

Decisions taken in the 118th meeting of the Genetic Engineering Appraisal Committee (GEAC) held on 21.3.2014

The 118th meeting of the GEAC was held on 21.3.2014 in the Ministry of Environment and Forests under the chairmanship of Shri Hem Pande, Additional Secretary, MoEF and Chairman, GEAC

The deliberations and decisions taken in the GEAC meeting in respect of agenda item 4 to 6 are as follows:

Agenda item No 4: Consideration of applications for confined field trials of transgenic crops (Event selection/ BRL-I/ BRL-II) as recommended by the RCGM.

4.1 Renewal of permission to conduct BRL-II trials and seed production of transgenic maize (Event MON 89034 x NK603) in Kharif 2013 and Rabi 2013-14 by M/s Monsanto

4.1.1 The Committee noted that the GEAC in its 104th meeting held on 15.11.2010 had granted permission to conduct BRL-II trials and limited seed production of transgenic maize hybrids viz. 900M Gold and Hishell containing Events MON 89034 x NK603 during Rabi 2010 and Kharif 2011, Subsequently, the GEAC on 21.9.2011 had extended the permission for conduct of trials at nine locations namely; Haryana, Punjab, Maharashtra, Tamil Nadu, Karnataka, Andhra Pradesh, Rajasthan and Uttar Pradesh in Kharif season and Andhra Pradesh, Bihar, Karnataka, Maharashtra, Gujarat and Tamil Nadu (six locations) in Rabi season.

4.1.2 The Committee also noted that the present request is for extension of permission for BRL-II trials and seed production of transgenic maize (Event MON 89034 x NK603) in Kharif 2013 and Rabi 2013-14 to demonstrate the advantages and safety of the technology.

4.1.3 The Committee also considered the requests for seed production and noted that the applicant's request for 20 tones (approx.) of seeds of each hybrid for undertaking large scale trials in demonstration plots in about 1000 locations (1 ha each) is on the higher side and thin on justification. The Committee was of the view that only limited seed production for conducting additional field trials may be allowed. It was therefore decided to advise the applicant to submit minimum seed production required for future trials / generating biosafety data with due justification on the quantity as well as area and location. The Committee decided to reconsider the request for seed production after receipt of the above information.

4.1.4 In view of the above stated facts, the Committee only approved the request for renewal of GEAC permission to conduct BRL-II trials of transgenic maize (Event MON 89034 x NK603) during any appropriate seasons subject to submission of NOC from the State Government where the trials will be conducted. The Committee decided to defer its decision on the request for seed production

4.2 Request for additional locations to conduct BRL-1 trials of genetically engineered maize hybrids at Madhya Pradesh by M/s. Pioneer Overseas Corporation, Hyderabad:

1. BRL-I trials of transgenic maize hybrids containing the events TC1507 X MON810 and

2. BRL-I trials of transgenic maize hybrids containing the events TC1507 X MON810 X NK603

4.2.1 The Committee was informed that the applicant has withdrawn their application regarding BRL-I trials of transgenic maize hybrids containing the events TC1507 X MON810 vide e-mail dated 20.3.2014.

4.2.2 In respect of the second proposal, it was noted that the GEAC in its 111th meeting held on 6.7.2011 had approved BRL-I trials of transgenic maize hybrids (P3501YHR and 30B07YHR) containing the events TC1507 X MON810 X NK603 at Gujarat, Haryana, Karnataka, Andhra Pradesh, Rajasthan Punjab and Tamil Nadu subject to submission of NOC from the respective State Governments.

4.2.3 The Committee also noted that the present request of the company for inclusion of two more additional locations at (i) Jawaharlal Nehru Krishi Vishwa Vidyalaya (JNKVV), Jabalpur and (ii) Directorate of Weed Science Research (DWSR), Jabalpur is with the view to have some flexibility in identifying the location as the applicant is finding difficulties in obtaining NOC from the State Government. The applicant has indicated that the trials will be conducted only at 3-4 locations based on the availability of NOC's.

4.2.4 The Committee noted that the RCGM has recommended the request in its 124th meeting held on 25.06.2013.

4.2.5. In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request for inclusion of two for conduct of BRL 1 trials with transgenic maize hybrids containing the events TC1507 X MON810 X NK603 at two additional locations namely (i) Jawaharlal Nehru Krishi Vishwa Vidyalaya (JNKVV), Jabalpur and (ii) Directorate of Weed Science Research (DWSR), Maharajpur, Jabalpur during any appropriate season subject to the conditions; (a) BRL 1 trial will be limited to three to four locations only and (b) submission of NOC from the respective State Governments where the trials will be conducted.

4.3 Permission for renewal to conduct event selection trials on transgenic Sorghum(*Sorghum Biocolor L. Moench*) with the following events: (i) Events with pCAMBIA 1300: *mtID* CRIDA 1-6-1-8-4, *mtID*CRIDA 4-7-1-7-4, *mtID* CRIDA 26-1-11-6-1, *mtID* CRIDA 75-2-21-2-1 (ii) Events with pCAMBIA 1305.1: *mtID* CRIDA 3-3-18-7-2 (iii) Untransformed control: SPV-462 by Central Research Institute for Dryland Agriculture (CRIDA), Hyderabad

4.3.1 The Committee noted that the GEAC in its meetings held on 6.7.2011 had accorded approval to conduct event selection trials of six transgenic Sorghum (*Sorghum biocolor L. Moench*) expressing event pCAMBIA1300 (*mtID* CRIDA 1-6-1-8-4, *mtID* CRIDA 2-9-3-3-5, *mtID*CRIDA 4-7-1-7-4, *mtID* CRIDA 26-1-11-6-1, *mtID* CRIDA 75-2-21-2-1) and event pCAMBIA 1305.1 (*mtID* CRIDA 3-3-18-7-2) and untransformed control: SPV-462 containing *mtID*genes). The trials will be conducted at one location at CRIDA Complex, Santoshnagar, Hyderabad.

4.3.2. The Committee also noted that CRIDA has requested for extension of permission to conduct the same trial to check the performance of transgenic Sorghum (*Sorghum Biocolor L. Moench*) with *mtID* gene under drought conditions during Rabi 2013 and Kharif 2014.

4.3.3 The Committee further noted that the RCGM has recommended the request in its 125th meeting held on 23.7.2013.

4.3.4 In view of the above stated facts and taking into consideration the recommendations of the RCGM in its 125th meeting held on 23.7.2013, the Committee approved the request to extend the validity period to conduct event selection trials on transgenic Sorghum with two events namely; (i) Events with pCAMBIA 1300: (*mtlD* CRIDA 1-6-1-8-4, *mtlD*CRIDA 4-7-1-7-4, *mtlD* CRIDA 26-1-11-6-1, *mtlD* CRIDA 75-2-21-2-1); (ii) Events with pCAMBIA 1305.1 (*mtlD* CRIDA 3-3-18-7-2) and (iii) Untransformed control: SPV-462 during any appropriate season subject to submission of NOC from the State Government where the trials will be conducted.

4.4 Request for extension to conduct event selection trials of transgenic rice containing ferritin gene for high iron content submitted by Department of Botany, University College of Science, University of Calcutta, Kolkata.

4.4.1 The Committee noted that the GEAC in its meetings held on 15.11.2010 had accorded approval to conduct event selection trials of transgenic rice events namely; RICE 1502, RICE 1503, RICE 1504, RICE 1507, RICE 1515, RICE 1526, RICE 1551, FR19-7-3-4, FR19-7-3-5, FR19-7-7-3, FR19-11-7-4, FR19-11-2 (progenies of FR19-7 & FR19-11 containing ferritin gene for high iron content at Rice Research Station, Chinsurah, West Bengal in an area of 11 m x 14 m during two seasons..

4.4.2. The Committee also noted that the present request for extension of validity of the GEAC approval for conducting the event selection trial is due to non-receipt of NOC from the State Government.

4.4.3 The Committee further noted that the RCGM has recommended the proposal in its 125th meeting held on 23.7.2013 .

4.4.4 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request for revalidating the GEAC approval to conduct event selection trials of transgenic rice containing ferritin gene for high iron content during any appropriate season subject to submission of NOC from the State Government where the trials will be conducted

4.5 Request to extend the validity period for conduct of pollen flow trials on Glyphosate tolerant Roundup Ready (RR) wheat line and change of location and approval of revised protocol containing the *cp4epsps* gene (event MON 71800) by Mahyco.

4.5.1 The Committee noted that the GEAC in its 114th meeting held on 14.12.2011 had accorded approval for conduct of pollen flow trials on Glyphosate tolerant Roundup Ready (RR) wheat line containing the *cp4epsps* gene (event MON 71800) at company's research farm in Jalna during 2012, subject to submission of NOC from the State Government.

4.5.2 The Committee noted that the applicant could not initiate the trials as they received NOC from the State Government only on 1.11.2013. Therefore, they have requested the GEAC to extend the validity period to 2014-2015 for conduct for event selection trials.

4.5.3 The Committee further noted that the State of Maharashtra vide their letter No NOC-2011/C.R. No. 378/1-A dated 1.11.2013 has issued NOC for conduct of pollen flow study subject to the condition that the trials must be conducted at the State Agricultural University's research farms. It is in this context the applicant has requested to change the location and protocol for conduct of trials from the company's research farm at Jalna to SAU's research farm at Mahatama Phule Krishi Vidyapeeth (MPKV), Rahuri, Maharashtra.

4.5.4 The Committee also approved the revised protocol for conducting pollen flow trial with Roundup Ready (RR) wheat line containing *cp4epsps gene*.

4.5.5 The Committee also noted that the RCGM has recommended the request in its 129th meeting held on 24.12.2013.

4.5.6 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to extend the validity period for conduct of pollen flow trials on Glyphosate tolerant Roundup Ready (RR) wheat line containing the *cp4epsps gene* (event MON 71800) in the SAU's research farm at MPKV, Rahuri during any appropriate season as per the revised protocol subject to submission of NOC from the State Government where the trials will be conducted. The Committee also approved the revised Protocol.

4.6 Request to extend the validity of event selection trials on transgenic rice events namely; MW-01 to MW-25 and change of location containing *AlaAT* gene by Mahyco.

4.6.1 The Committee noted that the GEAC in its 115th meeting held on 08.2.2012 had accorded approval for event selection trials on transgenic rice events namely; MW-01 to MW-25 containing *AlaAT* gene at Andhra Pradesh/ Maharashtra during the appropriate season in 2012 subject to submission of NOC from the respective State Governments

4.6.2 The Committee noted that the applicant could not initiate the trials as they received NOC from the State Government of Maharashtra only on 1.11.2013. Therefore, they have requested the GEAC to extend the validity period to 2014-2015 for conduct for event selection trials.

4.6.3 The Committee further noted that the State of Maharashtra (vide their letter No NOC-2011/C.R. No. 378/1-A) dated 1.11.2013, has issued NOC for event selection trials subject to the condition that trials must be conducted at the State Agricultural University's research farms. The Company therefore proposes to conduct the trials in SAU's research farm at DBSKKV, Dapoli, Panvel, Maharashtra

4.6.4 The Committee also noted that the RCGM has recommended the request in its 129th meeting held on 24.12.2013.

4.6.5 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to extend the validity period for conduct of event selection trials on transgenic rice events namely; MW-01 to MW-25 containing *AlaAT* gene in the SAU's research farm at DBSKKV, Dapoli, Panvel during any appropriate season subject to NOC from the State Government where the trials will be conducted.

4.7 Request to extend the validity of event selection trials on transgenic cotton events namely; MAH - 11501 to MAH-11512 and change of location containing *AlaAT* gene by Mahyco.

4.7.1 The Committee noted that the GEAC in its 115th meeting held on 08.2.2012 had accorded approval for event selection trials on transgenic cotton events namely; MAH - 11501 to MAH-11512 containing *AlaAT* gene at company's own farm at Jalna during the appropriate season in 2012 subject to submission of NOC from the State Government

4.7.2 The Committee also noted that the applicant could not initiate trials as they received NOC from the State Government only on 1.11.2013. Therefore, they have requested the GEAC to extend the validity period to 2014-2015 for conduct for event selection trials.

4.7.3 The Committee further noted that the State of Maharashtra vide their letter No NOC-2011/C.R. No. 378/1-A dated 1.11.2013, has issued NOC for conduct of field trials subject to the condition that the trials must be conducted at the State Agricultural University's research farms. It is in this context the applicant has requested to change the location for conduct of trials from the company's research farm at Jalna to SAU's research farm at Mahatama Phule Krishi Vidyapeeth (MPKV), Rahuri,

4.6.6 In view of the above stated facts the Committee approved the request to extend the validity of event selection trials on transgenic cotton events namely; MAH - 11501 to MAH-11512 containing *AlaAT* gene at SAU's research farm in MPKV, Rahuri, Maharashtra during any appropriate season subject to NOC from the State Government.

4.8 Request to extend the validity of event selection trials on salt tolerant transgenic rice events namely; OsN-1 to OsN-25 and change of location containing *OSnhx1* gene by Mahyco

4.8.1 The Committee noted that the GEAC in its 114th meeting held on 14.12.2011 had accorded approval for event selection trials on salt tolerant transgenic rice events namely; OsN-1 to OsN-25 containing *OSnhx1* gene at SAU's research farm at Panvel, Raigad, Maharashtra during the appropriate season in 2012-2013 subject to submission of NOC from the State Department of Agriculture where the trials would be conducted.

4.8.2 The Committee also noted that the applicant could not initiate the trials as they received NOC from the State Government only on 1.11.2013. Therefore, they have requested the GEAC to extend the validity period to 2014-2015 for conduct of event selection trials.

4.8.3 The Committee further noted that the State of Maharashtra vide their letter No NOC-2011/C.R. No. 378/1-A dated 1.11.2013, has issued NOC subject to the condition that the trials must be conducted at the State Agricultural University's research farms. The applicant proposes to conduct the trials at SAU's research farm DBSKKV, Dapoli, Raigad Maharashtra.

4.8.4 The Committee also noted that the RCGM has recommended the request in its 129th meeting held on 24.12.2013.

4.8.5 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to extend the validity of event selection trials on salt tolerant transgenic rice events namely; OsN-1 to OsN-25 containing *OSnhx1* gene at SAU's research farm in DBSKKV, Dapoli, Raigad, Maharashtra during any appropriate season subject to of NOC from the State Government.

4.9 Request to extend the validity of event selection trials on water use efficient cotton events namely; MAH - 10001 to MAH-10010 and change of location containing *ipt* gene by Mahyco.

4.9.1 The Committee noted that the GEAC in its 115th meeting held on 8.02.2012 had accorded approval for event selection trials on water use efficient cotton events namely; MAH - 10001 to MAH-10010 containing *ipt* gene at company's own research farm in Jalna during the appropriate season in 2012-2013 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

4.9.2 The Committee also noted that the applicant could not initiate trials as they received NOC from the State Government only on 1.11.2013. Therefore, they have requested the GEAC to extend the validity period to 2014-2015 for conduct for event selection trials.

4.9.3 The Committee further noted that State of Maharashtra vide their letter No NOC-2011/C.R. No. 378/1-A dated 1.11.2013 has issued NOC subject to the condition that the trials must be conducted at the State Agricultural University's research farms. It is in this context the applicant has requested to change the location for conduct of trials from the company's research farm at Jalna to SAU's research farm at Mahatama Phule Krishi Vidapeeth (MPKV), Rahuri, Maharashtra.

4.9.4 In view of the above stated facts, the Committee approved the request to extend the validity of event selection trials on water use efficient cotton events namely; MAH - 10001 to MAH-10010 containing *ipt* gene at SAU's research farm in MPKV, Rahuri, Maharashtra during any appropriate season subject to NOC from the State Government.

4.10 Permission for additional location to conduct event selection trials with 168 events of transgenic rice and F1 Hybrid seed production (Two cycles / year) from constructs RPD5-RPD17 two locations each in North, Central, South and East Zones by M/s. BASF India Ltd., New Delhi

4.10.1 The Committee noted that the GEAC in its 115th meeting held on 08.02.2012 had accorded permission to conduct event selection trials with 168 events of transgenic rice and F1 Hybrid seed production (Two cycles / year) with the above constructs at Coimbatore.

4.10.2 The Committee also noted that the present request of M/s. BASF India Ltd. Is for additional location to conduct Event selection trials with 168 events of transgenic rice and F1 Hybrid seed production (Two cycles per year) from constructs RPD5-RPD17 imported from USA and Belgium in any two locations each in North (Rajasthan, U.P), Central (Gujarat, Maharashtra, MP and Chhattisgarh), South (TN, AP, Karnataka and Kerala) and East (West Bengal and Jharkhand) zones.

4.10.3 The Committee extensively deliberated on the need for conducting event selection trials in more than one or two locations. It was also noted that the event selection trials are usually conducted within the company owned land. It was concluded that the present request is with a view to evaluate the performance of the events (yield assessment) under various agro-climatic conditions. After detailed deliberations, the Committee was of the view that the Company may be permitted to undertake the event selection trials initially only at one location each in two zones subject to NOC from the State Government.

4.10.4 The Committee was of the view that only limited seed production for conducting additional field trials may be allowed. It was therefore decided to advise the applicant to submit the minimum seed production required for future trials with due justification on the quantity as well as area required. The Committee decided to reconsider the request for seed production after receipt of the above information.

4.10.5 The Committee also noted that the IBSC has recommended the proposal on 25.09.2013 and RCGM has recommended the proposal in its 128th meeting held on 26.11.2013.

4.10.6 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the conduct of event selection trials with 168 events of transgenic rice from constructs RPD5-RPD17 at one location each in any two zones at during any appropriate season subject to submission of NOC from the respective State Governments where the trials will be conducted. The Committee further directed the applicant not to conduct the event selection trial in proximity to Basmati growing area. The Committee decided to defer its decision on the request for seed production

4.11 Request to extend the validity for conduct of event selection trials of drought tolerant transgenic Groundnut (*Arachishypogaea L.*) events viz., GNRD2, GNRD11, GNRD12, GNRD19, GNRD20, GNRD33 and GNRD44 carrying *rd29A* gene (DREB1A) for yield assessment, under imposed intermittent drought in confined field conditions by International Crops Research Institute for the Semi-Arid Tropics (ICRISAT), Patancheru, Andhra Pradesh.

4.11.1 The Committee noted that the GEAC in its 112th meeting held on 21.09.2011 had accorded approval for event selection trials on of drought tolerant transgenic Groundnut (*Arachishypogaea L.*) events viz., GNRD2, GNRD11, GNRD12, GNRD19, GNRD20, GNRD33 and GNRD44 carrying *rd29A* gene (DREB1A) for yield assessment, under imposed intermittent drought in confined field conditions subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted. The trial will be conducted at RM18 field located in ICRISAT premises in Patancheru under net covered confined field conditions during rainy and post rainy season 2013.

4.11.2 The Committee noted that the applicant could not conduct the trials due to expiry of the duration of the permission, although NOC from A.P. Government was obtained. Therefore, they have requested the GEAC to extend the validity period to 2014-2015 to conduct event selection trials.

4.11.3 The Committee also noted that the RCGM has recommended the proposal in its 129th meeting held on 24.12.2013

4.11.4 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to extend the validity for conduct of event selection trials of drought tolerant transgenic Groundnut (*Arachishypogaea L.*) events viz., GNRD2, GNRD11, GNRD12, GNRD19, GNRD20, GNRD33 and GNRD44 carrying *rd29A* gene (DREB1A) for yield assessment, under imposed intermittent drought conditions (during rainy and post rainy season) at ICRISAT during any appropriate season subject to submission of NOC from the State Government where the trials will be conducted.

4.12 Request for additional location to conduct Elite Event Selection trials with 168 events of transgenic rice and F1 hybrid seed production (two cycles/year), Andhra Pradesh by M/s BASF India Ltd.

4.12.1 The Committee noted that the GEAC in its meeting held on 08.02.2012 had accorded approval to conduct Elite Event Selection trials with 168 events of transgenic rice and F1 hybrid seed production (two cycles/year), at BASF owned land at Bellathi, Coimbatore, subject to submission of NOC from the State Government.

4.12.2 The Committee also noted the Company's subsequent request for additional location to conduct above trials at Eluru A.P, at SynTech Research Inc., Andhra Pradesh in addition to Bellathi, Coimbatore due to difficulty in getting NOC from the State Governments was considered by the GEAC in its meeting held on 22.3.2013. Decision on the proposal was deferred as the Committee was of the view that outsourcing of field trials cannot be allowed. Therefore the applicant was advised to submit the contract agreement between the company and SynTech Research Inc. for conducting event selection trials in the research farm of the institute at Eluru.

4.12.3 The Committee considered the following clarification provided by the company:

- i. BASF has not outsourced field trials to SyntTech.
- ii. As per the service agreement with SynTech, the trials are the sole responsibility of BASF India Ltd and SynTech is only a service provider. The service provided by SynTech to BASF is limited to making available land for field trials and administrative support such as fencing, site preparation, labour for farm maintenance, electricity and water connection.
- iii. BASF personnel will be the trial-in charge
- iv. BASF technical personnel will be permanently stationed at the site.
- v. BASF will be responsible for storage and transport of all material and
- vi. BASF will be liable for regulatory compliance and stewardship.

4.12.4 The Committee noted that as per the current practice, field trials are permitted only within the institutional research farm of the company/SAU/ IARI/ ICAR or long leased land under the control of the applicant to ensure full compliance with the post-harvest measures including monitoring requirements. Therefore the Committee was of the view that the trials involving third party should not be encouraged.

4.12.5 The Committee therefore rejected the proposal.

Agenda Item No 5: Consideration of applications related to r-Pharma Products

5.1 Permission for Import of processed food i.e Dried Distillers Grains with soluble (DDGS) - Corn from USA and market in India by M/s Godrej Agrovet Ltd, Mumbai.

5.1.1 The Committee considered the application submitted by M/s Godrej Agrovet Ltd, Mumbai for import of Dried Distillers Grains with Soluble (DDGS) from USA. DDGS is a processed feed which can be used as a high quality protein source in various types of animals feed i.e poultry feed, cattle feed and aqua feed. DDGS is a co-product of the ethanol industry. Corn is used to produce ethanol. DDGS is dried residue remaining after the starch portion of the grain is fermented in the ethanol production process with selected yeasts and enzymes. After the complete fermentation, the alcohol is removed by the process of distillation and the remaining fermentation residues are dried. The Committee noted that as per the information submitted by the applicant DDGS which is a by-product of ethanol industry by using imported corn from USA may contain LMO.

5.1.2 The Committee further noted that the request is for import of 5 MT of DDGS to test the sample for confirmation of LMOs and also conducting feed trials studies with DDGS at NBPGR /IVRI/NDRI/ NIN.

5.1.3 The Committee also observed that it is approved in the country of origin (USA) and other countries including Mexico, Kingdom of Saudi Arabia, Japan and Egypt and host of other countries.

5.1.4 After detailed deliberations, the Committee opined that in first instance, the applicant may be advised to submit information on (i) list of corn events used in the ethanol industry in USA; (ii) composition of DDGS which is by-product of ethanol industry including level of GM content for confirmation of the presence of introduced DNA or protein; and (iii) detailed food / feed safety data including toxicity data. The Committee also recommended that views of ICMR, Department of Animal Husbandry, National Research Centre for Poultry and IISC Bangalore may also be obtained prior to placing the proposal in GEAC agenda. Accordingly decision on the proposal was deferred.

5.2 Permission to carryout non-commercial scale up trials to scale up yeast biotransformation process using GMO yeast Category I yeast (*Saccharomyces cerevisiae*) with volume upto 4000L by M/s Embio Ltd. Mumbai

5.2.1 The Committee considered the proposal of M/s Embio Ltd. Mumbai for non-commercial scale-up trials up to 4 KI level of a Category 1 yeast (*Saccharomyces cerevisiae*) which would be used for whole cell biotransformation of chemical Benzaldehyde to of R-Phenyl acetyl carbinol, a chiral intermediate for API production. As per the information submitted by the applicant; after the process of biotransformation, solvent extraction is done to recover the product. This process denatures the cells. The spent broth is further subject to heating for inactivation before disposal to anaerobic digester in the main plant. Therefore there is no LMO in the final product or in the waste generated.

5.2.2 The Committee was informed that the biotransformation process is an outcome of two Drugs and Pharmaceuticals Research and Development Programs (DPRDP) undertaken since 2005 under DST with IIT Mumbai.

5.2.4 The Committee further noted that RCGM vide letter dated 11.10. 2012 has directed the applicant to approach GEAC for approval.

5.2.6 The Committee after detailed deliberations decided to obtain information on (i) details of gene construct of enzyme and their function and (ii) details of transformation. The Committee also requested RCGM to reconsider the application on the basis of the above information and if required the applicant may be requested to make a presentation before the RCGM. Accordingly decision on the proposal was deferred.

5.3. Import and Market of Bursal Disease-Marek's Disease Vaccine, Serotype 3, Marek's Disease Vector (Vaxxitek HVT+ IBD) by M/s Sanofi Synthelabo Indian Ltd.

5.3.1 The Committee considered the above application submitted by M/s SanofiSynthelabo seeking permission of GEAC for import and Market of Bursal Disease-Marek's Disease Vaccine, Serotype 3, Marek's Disease Vector (Vaxxitek HVT+ IBD) from M/s Merial Select Inc. USA in India. It is a veterinary medicine for use in healthy one day old chickens and healthy 18 to 19 days old chicken embryos as an aid in the prevention of Marek's disease and infectious bursal disease. The Vaxxitek HVT+IBD is a live vaccine against Bursal Disease-Marek's Disease prepared from a Marek's disease vectored Bursal Disease recombinant virus. The starting material is a Turkey Herpes virus (HVT), FC-126 strain isolated from turkey blood obtained through American Type Culture Collection.

5.3.2 After detailed deliberations, the Committee decided in the first instance to obtains views of ICMR, Department of Animal Husbandry, National Research Centre for Poultry, Indian Institute of Veterinary, Izatnagar, Tamil Nadu Veterinary and Animal Science University, Chennai and IISC, Bangalore prior to placing the proposal in GEAC agenda. Accordingly decision on proposal was deferred.

5.4 Import and market of the Canine Distemper -Adenovirus type 2-Coronavirus-Parainfluenza- Parvovirus Vaccine, Modified Live Virus, Live Canarypox Vector, LeptospiraCanicola – IcterohaemorrhagiaeBacterin (Recombitek® C6/CV) by M/s SanofiSynthelabo (India) Ltd.

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5.5 Import and market of the Canine Distemper-Adenovirus type 2-Parainfluenza-Parvovirus Vaccine, Modified Live Virus, Canarypox Vector, LeptospiraBacterin (Recombitek®C6) by M/s.SanofiSynthelabo (India) Ltd.

5.6 Import and market of the Canine Distemper-Adenovirus type 2- Parainfluenza -Parvovirus Vaccine, Modified Live Virus, Canarypox Vector (Recombitek® C4)by M/s SanofiSynthelabo (India) Ltd.

5.7 Import and market of the Canine Distemper-Adenovirus -Parvovirus Vaccine, Modified Live Virus, Canarypox Vector (Recombitek® C3) by M/s SanofiSynthelabo (India) Ltd.

1. The Committee considered the above mentioned four applications submitted by M/s SanofiSynthelabo (India) Ltd seeking permission of GEAC for import and marketing of canine veterinary vaccine in India. Recombitek[®] group of vaccines is recommended for the vaccination of healthy dogs, 6 weeks of age and older for prevention / use against disease caused by canine distemper virus, canine adenovirus type 1 and 2, coronavirus, canine parvovirus, canine parainfluenza type 2 virus, and leptospirosis.

2. After detailed deliberations, the Committee decided that in the first instance views of ICMR, Department of Animal Husbandry, Indian Institute of Veterinary, Izatnagar, Tamil Nadu Veterinary and Animal Science University, Chennai and IISC, Bangalore may be obtained prior to placing the proposal in GEAC agenda. Accordingly decision on proposal was deferred.

5.8 Permission for revalidation of GEAC for manufacture and marketing of foot and Mouth disease (FMD) Vaccine by M/s Intervet India Pvt. Ltd, Pune.

5.8.1 The Committee considered the request of M/s Intervet India Pvt. Ltd for revalidation of GEAC permission letter dated 1.6.2009 for manufacture and marketing of Foot and Mouth Disease (FMD) Vaccine. It was informed that in accordance with the provisions of Rules 1989, Section 13 (2), all approvals of the GEAC is valid for a period of four years in the first instance and subsequently renewable for 2 years at a time.

5.8.2 After detailed deliberations, the Committee opined that in the first instance, the applicant may be advised to submit information on (i) Post Marketing Surveillance data, (ii) Marketing feedback and (iii) Incidence of disease. Accordingly the proposal was deferred.

Agenda item no 6: Applications related to import of Soybean Oil

6.1 Permission to import transgenic Soybean Oil by three company's viz. M/s. Bayer BioSciences Pvt. Ltd, Gurgaon, M/s by BASF India Ltd and M/s Monsanto Holdings Pvt. Ltd.

6.1.1 The Committee noted that the GEAC in its earlier meetings held on 8.7.2009, 5.11.2010, 9.2.2011 and 21.9.2011 had deferred its decision on the requests for import of Soybean oil from the following applicants:

- i. Permission to import transgenic Liberty Link Soybean Oil from USA by M/s. Bayer BioSciences Pvt. Ltd, Gurgaon.
- ii. Import of crude degummed oil derived from BPS-CV127-9 soybean (CV127) from Brazil by BASF India Ltd.
- iii. Import of crude degummed oil produced from Genuity[™] Insect Protected Roundup Ready 2 yield^R(BtRR2Y) soybean (breeding stack of Events MON87701XMON89788) from Brazil by M/s Monsanto Holdings Pvt. Ltd.

6.1.2 The Committee considered the clarifications submitted by the three applicants with respect to its composition and noted that the Test Reports received from CFTRI on compositional analysis indicate (a) DNA was absent in Refined Soybean oil and Crude Oil LL Soybean for all events (LL

event AA547-127, LL event A2704-12, RR event (BtRR2Y) and event BPS-CV127-9); and (b) No protein was detected by amino acid analysis for all Soybean events mentioned above. The Committee found some discrepancies in the test report and sought clarifications on (i) why +ve controls show –ve results and (ii) why – ve controls show + results. Further, the Committee was also of the view that +ve control should be same oil spiked with r-DNA or Protein.

6.1.11 The Committee decided to obtain clarifications from CFTRI, Mysore on the above discrepancies. Accordingly decision on the applications was deferred.
