

## **Decisions taken in the 124th meeting of the Genetic Engineering Appraisal Committee (GEAC) held on 3<sup>rd</sup> September, 2015**

The 124<sup>th</sup> meeting of the GEAC was held on 3<sup>rd</sup> September, 2015 in the Ministry of Environment, Forest and Climate Change (MoEF& CC) under the chairmanship of Shri Hem Pande, then Additional Secretary and now Special Secretary, MoEF&CC and Chairman, GEAC.

The deliberations and decisions taken in the GEAC meeting in respect of Agenda item 4 to 7 are as follows:

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

#### **4.1 Permission to conduct event selection trials on 8 transgenic maize (*Zea mays*) events namely MHtM01 to MHtM08 expressing *cp4epsps* gene for herbicide tolerance in hybrid and line background by M/s. Metahelix Life Sciences Limited, Bangalore**

4.1.1 M/s. Metahelix Life Sciences Limited, Bangalore has requested for permission to conduct event selection trial on 8 transgenic maize (*Zea mays*) events namely; MHtM01 to MHtM08 expressing *cp4epsps* gene for herbicide tolerance in hybrid and line background at company's long leased land at Bangalore, Karnataka; Aurangabad, Maharashtra and Sonipat, Haryana in an area of 2500m<sup>2</sup>.

#### **4.1.2 The Objective of the trials is:**

- i. To identify and compare events performance and
- ii. The efficacy of transgenic hybrids to tolerate 1.4% of glyphosate spray.

4.1.3 The RCGM vide their letter dated 3.6.2014 informed that applicant has submitted additional information/ clarifications and recommended in its 135<sup>th</sup> meeting held on 25.3.2014.

4.1.4 The GEAC deliberated on the information provided by the applicant and the recommendations of the RCGM. After detailed deliberations, **the Committee approved for the permission** to conduct event selection trials on 8 transgenic maize (*Zea mays*) events namely MHtM01 to MHtM08 expressing *cp4epsps* gene for herbicide tolerance in hybrid and line background by M/s. Metahelix Life Sciences Limited, Bangalore.

#### **4.2 Permission to conduct event selection trials on marker free transgenic rice (*Oryza sativa*) on events namely: W1-MF-001 to W1-MF-007; W2-MF-001 to W2-MF-024; 01-MF-001 to 01-MF-011; N1-MF-001 to N1-MF-007; N3-MF-001 to N3-MF-006; N4-MF-001 to N4-MF-008; Y1-MF-001 to Y1-MF-005 carrying genes for abiotic stress tolerance namely drought & salinity and nutrition stress by M/s. Bioseed Research India Pvt. Ltd., Hyderabad**

4.2.1 M/s. Bioseed Research India Pvt. Ltd., Hyderabad has requested for permission to conduct event selection trials events namely: W1-MF-001 to W1-MF-007; W2-MF-001 to W2-MF-024; 01-MF-001 to 01-MF-011; N1-MF-001 to N1-MF-007; N3-MF-001 to N3-MF-006;

N4-MF-001 to N4-MF-008; Y1-MF-001 to Y1-MF-005 on marker free transgenic rice (*Oryza sativa*) carrying genes for abiotic stress tolerance namely drought & salinity and nutrition stress at company's own research farm at Rangareddy, Hyderabad in an area of 1400m<sup>2</sup>

#### 4.2.2 The Objectives of the trial are:

- i. To evaluate the performance of transgenic events compared to their non-transgenic counterparts and checks.
- ii. Comparative assessment of phenotypic characters
- iii. Molecular characterization of events by PCR, RT-PCR, gene expression and quantification of expressed protein
- iv. Selection of transgenic events for further experiments.

4.2.3 The RCGM informed vide his letter dated 2.7.2014 the applicant has re-submitted revised application and same has been approved by the RCGM.

4.2.4 The GEAC after deliberation sought to know whether there is a foreign gene and if so what the advantages there are from. GEAC sought clarifications from the RCGM, in a tabular form, about the genes, events and stacked genes, etc. Decision of the proposal was deferred.

#### 4.3 Permission to conduct Biosafety Research Level-1 (BRL-1) trials on transgenic rice (*Oryza sativa L.*) hybrid JKRH 4001 containing *cry2Ax1* gene (event JKOsE081) by M/s. JK Agri Genetics Ltd., Hyderabad

4.3.1 M/s. JK Agri Genetics Ltd., Hyderabad has requested for permission to conduct BRL-1 trials on transgenic rice (*Oryza sativa L.*) hybrid JKRH 4001 containing *cry2Ax1* gene (event JKOsE081) to evaluate resistance against *lepidopteran* insects and evaluate true-to-type agronomic performance. The trials will be conducted at three locations at Warangal, Telangana and Guntur Andhra Pradesh at Company farm/leased land in an area of 0.5 ha.

#### 4.3.2 The Objectives of the trials are to:

- i. To evaluate JKRH 401 hybrid rice containing *Btcry2Ax1* event for resistance against *lepidopteran* insects and
- ii. Evaluate true-to-type agronomic performance
- iii. To conduct biosafety studies and compositional analysis of the transgenic event.
- iv. To collect phenotype data, Agronomic performance, confirmation of new traits, insect data, list of beneficial insects for field studies, Rhizopre studies, bio-safety parameters, compositional analysis and list of grain quality parameters for quality studies.

4.3.3 The RCGM vide their letter dated 16.9.2014 informed that applicant has submitted additional information/ clarifications. Clarifications were reviewed by the experts wherein experts sought additional clarifications from the applicant.

4.3.4 After detailed deliberations, the Committee approved for the permission to conduct Biosafety Research Level-1 (BRL-1) trials on transgenic rice (*Oryza sativa L.*) hybrid JKRH 4001

containing cry2Ax1 gene (event JKOsE081) by M/s. JK Agri Genetics Ltd., Hyderabad. However, the GEAC requested the RCGM to document and apprise the GEAC about the scientific data with regard to wild variety and the transgenic rice.

#### **4.4 Permission to conduct Biosafety Research Level-1 (BRL-1) trials on transgenic rice (*Oryza sativa* L.) hybrid JKRH 4001 containing *cryI*Ac gene (event JKOsE016) by M/s. JK Agri Genetics Ltd., Hyderabad.**

4.4.1 M/s. JK Agri Genetics Ltd., Hyderabad has requested for permission to conduct BRL-1 trials on transgenic rice (*Oryza sativa* L.) hybrid JKRH 4001 containing *cryI*Ac gene (event JKOsE016) to evaluate resistance against *lepidopteran* insects and evaluate true-to-type agronomic performance. The trials will be conducted at three locations at Warangal in Telangana and Guntur in Andhra Pradesh at Company farm/leased land in an area of 0.5 ha.

4.4.2 Details of the parental lines: JKRH 4001 is nothing but a registered and notified hybrid called JKRH-401 (IET 18181). It is an F1 of cross between IR58025AXJKRV44.

#### **4.4.3 The Objectives of the trials is to:**

- i. Evaluate JKRH 401 hybrid rice containing *BtcryI*Ac event for resistance against *lepidopteran* insects and
- ii. Evaluate true-to-type agronomic performance
- iii. Conduct biosafety studies and compositional analysis of the transgenic event.
- iv. Collect phenotype data, Agronomic performance, confirmation of new traits, insect data, list of beneficial insects for field studies, Rhizopre studies, bio-safety parameters, compositional analysis and list of grain quality parameters for quality studies.

4.4.4 After detailed deliberations, the Committee approved for the permission to conduct Biosafety Research Level-1 (BRL-1) trials on transgenic rice (*Oryza sativa* L.) hybrid JKRH 4001 containing *cryI*Ac gene (event JKOsE016) by M/s. JK Agri Genetics Ltd., Hyderabad. However, the GEAC requested the RCGM to document and apprise the GEAC about the scientific data with regard to wild variety and the transgenic rice.

#### **4.5 Permission to conduct Bio-safety Research Level-1 (BRL-1) trials on transgenic rice (*Oryza sativa*) containing two independent events namely; JKOsE081 (containing *cry2Ax1* gene) & JKOsE016 (containing *cryI*Ac gene) and one stacked event JKOsE081xE016 with (*cry2Ax1* and *cryI*Ac gene) by M/s. JK Agri Genetics Ltd., Hyderabad.**

4.5.1 GEAC in its meeting held on 25.4.2014 had considered the request of M/s. JK Agri Genetics Ltd., Hyderabad to conduct BRL-1 trials on transgenic rice (*Oryza sativa*) with two independent events JKOs E081 and JKOs E016 containing *cry2Ax1* and *cryI*Ac genes respectively and one stacked event containing *cry2Ax1* and *cryI*Ac gene.

4.5.2 IBSC has recommended the proposal in its 26<sup>th</sup> meeting held on 13.02.2012. RCGM has

also recommended the proposal in its 113<sup>th</sup> meeting held on 22.5.2012.

4.5.3 The after a detailed deliberations, the Committee approved for the permission to conduct permission to conduct Bio-safety Research Level-1 (BRL-1) trials on transgenic rice (*Oryza sativa*) containing two independent events namely; JKOsE081 (containing *cry2Ax1* gene) & JKOsE016 (containing *cry1Ac* gene) and one stacked event JKOsE081xE016 with (*cry2Ax1* and *cry1Ac* gene) by M/s. JK Agri Genetics Ltd., Hyderabad. However, the GEAC requested the RCGM to document and apprise the GEAC about the scientific data with regard to wild variety and the transgenic rice.

**4.6 Permission to conduct Biosafety Research Level-I (BRL-I) trials on two transgenic rice (*Oryza sativa*) events namely; B6 and C15 expressing *gly I* and *gly II* genes by M/s Bioseed Research India Pvt. Ltd, Hyderabad.**

4.6.1 The GEAC in its meeting held on 25.4.2014 had considered the request of M/s Bioseed Research India Pvt. Ltd, Hyderabad for conduct of Biosafety Research Level-I (BRL-I) trials on two transgenic rice (*Oryza sativa*) events namely; B6 and C 15 expressing *gly I* and *gly II* genes was considered by the GEAC in its meeting held on 25.4.2014. The trials proposed to be conducted at Company's Research farm at Rangareddy, AP, to generate information on drought and salinity tolerance rice as compared to non-transgenic counterparts in an area of 72 m<sup>2</sup> (excluding isolation distance).

4.6.2 IBSC has recommended the proposal in its 13<sup>th</sup> meeting held on 20.04.2012. RCGM has also recommended the proposal in its 114<sup>th</sup> meeting held on 26.06.2012.

4.6.3 The GEAC after a detailed deliberations, the Committee approved for the permission to conduct permission to conduct Biosafety Research Level-I (BRL-I) trials on two transgenic rice (*Oryza sativa*) events namely; B6 and C15 expressing *gly I* and *gly II* genes by M/s Bioseed Research India Pvt. Ltd, Hyderabad.

**4.7. Permission to conduct Biosafety Research Level-I (BRL-I) trials on two transgenic rice (*Oryza sativa*) events namely; T I-3 and T I-5 expressing DREB genes and three transgenic rice events namely; LEA-11, LEA-20 and LEA-21 expressing *lea* gene by M/s Bioseed Research India Pvt. Ltd, Hyderabad.**

4.7.1 The GEAC in its meeting held on 25.4.2014 had considered the request of M/s Bioseed Research India Pvt. Ltd, Hyderabad for conduct of Biosafety Research Level-I (BRL-I) trials on two transgenic rice (*Oryza sativa*) events namely; T I-3 and T I-5 expressing DREB genes.

4.7.2 The trial will be conducted at Company's Research farm at Rangareddy, AP, in an area of 25m<sup>2</sup> (excluding isolation distance).

4.7.3 IBSC has recommended the proposal in its 13<sup>th</sup> meeting held on 20.04.2012. RCGM has also recommended the proposal in its 114<sup>th</sup> meeting held on 26.06.2012.

4.7.4 The GEAC after a detailed deliberations, the Committee approved for the permission to

conduct permission to conduct Biosafety Research Level-I (BRL-I) trials on two transgenic rice (*Oryza sativa*) events namely; T I-3 and T I-5 expressing DREB genes and three transgenic rice events namely; LEA-11, LEA-20 and LEA-21 expressing *lea* gene by M/s Bioseed Research India Pvt. Ltd, Hyderabad.

**4.8 Permission to carryout research work for scale up of fermentation, involving imported genetically modified *Pichia pastoris* MSP 8.6 for commercial production of Pyruvate and D-Lactate by M/s Godavari Biorefineries Ltd. Sameerwadi, Karnataka.**

4.8.1 M/s Godavari Biorefineries Ltd. Sameerwadi, Karnataka requested to carryout research work for scale up of fermentation, involving imported genetically modified *Pichiapastoris* MSP 8.6 for commercial production of Pyruvate and D-Lactate. Yeast genetically modified (GMO) *Pichiapastoris* MSP 8.6 would be used for fermentation. Yeast cells genetically modified with GO and Catalase enzyme. After fermentation these fermented cells were separated by filtration and spray dried. Spray dried cells were act as biocatalyst. Spray dried powdered was used for the production product like Na- Pyruvate and D-Lactate. The company wants to scale –up this technology by set wise scale-up from 10 L fermentation to 30 KL fermentation.

4.8.2 Objectives of the proposed work plan utilizing GMOs are:

- Basic transformation and laboratory work to assess the expression of the target gene.
- Standardization of fermentation /production procedures.

4.8.3 The GEAC was of the view that the views of the RCGM may be sought before further consideration in the GEAC.

**4.9 Permission to conduct event selection trails on transgenic Sugarcane (*Saccharum*spp.) containing eighteen events namely Co 86032 (DREB2-3, DREB 2-13, DREB 2-14, DREB 2-15, DREB 2-24, HSP70-6, HSP70-8, HSP70-9, HSP70-10, HSP70-22, DREB2+PDH45-2, DREB2+PDH45-3, DREB2+PDH45-4, DREB2+PDH45-5, PDH45-2, PDH45-10, PDH45-20, PDH45-23) at own site by Sugarcane Research Institute, U.P Council of Sugarcane Research (UPCSUR), Shahjahanpur**

4.9.1 M/s ICAR-Sugarcane Breeding Institute requested for permission to conduct even selection trials on transgenic Sugarcane (*Saccharum spp.*) containing eighteen events (DREB2-3, DREB 2-13, DREB 2-14, DREB 2-15, DREB 2-24, HSP70-6, HSP70-8, HSP70-9, HSP70-10, HSP70-22, DREB2+PDH45-2, DREB2+PDH45-3, DREB2+PDH45-4, DREB2+PDH45-5, PDH45-2, PDH45-10, PDH45-20, PDH45-23) at own site by Sugarcane Research Institute, U.P Council of Sugarcane Research (UPCSUR), Shahjahanpur.

4.9.2 **The objectives of the trail are to:**

To determine different agronomic performance of GM sugarcane events under field conditions, specifically:

- i. Any direct effects of the modifications on yield, attributes like cane weight, cane length and sugar content.
- ii. Effects including altered sensitivity to soil moisture stress. The trail would include 18 events and 2 control in two replications, each replications containing 4 rows of 3m

- each.
- iii. Germination percentage, tiller count, morphological characters, sucrose and yield would be recorded. Herbicide would be used before germination of the setts.

4.9.3 The GEAC was of the view that the views of the RCGM may be sought before further consideration in the GEAC.

#### **4.10 Permission to conduct confined field trial (Event Selection) in 31 transgenic Rice events expressing cry2As2 along with 1 non-transgenic counterpart at company own farm M/s Rasi Seeds Research Farm, Masaipet, Medak Dist, Telangana**

4.10.1 M/s Rasi Seeds Research Farm, Telangana has requested for Permission to conduct confined field trial (Event Selection) in 31 transgenic Rice events expressing cry2As2 along with 1 non-transgenic counterpart at company own farm. The objective of the trial is to select the best performing transgenic rice event, based on the comparison of the level of resistance to the yellow stem borer, grain yield, grain quality and other agronomic parameters of insect resistant rice events corresponding to their non-transgenic counterpart.

4.10.2 IBSC in its 33<sup>rd</sup> Meeting held on 24th July 2014 recommended Rasi Seeds to apply to RCGM for getting the permission to conduct confined field trial (Event Selection) in 31 transgenic Rice events expressing cry2As2 along with 1 non-transgenic counterpart at company own farm.

4.10.3 The GEAC sought the views of the RCGM before further consideration in the GEAC.

#### **4.11 Request for re-extension of the validity period from 2015-2016 to 2016-2017 for conduct of BRL-I trials with Bt rice events expressing Cry 1Ac and Cry 1Ab by M/s Metahelix Life Science**

4.11.1 GEAC in its 112<sup>th</sup> meeting held on 21.09.2011 approved the request for extension of the validity period from 2011-2012 to 2012-2013 for conduct of BRL-I trials with Bt rice events expressing Cry 1Ac and Cry 1Ab gene subject to submission of NOC from respective State Department of Agriculture where the trials would be conducted.

4.11.2 M/s Metahelix in its letter dated 28<sup>th</sup> July 2014 to GEAC requested a fresh letter with extended trial validity and revised address, mentioning Telangana in place of Andhra Pradesh, for resubmission to State Department of Agriculture and seeking NOC.

4.11.3 The GEAC approved the request for re-extension of the validity period from 2015-2016 to 2016-2017 for conduct of BRL-I trials with Bt rice events expressing Cry 1Ac and Cry 1Ab by M/s Metahelix Life Science.

#### **4.12 Request for additional location for conduct event selection trial on transgenic rice (*Oryza sativa*) Bt events namely MHRM01 to MHRM20 containing cry1AB gene for resistance to Rice Yellow Stem Borer (*Scirppophagaincertulas*) at Andhra Pradesh, Bihar, Chhattisgarh, Haryana, Jarkhand, Karnataka, Maharashtra and Uttar Pradesh By M/s Metahelix Life Sciences Limited**

4.12.1 GEAC in its 121<sup>st</sup> meeting held on 18.07.2014 had accorded approved to conduct of event selection on transgenic rice (*Oryza sativa*) Bt events namely MHRM01 to MHRM20 containing cry1AB gene for resistance to Rice Yellow Stem Borer (*Scirppophagaincertulas*) at Vattinagulapalli Village, RR Dist, Andhra Pradesh during any appropriate season subject to submission of NOC from State Government where the trails will be conducted.

4.12.2 The project proponent also requested additional location at Punjab and Gujarat, Proposed trials at the two locations are exactly same as the one for which application was made previously i.e. With the same events, genes, trial plan etc.

4.12.3 RCGM has recommended the request in its 132<sup>nd</sup> meeting held on 25.03.2014.

4.12.4 The GEAC approved the request for additional location for conduct event selection trial on transgenic rice (*Oryza sativa*) Bt events namely MHRM01 to MHRM20 containing cry1AB gene for resistance to Rice Yellow Stem Borer (*Scirppophagaincertulas*) at Andhra Pradesh, Bihar, Chhattisgarh, Haryana, Jarkhand, Karnataka, Maharashtra and Uttar Pradesh By M/s Metahelix Life Sciences Limited.

#### **Agenda item No 5: Consideration of applications related to recombinant Pharma (reconsideration cases)**

##### **5.1 Permission for import of Vector Mune Fowl Pox-*Mycoplasma gallisepticum* (MG) Poultry Vaccine from USA and Marketing in India by M/s Ceva India Pvt Ltd., Delhi.**

5.1.1 M/s Ceva India Pvt Ltd, Delhi in its proposal requested for Permission for import of Vector Mune Fowl Pox-*Mycoplasma gallisepticum* (MG) Poultry Vaccine from USA and Marketing in India.

5.1.2 The proposal was discussed in its 121<sup>st</sup> meeting of the GEAC held on 18.07.2014 where in the committee decided to obtain comments from the experts prior to placing the proposal in GEAC agenda.

5.1.3 The GEAC noted that comments from other experts as sought earlier have not been received. This may be obtained. Further, comments from TNVAS may also be obtained before this application is further considered. GEAC desired that GEAC Secretariat may prepare a list of roaster of veterinary experts whose comments and guidance may be sought while considering the applications.

##### **5.2 Permission for Import and Marketing of Bursal Disease-Marek's Disease Vaccine, Serotype 3, Marek's Disease Vector (Vaxxitek HVT+ IBD) by M/s Sanofi-Synthelabo (Indian) Ltd.**

5.2.1 The proposal of M/s Sanofi-Synthelabo (Indian) Ltd. for import and marketing of Bursal Disease-Marek's Disease Vaccine, Serotype 3, Marek's Disease Vector (Vaxxitek HVT+

IBD) was considered by the GEAC in its 118<sup>th</sup> meeting held on 21.03.2014 and 123<sup>rd</sup> meeting held on 27.02.2015.

5.2.2 The GEAC noted that the applicant may be called for a presentation in the next GEAC meeting. Further, comments from other experts as sought earlier have not been received, which may be obtained. Comments from TNVAS may also be obtained before this application is further considered. GEAC desired that GEAC Secretariat may prepare a list of roaster of veterinary experts whose comments and guidance may be sought while considering the applications.

**5.3 Permission for Import and Marketing of the Canine Distemper -Adenovirus type 2-Coronavirus-Parainfluenza- Parvovirus Vaccine, Modified Live Virus, Live Canarypox Vector, Leptospira Canicola – Icterohaemorrhagiae Bacterin (Recombitek<sup>®</sup> C6/CV) by M/s SanofiSynthelabo (India) Ltd.**

5.3.1 The proposal of M/s SanofiSynthelabo (India) Ltd for import and marketing of the Canine Distemper -Adenovirus type 2-Coronavirus-Parainfluenza- Parvovirus Vaccine, Modified Live Virus, Live Canarypox Vector, LeptospiraCanicola – Icterohaemorrhagiae Bacterin (Recombitek<sup>®</sup> C6/CV) was considered by the GEAC in its 118<sup>th</sup> meeting held on 21.03.2014 and 123<sup>rd</sup> meeting held on 27.02.2015 respectively.

5.3.2 The GEAC noted that the applicant may be called for a presentation in the next GEAC meeting. Further, comments from other experts as sought earlier have not been received, which may be obtained. Comments from TNVAS may also be obtained before this application is further considered. GEAC desired that GEAC Secretariat may prepare a list of roaster of veterinary experts whose comments and guidance may be sought while considering the applications and guidance may be sought while considering the applications.

**5.4 Permission for Import and Marketing of the Canine Distemper-Adenovirus type 2-Parainfluenza-Parvovirus Vaccine, Modified Live Virus, Canarypox Vector, Leptospira Bacterin (Recombitek<sup>®</sup> C6) by M/s.SanofiSynthelabo (India) Ltd.**

5.4.1 The proposal of M/s SanofiSynthelabo (India) Ltd for import and marketing of the Canine Distemper -Adenovirus type 2-Coronavirus-Parainfluenza- Parvovirus Vaccine, Modified Live Virus, Live Canarypox Vector, LeptospiraCanicola – Icterohaemorrhagiae Bacterin (Recombitek<sup>®</sup> C6/CV) was considered by the GEAC in its 118<sup>th</sup> meeting held on 21.03.2014 and 123<sup>rd</sup> meeting held on 27.02.2015 respectively.

5.4.2 The GEAC noted that the applicant may be called for a presentation in the next GEAC meeting. Further, comments from other experts as sought earlier have not been received, which may be obtained. Comments from TNVAS may also be obtained before this application is further considered. GEAC desired that GEAC Secretariat may prepare a list of roaster of veterinary experts whose comments and guidance may be sought while considering the applications.

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

5.5.1 The proposal of M/s SanofiSynthelabo (India) Ltd for import and marketing of the Canine Distemper -Adenovirus type 2-Coronavirus-Parainfluenza- Parvovirus Vaccine, Modified Live Virus, Live Canarypox Vector, LeptospiraCanicola – Icterohaemorrhagiae Bacterin (Recombitek® C6/CV) was considered by the GEAC in its 118<sup>th</sup> meeting held on 21.03.2014 and 123<sup>rd</sup> meeting held on 27.02.2015 respectively.

5.5.2 The GEAC noted that the applicant may be called for a presentation in the next GEAC meeting. Further, comments from other experts as sought earlier have not been received, which may be obtained. Comments from TNVAS may also be obtained before this application is further considered. GEAC desired that GEAC Secretariat may prepare a list of roaster of veterinary experts whose comments and guidance may be sought while considering the applications.

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

5.6.1 The proposal of M/s SanofiSynthelabo (India) Ltd for import and marketing of the Canine Distemper -Adenovirus type 2-Coronavirus-Parainfluenza- Parvovirus Vaccine, Modified Live Virus, Live Canarypox Vector, Leptospira Canicola – Icterohaemorrhagiae Bacterin (Recombitek® C6/CV) was considered by the GEAC in its 118<sup>th</sup> meeting held on 21.03.2014 and 123<sup>rd</sup> meeting held on 27.02.2015 respectively.

5.6.2 The GEAC noted that the applicant may be called for a presentation in the next GEAC meeting. Further, comments from other experts as sought earlier have not been received, which may be obtained. Comments from TNVAS may also be obtained before this application is further considered. GEAC desired that GEAC Secretariat may prepare a list of roaster of veterinary experts whose comments and guidance may be sought while considering the applications.

**Agenda Item No 6: Policy issues:**

**6.1 Change the hybrids in protocol proposed for BRL –I trial of transgenic cotton containing breeding stacks of Events 15985xCOT102 (BGIII), Events 15958 X COT102 x MON88913 (BGIIRRF) and events COT102 by M/s Monsanto India ltd.**

6.1.1 M/s Monsanto India has requested for Change in the hybrids in protocol proposed for BRL –I trial of transgenic cotton containing breeding stacks of Events 15985xCOT102 (BGIII), Events 15958 X COT102 x MON88913 (BGIIRRF) and events COT102 by M/s Monsanto India ltd.

6.1.2. The GEAC granted permission to the project proponent to conduct the Biosafety

Research Level-I (BRL-I) trials in its 120<sup>th</sup> meeting held on 12.05.2014. However these trials could not be undertaken during Kharif 2014 due to the lack of state NOCs.

6.1.3 The GEAC in its letter dated July 16, 2014 permitted to undertake the trials during 2015-2016 and 2016-17 in north, central and south zone of the country. However BRL-1 trial for these events could not be conducted. The project proponent informed in letter dated 8<sup>th</sup> April 2015 that their breeding team has developed advanced germplasm cotton hybrids superior to the ones originally proposed for the BRL-1 trials. These advanced germplasm hybrids have been converted to BGIII, BGIIIRRF and COT 102 versions with due permission of IBSC.

6.1.4 The GEAC after detailed deliberations, has not approved the request for change in hybrids in protocol proposed for BRL –I trial of transgenic cotton containing breeding stacks of Events 15985xCOT102 (BGIII), Events 15958 X COT102 x MON88913 (BGIIIRRF) and events COT102 by M/s Monsanto India Ltd

#### **Agenda Item No 7 : Application related to Export /Import**

##### **7.1 Permission to export Eight (08) Bollgard II (BG-II) hybrid seeds to Malawi for conduct of confined field trials by M/s Mahyco Hybrid Seeds Co. Ltd**

7.1.1 M/s Mahyco has requested for permission to export the following BG-II hybrids containing cry1Ac and cry2Ab gene Event (MON 15985) to Malawi by letter dated January 13<sup>th</sup> 2015 to GEAC

1. MRC 7361 BG-II containing cry1AC and cry 2Ab genes
2. MRC 7071 BG-II containing cry1AC and cry 2Ab genes
3. MRC 7031 BG-II containing cry1AC and cry 2Ab genes
4. MRC 7377 BG-II containing cry1AC and cry 2Ab genes
5. MRC 7041 BG-II containing cry1AC and cry 2Ab genes
6. MRC 7347 BG-II containing cry1AC and cry 2Ab genes
7. MRC 7365 BG-II containing cry1AC and cry 2Ab genes
8. MRC 7381 BG-II containing cry1AC and cry 2Ab genes

7.1.2 The GEAC, keeping in view that all these events of Bt cotton seeds were approved by the GEAC for commercial release in India and therefore approved for permission to export eight (08) Bollgard II (BG-II) hybrid seeds to Malawi for conduct of confined field trials by M/s Mahyco Hybrid Seeds Co. Ltd

##### **7.2 Permission to import Soybean oil derived from herbicide tolerant Soybean (Event FG72) by M/s Bayer Bioscience Pvt Ltd**

7.2.1 M/s Bayer Bioscience requested permission to import Soybean oil derived from herbicide tolerant Soybean (Event FG72), tolerant to Glyphosate and Isoxaflutole herbicide for Food purpose (human consumption) and processing.

7.2.2 The GEAC approved the request to import Soybean oil derived from herbicide tolerant Soybean (Event FG72) by M/s Bayer Bioscience Pvt Ltd.

**7.3 Permission to import Canola oil derived from herbicide tolerant canola (Event Ms8xRF3) by M/s Bayer Bioscience Pvt Ltd**

7.3.1 M/s Bayer Bioscience requested for permission to import Canola oil derived from herbicide tolerant canola (Event Ms8xRF<sub>3</sub>).

7.3.2 The GEAC approved the request to import Canola oil derived from herbicide tolerant canola (Event Ms8xRF3) by M/s Bayer Bioscience Pvt Ltd.

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