			
1.	**Mrs. B. V. Umadevi** Chairperson, GEAC & Additional Secretary, Ministry of Environme nt, Forest & Climate Change, Jor Bagh, Aliganj, New Delhi.	**3.**	**Shri Tarun Kathula** Scientist-F, and Member Secret ary (GEAC), Ministry of Environ ment, Forests & Climate Chang e, JorBagh, Aliganj, New Delhi.
2.	**Dr. K. Veluthambi** Co-Chairman, GEAC and Professor (retd) & Head, School of Biotechnology, Madurai Kamaraj University, Mad urai	**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.	**9.**	**Dr. Dinesh K Agarwal,** Principal Scientist, In charge, Plant Breeding & Genetics, IC AR-Indian Institute of Seed Science Mau, U. P
2.	**Dr. Ashok Bhatnagar,** Former Professor, Depa rtment of Botany, University of Delhi, New Delhi	**10.**	**Dr. Yashpal Yadav** Central Pollution Control Board Parviesh Bhawan, CBD cum offi ce complex, East Arjun Nagar, New Delhi- 110032
3.	**Dr. B. Venkateswarlu** Former Vice-Chancellor Vasantrao Naik Marathwada Krishi Vidyapeeth, Parbani (Maharashtra).	**11.**	**Dr. S. K. Barik** Director CSIR- National Botanical Rese arch Institute, Lucknow
4.	**Dr. S. J. Rahman,** Principal Scientist & Univ. Head of Entomology, AICRP on Biological Co ntrol Agricultural Research Institut e (ARI), Prof. Jayashankar Telangan a State Agri. University, Rajendranagar, Hyderab ad.	**12.**	**Dr. S De** Principal Scientist Animal Biotechnology Centre, National Dairy Research Ins titute, Karnal.
5.	**Dr. Madhu Dikshit** Former Director CSIR-Central Drug Research Institu te, Lucknow.	**13.**	**Dr. Geeta Jotwani** Scientist F Indian Council of Medical Research, New Delhi.
6.	**Mr. Jayant Gangakhedkar** Assistant Drugs Controller (I) Central Drugs Standard Control Or ganizations, FDA Bhawan Kotla Road, New Delhi-110002.	**14.**	**Dr. P. Suprasanna** Scientific Officer H (level 14) Bi osciences Group, BARC, Mumb ai.

7.	**Shri Sunil Bakshi** Food Safety and Standards Authority of India (FSSAI), FDA Bhawan, Kotla Road, New Delhi	**15.**	**Dr. Lalitha Gowda,** Former Chief Scientist, CSIR-CFTRI Mysore, Karnataka-570 020, India
8.	**Dr. Sushil Gupta,** Former Chairman, Central Ground Water Board, New Delhi		
Member who did not participate			
1.	**Prof. P. Balasubramanian** Former Director, Centre for Plant Molecular Biology, TNAU, Coimbatore	**3.**	**Dr. N. Sathyanarayana** Joint Director Plant Protection Quarantine & storage, NH-IV, Faridabad, Haryana.
2.	**Dr. A.K. Singh** Head, Division of Genetics, IARI, New Delhi.	**4.**	**Dr. Usha Rao** Assistant Controller of Patents & Designs, Patent Office, New Delhi, India