MINUTES OF THE 145th MEETING OF THE GENETIC ENGINEERING APPRAISAL COMMITTEE HELD ON 27.07.2022

The 145th meeting of the Genetic Engineering Appraisal Committee (GEAC) was held on 27.07.2022 in hybrid mode at Teesta Conference Hall, First Floor, Vayu Block, Ministry of Environment, Forest and Climate Change (MoEF&CC), Indira Paryavaran Bhawan, New Delhi. The meeting was chaired by Shri Naresh Pal Gangwar, Additional Secretary, MoEF&CC. The list of participants is placed at **Annexure I.**

At the outset, Shri Naresh Pal Gangwar, Chairperson, GEAC welcomed all the members and requested the Member Secretary to start the discussion on agenda items.

Member Secretary, Dr. Satyendra Kumar made a brief introduction about committee. He informed that the GEAC, has been reconstituted in accordance with Rule (4), sub section (i) to (iv) of the notification No. GSR 1037 (E) dated 5th December, 1989 of the 'Rules for the Manufacture, Use/ Import /Export and Storage of Hazardous Microorganisms/Genetically Engineering organisms or Cells, 1989' (known as Rules, 1989), notified under the Environment (Protection) Act, 1986. GEAC is mainly responsible for appraisal of activities involving large scale use of hazardous microorganisms and recombinants in research and industrial production from the environmental angle. The committee is also responsible for appraisal of proposals relating to release of genetically engineered (GE) organisms and products into the enviornment including experimental field trials.

Agenda Item No. 1: Leave of absence

Two members did not participate in the 145th meeting of GEAC, namely Dr. Dinkar M. Salunkhe and Ms. Shruti Singh.

Decision:

Absence of members who could not attend the meeting was noted.

Action: GEAC Secretariat

Agenda Item No. 2: Confirmation of minutes of the 144th GEAC meeting

Minutes of the 144th 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 144th GEAC meeting.

Action: GEAC Secretariat

Agenda Item No. 3: Action taken report on the decision taken in the 144th GEAC meeting

Member Secretary, GEAC briefed about the action taken on the decisions of the 144th 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 Confined Field Trials of GE crops (Event Selection/ BRL-I/ BRL-II Trials)

4.1 M/s Rallis India Limited, Karnataka submitted to conduct BRL-I trials (1st Year and 2nd Year) with two GE cotton breeding stacks (MLS2154 x MLS4301x MLS2531 and MLS2154 x MLS4301).

The applicant made a presentation on the proposal and informed the committee that BRL-1 trials (1st Year and 2nd Year) are to be conducted with two GE cotton breeding stacks (MLS2154 x MLS4301x MLS2531 and MLS2154 x MLS4301) expressing *cry1Ac, cry1F* and synthetic *epsps* genes to evaluate resistance against *Helicoverpa armigera* and *Spodoptera litura* and tolerance to herbicide glyphosate during 2022-23 and 2023-24 at two trial locations per year.

This application was considered by the Review Committee on Genetic Manipulation (RCGM) in its 204th meeting held on 15.04.2021. RCGM, vide its Letter No. BT/IBKP/223/2020 dated 03.05.2021, further recommended this application to GEAC.

It was informed that the applicant has obtained 'No Objection Certificate (NOC)' for conducting BRL-1 trials from the Government(s) of Haryana and Karnataka; and accordingly has proposed to conduct BRL-1 trials (1st and 2nd year) at University of Agricultural Sciences, Dharwad, Karnataka; University of Agricultural Sciences, Raichur, Karnataka; and Chaudhary Charan Singh Haryana Agricultural University, Hisar, Haryana.

The concentration of Glyphosate (41% SL, IPA) to be used to evaluate tolerance to herbicide glyphosate in the BRL-1 trials shall be 0.7% (1300g a.e./ha).

The committee deliberated that the trial locations should be the hotspot regions in order to study the effect on target and non-target organisms.

Decision:

The proposal of M/s Rallis India Limited, Karnataka seeking permission to conduct BRL-1 trials (1st Year and 2nd Year) with two GE cotton breeding stacks (MLS2154 x MLS4301x MLS2531 and MLS2154 x MLS4301) expressing *cry1Ac, cry1F* and synthetic *epsps* genes to evaluate resistance against *Helicoverpa armigera* and *Spodoptera litura* and tolerance to herbicide glyphosate during 2022-23 and 2023-24 at two locations amongst the proposed sites, namely, University of Agricultural Sciences, Dharwad, Karnataka; University of Agricultural Sciences, Raichur, Karnataka; and Chaudhary Charan Singh Haryana Agricultural University, Hisar, Haryana per year was recommended by the committee subject to the following conditions:

i. The applicant shall adhere with the conditions and recommendations as per RCGM Letter No. BT/IBKP/223/2020 dated 03.05.2021, and conduct additional studies on micro-organisms as per existing protocols.
ii. The use of only up to 0.7% (1300g a.e./ha) of Glyphosate (41% SL, IPA; Brand:Glycel) is permitted. The applicant shall intimate the Central Insecticide Board and Registration Committee (CIB&RC)- Directorate of Plant Protection, Quarantine & Storage about use of Glyphosate.

iii. The BRL-1 confined field trials should be conducted at the hotspot locations in the State.
iv. The applicant shall share details of the trial site as required under part G of the Guidelines and SOPs for Confined Field Trials of regulated GE plants, 2008 including ownership of trial site, before start of the trial.
v. The applicant shall share information regarding confirmed availability of isolation distance, land use and its ownership, before start of the trial.
vi. The applicant shall share information regarding name of the lead scientist responsible for each trial, as well as expected date of sowing, before start of the trial.
vii. The results of the field trials will also be shared with State Biodiversity Board and local panchayat Biodiversity Management Committees.

The Review Committee on Genetic Manipulation may issue the permit letters and monitor confined field trials to ensure compliance of prescribed terms and conditions.

Action: RCGM & GEAC Secretariat

4.2 M/s Rallis India Limited, Karnataka submitted to conduct BRL-I trials (1st Year and 2nd Year) with GE maize breeding stack (MLS10101 x MLS13621).

The applicant made a presentation on the proposal and informed the committee that BRL-1 trials (1st Year and 2nd Year) are to be conducted with GE maize breeding stack (MLS10101 x MLS13621) expressing *cry1Ab, cry1F* and synthetic *epsps* genes to evaluate resistance against *Spodoptera frugiperda* and tolerance to herbicide glyphosate during 2022-23 and 2023-24 at two (hot spot) trial locations per year.

This application was considered by the Review Committee on Genetic Manipulation (RCGM) in its 204th meeting held on 15.04.2021. RCGM, vide its Letter No. BT/IBKP/223/2020 dated 03.05.2021, further recommended this application to GEAC.

The applicant has obtained 'No Objection Certificate (NOC)' for conducting BRL-1 trials from the Government(s) of Haryana and Karnataka; and accordingly has proposed to conduct BRL-1 trials (1st and 2nd year) at University of Agricultural Sciences, Dharwad, Karnataka; University of Agricultural Sciences, Raichur, Karnataka; and Chaudhary Charan Singh Haryana Agricultural University, Hisar, Haryana.

The concentration of Glyphosate (41% SL, IPA) to be used to evaluate tolerance to herbicide glyphosate in the BRL-1 trials shall be 0.7% (1300g a.e./ha).

Members of GEAC examined and discussed the proposal from the perspective of environmental safety, impact on biodiversity and measures for ensuring biosafety during trials. The committee deliberated that the trial locations should be the hotspot regions in order to study the effect on target and non-target organisms.

Decision:

The proposal of M/s Rallis India Limited, Karnataka seeking permission to conduct BRL-1 trials (1st Year and 2nd Year) with GE maize breeding stack (MLS10101 x MLS13621) expressing *cry1Ab, cry1F* and synthetic *epsps* genes to evaluate resistance against *Spodoptera frugiperda* and tolerance to herbicide glyphosate

during 2022-23 and 2023-24 at two (hot spot) trial locations amongst the proposed sites, namely, University of Agricultural Sciences, Dharwad, Karnataka; University of Agricultural Sciences, Raichur, Karnataka; and Chaudhary Charan Singh Haryana Agricultural University, Hisar, Haryana per year was recommended by the committee subject to the following conditions:

i. The applicant shall adhere with the conditions and recommendations as per RCGM Letter No. BT/IBKP/223/2020 dated 03.05.2021, and conduct additional studies on micro-organisms as per existing protocols.
ii. The use of only up to 0.7% (1300g a.e./ha) of Glyphosate (41% SL, IPA; Brand:Glycel) is permitted. The applicant shall intimate to the Central Insecticide Board and Registration Committee (CIB&RC)- Directorate of Plant Protection, Quarantine & Storage about use of Glyphosate.
iii. The BRL-1 confined field trials should be conducted at the hotspot locations in the State.
iv. The applicant shall share details of the trial site as required under part G of the Guidelines and SOPs for Confined Field Trials of regulated GE plants, 2008 including ownership of trial site, before start of the trial.
v. The applicant shall share information regarding confirmed availability of isolation distance, land use and its ownership, before start of the trial.
vi. The applicant shall share information regarding name of the lead scientist responsible for each trial, as well as expected date of sowing, before start of the trial.
vii. The results of the field trials will also be shared with State Biodiversity Board and local panchayat Biodiversity Management Committees.

The Review Committee on Genetic Manipulation (RCGM) may issue the permit letters and monitor confined field trials to ensure compliance of prescribed terms and conditions.

Action: RCGM & GEAC Secretariat

Agenda Item No. 5: Applications related to Commercial/ Environmental release

5.1 M/s Mahyco Private Ltd., Mumbai submitted for environmental release of Bollgard II Roundup Ready Flex (BGII™ RRF™) cotton incorporating events MON 15985 x MON 88913.

The applicant made a presentation on the proposal and informed the committee that the BGII™ RRF™ cotton is a genetically modified cotton incorporating gene events MON 15985 X MON 88913. The individual event MON 15985, approved for commercial cultivation in India, helps manage bollworms. The BGII™ RRF™ cotton offers additional resistance to insects and tolerance to Glyphosate.

The BRL-1 and BRL-2 trials for BGII™ RRF™ cotton were conducted in 2008 and 2009, respectively. The BRL-2 trials were conducted in 2012 at total three locations in North and South zones of India. As per the field trial and socio-economic study findings, submitted as a part of the dossier, BGIITM RRFTM cotton can help in effective, efficient and convenient weed management.

The applicant also informed the committee that they requested temporary withdrawal of the dossier for environmental release of BGII™ RRF™ cotton in 2016. Accordingly, GEAC secretariat returned the dossier on the request of the applicant that time. The dossier is resubmitted for submitted for consideration again.

Decision:

The committee deliberated on the proposal for environmental release of BGII™ RRF™ cotton incorporating gene events MON 15985 X MON 88913 and decided to constitute an Expert-Committee under the Chairmanship of Dr. Sanjay Kumar Mishra, Co-Chair, GEAC for detailed review of the dossier submitted by M/s Mahyco Private Ltd., Mumbai. The composition of the said Sub-Committee is as below:

i.	**Dr. Sanjay Kumar Mishra** Scientist H, Department of Biotechnology, New Delhi	Chairman
ii.	**Dr. Ashok Kumar Singh** Director, Indian Agricultural Research Institute, New Delhi	Member
iii.	**Dr. D. K. Yadav** ADG (Seeds), Crop Science Division, ICAR, New Delhi	Member
iv.	**Dr. A. H. Prakash** Project Coordinator (Cotton Improvement) and Head, AICRP on Cotton, ICAR-Central Institute for Cotton Research, Coimbatore	Member
v.	**Dr K. Annapurna** Former Head, Division of Microbiology ICAR-Indian Agricultural Research Institute, New Delhi	Member
vi.	**Dr. Nitin K. Jain** Scientist F, Department of Biotechnology, New Delhi	Member
vii.	**Dr. Abhilasha Singh Mathuriya** Scientist D, Ministry of Environment, Forests and Climate Change, New Delhi	Member Secretary

Action: GEAC Secretariat

5.2 M/s Embio Limited, Mumbai submitted for scale-up and commercial production of L-norephedrine using *E. coli* RB791(K12 derivate).

The applicant made a presentation on the proposal and informed to the committee that L-norephedrine is intended to be used as chiral resolution agent in production of HIV antiviral compound, Efavirenz.

The fermentation system using *E. coli* RB791(K12 derivate) will be employed for production of L-norephedrine. The transaminase gene from *Rhodobacter sphaeroides* is inserted into the host cell line of E. coli RB791 (K12 derivative) which is a Risk

Group-1 category organism. The production process involves whole cell biotransformation of R-Phenylacetylcarbinol (R-PAC) to L-norephedrine by omega transaminase enzyme. The R-Phenylacetylcarbinol (R-PAC), a key intermediate of production process, is produced in-house by biotransformation of Benzaldehyde using yeast (Pyruvate decarboxylase).
The applicant intends to manufacture 50 Tonnes of l-norephedrine per annum.

Decision:

The proposal of M/s Embio Limited, Mumbai seeking permission for scale-up and commercial production of L-norephedrine using *E. coli* RB791(K12 derivate) was recommended by the committee subject to the following conditions:

a. The project should be implemented under the oversight of IBSC of the applicant with regular annual reports to RCGM.
b. The applicant will submit Environmental Risk Management and Safety Plan (ERMP) within 3 months, after approval to this Ministry;
c. The applicant will submit compliance report on ERMP plan every 6 months to the concerned Regional Office of this Ministry;
d. It is obligated to ensure environmentally sound and safe management of any residue/discharge of the production process as per existing laws, rules, regulations applicable.
e. The records of generation, treatment, recycle/reuse and disposal of related to production process shall be maintained and submitted to concerned SPCB at regular intervals of twice in a year, on 15th October (for April-September) and 15th April for October to March).
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. The clearance granted to the project/activity is strictly under the provisions of the EIA Notification 2006 and its subsequent amendments. It does not tantamount/construe to approvals/consent/permissions etc. required to be obtained or standards/conditions to be followed under any other Acts/ Rules/ Subordinate legislations, etc., as may be applicable to the project. The applicant shall obtain necessary permission as mandated under the Water (Prevention and Control of Pollution) Act, 1974 and the Air (Prevention and Control of Pollution) Act, 1981, as applicable from time to time, from the State Pollution Control Board, prior to construction & operation of the project.
j. The approval is subject to other statutory clearances.

The RCGM to examine and submit a Risk Assessment and Risk Management Plan to GEAC, which would be shared with applicant for compliance.

Action: RCGM & GEAC Secretariat

5.3 M/s Embio Limited, Mumbai submitted for scale-up and commercial production of Pyruvic acid from *E. coli*.

The applicant made a presentation on the proposal and informed to the committee that pyruvic acid is intended to be used for in-house consumption for Levodopa (L-DOPA) production. The applicant has obtained permission from RCGM for commercial production of Levodopa (using *E. coli* grown upto a scale of 20 KL) in licensed from IIT Bombay and optimized as a part of SBIRI program.

The fermentation system using *E. coli* MEC992 will be employed for production of pyruvic acid. The *E.coli* MEC992 is derived from *Escherichia coli* C (ATCC 8739), a Risk Group-1 category organism, with deletions of the aceE, ldhA, poxB and ppsA genes.
The applicant intends to manufacture 50 Tonnes of pyruvic acid per annum.

Decision:

The proposal of M/s Embio Limited, Mumbai seeking permission for scale-up and commercial production of pyruvic acid using *E. coli* MEC992 was recommended by the committee subject to the following conditions:

a. The project should be implemented under the oversight of IBSC of the applicant with regular annual reports to RCGM.
b. The applicant will submit Environmental Risk Management and Safety Plan (ERMP) within 3 months, after approval to this Ministry;
c. The applicant will submit compliance report on ERMP plan every 6 months to the concerned Regional Office of this Ministry;
d. It is obligated to ensure environmentally sound and safe management of any residue/discharge of the production process as per existing laws, rules, regulations applicable.
e. The records of generation, treatment, recycle/reuse and disposal of related to production process shall be maintained and submitted to concerned SPCB at regular intervals of twice in a year, on 15th October (for April-September) and 15th April for October to March).
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. The clearance granted to the project/activity is strictly under the provisions of the EIA Notification 2006 and its subsequent amendments. It does not tantamount/construe to approvals/consent/permissions etc. required to be obtained or standards/conditions to be followed under any other Acts/ Rules/ Subordinate legislations, etc., as may be applicable to the project. The applicant shall obtain necessary permission as mandated under the Water (Prevention and Control of Pollution) Act, 1974 and the Air (Prevention and Control of Pollution) Act, 1981, as applicable from time to time, from the State Pollution Control Board, prior to construction & operation of the project.
j. The approval is subject to other statutory clearances.

The RCGM to examine and submit a Risk Assessment and Risk Management Plan to GEAC, which would be shared with applicant for compliance.

Action: RCGM & GEAC Secretariat

Agenda Item No. 6: Applications related to Import/ Export

6.1 M/s Ceva Polchem Private Limited, Pune submitted for import and distribution of VECTORMUNE ND recombinant veterinary vaccine.

The proposal for import and distribution of Recombinant HVT virus with inserted F gene of NDV, Live Frozen vaccine (VECTORMUNE ND) was considered by the committee.

The recombinant virus of VECTORMUNE ND is developed by inserting the Fusion (F) gene of Newcastle disease virus (NDV) lentogenic strain into the Herpesvirus of Turkeys (HVT) genome. VECTORMUNE ND is recommended for use in ovo on the 18th day of embryonation or SC in day-old chicks as an aid in the prevention of Newcastle disease caused by Newcastle disease virus and Marek's disease caused by virulent pathotype of Marek's disease virus.

The vaccine under application contains adapted strain from already permitted vaccine Vectormune HVT ND: Marek's Disease-Newcastle Disease Vaccine, Serotype 3, Live Marek's Disease Vector manufactured by Ceva Animal Health LLC, (M/S Biomune Co) Lenexa US.
The applicant intends to import 200 million doses of vaccine per year.

Decision:

The committee recommended the proposal of M/s Ceva Polchem Private Limited, Pune for import of Recombinant HVT virus with inserted F gene of NDV, Live Frozen vaccine (VECTORMUNE ND) 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 laws, rules, regulations 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

6.2 M/s Boehringer Ingelheim India Private Ltd., Mumbai submitted for Vaxxitek HVT+IBD+ILT recombinant veterinary vaccine.

The proposal for import of Bursal Disease-Infectious Laryngotracheitis-Marek's Disease Vaccine, Serotype 3, Live Marek's Disease Vector (Vaxxitek HVT+IBD+ILT) veterinary vaccine was considered by the committee.

The Vaxxitek HVT+IBD+ILT vaccine is a live serotype 3 Marek's Disease Viral vector (labelled as vHVT317), which expresses Infectious Bursal Disease Virus viral protein

2 (VP2), and Laryngotracheitis Disease Virus ILTV-gD (glycoprotein D). This product has been shown to be effective for the vaccination of healthy 18 to 19-day-old chicken embryos and one-day-old chickens against Standard and Variant Bursal Disease, Fowl Laryngotracheitis and Marek's Disease. The VAXXITEK® HVT + IBD product therefore offers effective protection against three serious threats in a single vaccine.

The applicant intends to import 10000 vials per year from M/s Boehringer Ingelheim Animal Health USA Inc., 1168 Airport Parkway, SW, Gainesville, Georgia 30501 USA.

Decision:

The committee recommended the proposal of M/s Boehringer Ingelheim India Private Ltd., Mumbai for import of Bursal Disease-Infectious Laryngotracheitis-Marek's Disease Vaccine, Serotype 3, Live Marek's Disease Vector (Vaxxitek HVT+IBD+ILT) veterinary vaccine 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 laws, rules, regulations 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

6.3 M/s Boehringer Ingelheim India Private Ltd., Mumbai submitted for import of NEWXXITEK HVT + ND recombinant veterinary vaccine.

The proposal for import of Marek's Disease-Newcastle Disease Vaccine, Serotype 3, Live Marek's Disease Vector (NEWXXITEK HVT + ND) veterinary vaccine was considered by the committee.

NEWXXITEK HVT+ND is a vaccine that contains a Turkey Herpesvirus (HVT) Serotype 3 Marek's disease vector expressing a Newcastle Disease Virus Fusion gene. This vaccine is presented in frozen form in one ampule containing a suspension of chicken embryo cells infected with Turkey Herpesvirus (HVT) vectored Newcastle disease recombinant virus (vHVT19-NDV). The vaccine is recommended for in ovo vaccination of healthy 18 to 19-day-old embryos and subcutaneous vaccination of one-day-old chickens, against Marek's disease and Newcastle disease.

The applicant intends to import 10000 vials per year from M/s Boehringer Ingelheim Animal Health USA Inc., 1168 Airport Parkway, SW, Gainesville, Georgia 30501 USA.

Decision:

The committee recommended the proposal of M/s Boehringer Ingelheim India Private Ltd., Mumbai for import of Marek's Disease-Newcastle Disease Vaccine, Serotype 3, Live Marek's Disease Vector (NEWXXITEK HVT + ND) veterinary vaccine 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 laws, rules, regulations 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

6.4 M/s Zoetis India Limited, Mumbai submitted for import and market of Bedinvetmab Solution (Brand Name: Librela).

The proposal for import of Bedinvetmab Solution for Injection 5mg/ml, 10mg/ml, 20mg/ml and 30mg/ml (Brand Name: Librela) for veterinary use was considered by the committee.

Bedinvetmab is a canine monoclonal antibody (mAb) specifically targeting nerve growth factor (NGF). It is indicated to be used for the treatment of pain associated with osteoarthritis in dogs. The product is proposed to be administered monthly, at a minimum dose of 0.5 mg/kg body weight subcutaneously. There is no proposed limit of the duration of treatment. Vial presentations at various concentrations (5, 10, 20, and 30 mg/ml) will be delivered at a fixed 1 ml injection volume. The dosage form is a ready to use single dose injectable solution, which is a commonly used dosage form for monoclonal antibody medicines for human. The applicant intends to import the product from M/s Zoetis, Belgium.

Decision:

The committee recommended the proposal of M/s Zoetis India Limited, Mumbai for import of Bedinvetmab Solution for Injection 5mg/ml, 10mg/ml, 20mg/ml and 30mg/ml (Brand Name: Librela) for veterinary use subject to the following conditions:

i. Applicant needs to inform the quantity of import per annum 30 days before import to the GEAC.
ii. the Initial 3 batches of the subject vaccine to be certified in ICAR-Indian Veterinary Research Institute (ICAR-IVRI).
iii. Obtain relevant approvals from Department of Animal Husbandry and Dairying, Drug Controller General of India etc. as per existing laws, rules, regulations applicable for import of vaccines.
iv. 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

6.5 M/s Intervet India Pvt. Ltd., Pune submitted for import and marketing of Nobivac Puppy DP Plus recombinant veterinary vaccine.

The proposal for import and marketing of Combined Canine Distemper and Canine Parvovirus Vaccine, Live, Freeze dried (Nobivac Puppy DP Plus) including Solvent was considered by the committee.

Nobivac Puppy DP PLUS is a lyophilised live vaccine containing canine distemper virus (CDV) strain Onderstepoort and canine parvovirus (CPV) strain 630a. The canine parvovirus strain 630a (CPV component) in the vaccine is a recombinant vaccine virus that was derived from the backbone of the existing canine parvo vaccine virus strain 154 and the attenuated capsid of a currently circulating type 2c isolate. The product is intended to be used for the active immunisation of puppies from 4 weeks of age onwards to prevent clinical signs and mortality of canine distemper and parvovirus infection and to prevent viral excretion following canine distemper and parvovirus infection.

The applicant intends to import 2600 vials of 1 dose per annum from M/s Intervet International B.V. Boxmeer, The Netherlands.

Decision:

The committee recommended the proposal of M/s Intervet India Pvt. Ltd., Pune for import of Combined Canine Distemper and Canine Parvovirus Vaccine, Live, Freeze dried (Nobivac Puppy DP Plus) including Solvent 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 laws, rules, regulations 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

6.6 M/s Royal Swine Genetics, Tamil Nadu submitted for import of PIGIPRO P3 S Piglet milk replacer and creed feed.

The proposal for import of PIGIPRO P3 S Piglet milk replacer and creed feed for the purpose of piglet feed was deliberated by the committee.

PIGIPRO P3 S as a Creep Feed for Piglets is fed from Day 17 to 49 (early weaning), before weaning and after weaning. It's a creamy powder/pellet animal feed product which is mixed with water for feeding purpose.

The applicant was granted permit for import from the Department of Animal Husbandry and Dairying (DAHD), vide Permit No: 14261/2021/DADF dated 22.11.2021, which was valid upto 21.05.2022. The Animal Quarantine and Certification Services (AQCS)-DAHD, vide Letter No. 14-42/2022/AQCS(SR)/410 dated 29.04.2022, informed the applicant that imported consignment of PIGIPRO P3 S contains genetically modified ingredients and directed them to obtain GEAC approval, as per the DGFT import policy.

Decision:

Taking cognizance of the supreme court judgement for W.P. (C) No. 173/2006 dated 11.08.2017, any activity in connection with genetically engineered and modified food are permissible only under the regulations framed under Section 22 of the Food Safety and Standard Act, 2006. Since the product (PIGIPRO P3 S) is to be used as animal food, the committee recommended to forward the application to Food Safety and Standards Authority of India (FSSAI) for necessary action.

Action: GEAC Secretariat

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

Annexure I

List of Participants

Members who participated			
1.	**Shri Naresh Pal Gangwar** Additional Secretary, Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhawan, Jorbagh road, Aliganj, New Delhi- 110003	**11.**	**Dr. Satish Wate** Former Director CSIR-National Environmental Engineering Research Institute Nagpur- 440020
2.	**Dr. Sanjay Kumar Mishra** Scientist H, Department of Biotechnology, Block 2 CGO Complex, Lodhi Road New Delhi - 110 003	**12.**	**Dr. P.K. Dass** Department of Anatomy LHMC & Associated hospitals New Delhi- 110 001
3.	**Ms. Rita Khanna** Advisor, MoEFCC Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhawan, Jorbagh road, Aliganj, New Delhi- 110003	**13.**	**Dr. Chaitanya Joshi** Director, Gujarat Biotechnology Research Centre, Gandhinagar, Gujarat- 382 011
4.	**Dr. Satyendra Kumar** Director, CS-III Division Ministry of Environment, Forest and Climate Change, Jorbagh, New Delhi-110003	**14.**	**Dr. Rekha S. Singhal** Professor, Food Technology, Institute of Chemical Technology, Mumbai- 400 019
5.	**Dr. Nitin K. Jain** Scientist–F and Member Secretary RCGM Department of Biotechnology, C. G. O, Complex, Lodhi Road, New Delhi-110003	**15.**	**Dr. D.K. Yadav** ADG (Seed), Crop Science Division Indian Council of Agricultural Research, Krishi Bhawan, New Delhi-110001
6.	**Dr. S. J. Rahman,** Principal Scientist & Univ. Head of Entomology, AICRP on Biological Control Agricultural Research Institute (ARI), Prof. Jayashankar Telangana State Agri. University, Hyderabad-500 030	**16.**	**Dr. Geeta Jotwani** Scientist G Indian Council of Medical Research (ICMR) Ministry of Health and Family Welfare Ramalingaswami Bhavan, Ansari Nagar, New Delhi—110029
7.	**Dr. H. K. Sharma** Director, National Institute of Technology, Agartala, Tripura- 799 046	**17.**	**Dr. P. Suprasanna** Scientific Officer H (Retd.) Biosciences group BARC, Mumbai-400085
8.	**Dr. Vinay K. Nandicoori** Director, CSIR-Centre for Cellular & Molecular Biology, Hyderabad - 500 007	**18.**	**Dr. Sanjeev Khosla** Director, CSIR-Institute of Microbial Technology, Chandigarh- 160 036

9.	**Dr. J. P. Shukla** Scientist, CSIR-Advanced Materials and Process Research Institute, Bhopal- 462 026	**19.**	**Dr. J.P. Singh** Addl. Plant Protection Adviser(APPA) Directorate of Plant Protection, Quarantine & Storage, NH IV, Faridabad-121001. New Delhi
10.	**Dr. U. S. N. Murthy** Director, National Institute of Pharmaceutical Education and Research, Guwahati-781 101	**20.**	**Shri V.P. Yadav** Scientist F Central Pollution Control Board Parivesh Bhawan, East Arjun Nagar, Delhi-110 032
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