Decisions taken in the 92nd Meeting of the Genetic Engineering Approval Committee held on 11.2.2009.

The 92nd meeting of the Genetically Engineering Approval Committee (GEAC) was held on 11.2.2009 in the Ministry of Environment and Forests under the Chairmanship of Shri B. S. Parsheera, Special Secretary, MoEF and Chairman GEAC.

The deliberations of the GEAC in respect of Agenda Items 4 to 9 are as follows:

Agenda item No. 4: Consideration of application related to Pharmaceuticals.

4.1 **Permission for import and marketing of live vaccine Innovax- ND-SB vaccine, a preventive vaccine in poultry by M/s Intervet India Pvt.Ltd.**

4.1.1 The Committee considered the request from M/s Intervet India Pvt. Ltd. for import and marketing of live vaccine Innovax-ND-SB vaccine, a preventive vaccine in poultry. The Innovax-ND-SB vaccine would be imported from USA. The product is already commercialized in USA and Latin America. Similar product of other companies is being marketed in North America, South America, Europe and Asia. It was also noted that conventional Mareks bivalent cell associated vaccine comprising of Herpes Virus of Turkey and Chicken Herpes Virus (viz. Nobilis Marexine CA 126+ SB1) is being marketed in India.

4.1.2 During the deliberations, the representative of DCGI informed that import of live poultry vaccines have been banned by the Department of Animal Husbandry, Ministry of Agriculture. The Committee also gave an opportunity to the company representatives for providing the necessary clarifications regarding status of import of live poultry vaccines, nature of vaccine, safety, stability and label claim. The following points were noted:

- Import of Marek's (MD) and Newcastle Disease (ND) live vaccines are permitted since year 2005 & 2007 respectively. However, it is also imperative to note that these MD and ND live vaccines were used extensively before 2003 for long time. Currently live vaccines for both diseases are imported and used in India. The applicant agreed to forward copies of the relevant notification.

- Gene coding for F protein of NDV, Lasota vaccine strain (Clone 30) is inserted in to vector genome at US 10 region of HVT genome, another vaccine strain of Marek's disease (which is being used as a conventional vaccine) by using RSV promoter. The recombinant HVT vaccine is combined with SB1 strain (another serotype) and given as a conventional vaccine, Nobilis Marexine CA126 +SB1. Advantage with the proposed recombinant vaccine – Innovax is with one application; two diseases can be control at a cost of Rs. 2/- against the present cost of Rs.3.5 per bird. At present 7-10 applications are required besides being labour intensive and expensive.

- Innovax vaccine is safe when applied 10 times the field dose both in target (chickens) and non-target species (ducks and pigeons) and doesn't spread after vaccination like conventional Marexine.

- The recombinant Innovax vaccine has been proved that it's genetically stable and doesn't revert to virulence after 5 back passages on the natural host – chicken (data submitted). Genetic combination is found stable even after 11 passages in chick embryo fibroflast (CEF) culture, which is used for vaccine production and the same has been demonstrated by DNA pattern, sequencing, southern blotting, immunofluorescence, etc. Recombination potential is nil since modification is not by gene deletion and HVT is a DNA virus and NDV is RNA virus. The vaccine is physically stable for more than 3 years when stored in liquid nitrogen (official shelf-life).
- The label claim was read as 1534 PFU of HVT and 1514 PFU of SB-1 per chicken dose.

After detailed deliberations, it was decided to consider the proposal in the next GEAC meeting after obtaining comments from Department of Animal Husbandry, Ministry of Agriculture and Expert Members.

Agenda Item No 5: Consideration of Applications for MLRT/strip trials and experimental seed production of transgenic crops expressing new gene/events as recommended by the RCGM.

5.1 Permission for generation of plant material of Bt rice hybrid namely MRP 5401 Bt expressing the cry 1Ac gene along with its non-Bt counterpart in confined conditions at Shamshabad (Ranga Reddy) Andhra Pradesh during Rabi-2008 for generating toxicity/ biosafety studies by M/s Mahyco.

5.1.1 The Committee considered the request from M/s. Mahyco for generation of plant material of Bt rice hybrid namely MRP 5401 Bt expressing cry 1Ac gene along with its non-Bt counterpart in confined conditions at Shamshabad (Ranga Reddy District) Andhra Pradesh during Rabi-2008 for conducting toxicity/ biosafety studies. The main objective of the proposal is to supply transgenic Bt rice and non-Bt rice material for conducting the following studies:

a. A repeated dose 90 days oral (gavage) study of Bt rice grain panicle and leaves and conventional non-Bt. rice in *Wistar rats.*
b. A*ssessment of the response of boiler chickens to the diets containing leaf or grain panicle powder of Bt rice plant.*

5.1.2 The Committee further noted that the RCGM in its 73rd meeting held on 30.12.2008 has recommended the above proposal.

5.1.3 After detailed deliberations and taking into consideration that the company had earlier been permitted by RCGM/GEAC to conduct MLRT on Bt rice during year 2007 and 2008, the GEAC decided to approve the request for generation of plant material of Bt rice hybrid namely MRP 5401 Bt expressing the cry 1Ac gene along with its non-Bt counterpart in confined conditions at Shamshabad (Ranga Reddy) Andhra Pradesh during Rabi-2008 for conducting toxicity/ biosafety studies by M/s Mahyco.

5.2 Permission for generation of plant material of Bt okra hybrid namely MHOK 10 Bt expressing cry 1Ac gene along with its non-Bt counterpart in confined fields conditions at Jalna District, Maharashtra during Rabi-2008 for conducting toxicity/ biosafety studies by M/s Mahyco.

5.2.1 The Committee considered the request from M/s. Mahyco for generation of plant material of Bt okra hybrid namely MHOK 10 Bt expressing cry 1Ac gene along with its non-Bt counterpart in confined fields conditions within the company's own R&D centre during Rabi-2008 for conducting toxicity/ biosafety studies.

5.2.2 The main objective of the proposal is to supply transgenic Bt okra and non- Bt okra material for conducting the following studies:

- A repeated dose 90 days oral (gavage) study of Bt okra (*Abelmoschus esculentus) fruit and leaves and conventional non-Bt okra in Wistar rats.*
- *Assessment of the response of boiler chickens to the diets containing leaf or fruit powder of Bt Okra plant.*

5.2.3 The Committee further noted that the RCGM in its 73rd meeting held on 30.12.2008 has recommended the above proposal.

5.2.4 After detailed deliberations and taking into consideration that the company has earlier been permitted by RCGM/GEAC to conduct MLRT on Bt okra during year 2007 and 2008, the GEAC decided to approve the request for generation of plant material namely Bt okra hybrid namely MHOK 10 Bt expressing cry 1Ac gene along with its non-Bt counterpart in confined fields conditions at Jalna District, Maharashtra during Rabi-2008 for conducting toxicity/ biosafety studies by M/s Mahyco.

Agenda Item No 6: Consideration of Applications for strip trials of Bt cotton expressing approved gene/events as recommended by the RCGM.

6.1 Permission for strip trials with ten Bt cotton hybrids namely PCH-99, PCH-77, PCH-55, PCH-22, PCH-88, PCH-66, PCH-216, PCH-218, PCH-214, PCH-212 expressing cry 1 Ac gene (event 1) at one location at R&D farm at Bhootpur Village, Mahaboobnagar (A.P.) by M/s Palamoor Seeds Pvt.

6.1.1 The Committee considered the request from M/s Palamoor Seeds Pvt. Ltd**.** to conduct strip trials with ten Bt cotton hybrids namely PCH-99, PCH-77, PCH-55, PCH-22, PCH-88, PCH-66, PCH-216, PCH-218, PCH-214, PCH-212 expressing cry 1 Ac gene (event 1) at one location within their own R&D farm at Bhootpur Village, Mahaboobnagar (A.P.) in light of the new policy decision to follow an 'event based approval mechanism'.

6.1.2 The GEAC approved the above request for conducting strip trials with ten Bt cotton hybrids at one location within the company's research farm.

Agenda Item No 7: Consideration of applications for renewal of GEAC permission for commercial cultivation of Bt cotton of approved gene events in North, Central and South zones.

7.1 Renewal of GEAC permission for commercial cultivation of Bt cotton hybrids namely JKAL 1947 in North zone, JK Varun Bt in Central zone and JKCH 99 Bt, JK Durga Bt in South Zone *expressing cry 1A*c gene (event 1) developed by M/s J.K. Agri Genetics Ltd.

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7.2 Renewal of GEAC permission for commercial cultivation of Bt cotton hybrids namely NCS-138 Bt, NCS-913 in North zone and NCS-913 Bt in Central and South zones *expressing cry 1A*c gene (Mon-531 event) developed by M/s Nuziveedu Seeds Pvt. Ld.

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7.3 Renewal of GEAC permission for commercial cultivation of Bt cotton hybrids namely PCH-2171 in Central zone and PCH-2270 Bt in South zone *expressing cry 1A*c gene (Mon-531 event) developed by M/s. Prabhat Agri biotech Ltd.

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7.4 Renewal of GEAC permission for commercial cultivation of Bt cotton hybrids namely Tulasi -4 Bt , Tulasi-117 Bt in South and Central and Tulasi -9 in Central Zone *expressing cry 1A*c gene (Mon-531 event) developed by M/s Tulasi Seeds Pvt. Ltd.

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7.5 Renewal of GEAC permission for commercial cultivation of Bt cotton hybrids namely ACH-33-1, ACH-155-1 in Central and South zones *expressing cry 1A*c gene (Mon-531 event) developed by M/s Ajeet seeds Ltd.

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7.6 Renewal of GEAC permission for commercial cultivation of Bt cotton hybrid namely Brahma BG *expressing cry 1A*c gene (Mon-531 event) in Central and South zone developed by M/s Monsanto Holding Pvt Ltd.

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7.7 Renewal of GEAC permission for commercial cultivation of Bt cotton hybrids namely RCH-377 Bt in Central zone, RCH-111, RCHB-708 in South Zone *expressing cry 1A*c gene (Mon-531 event) developed by M/s Rasi Seeds Pvt Ltd.

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7.8 Renewal of GEAC permission for commercial cultivation of Bt cotton hybrids namely KDCHH-9810 Bt, KDCHH-9632 and KDCHH-9821 Bt in Central zone, KDCHH-9810 Bt, KDCHH-9632 Bt in South Zone *expressing cry 1A*c gene (Mon-531 event) developed by M/s Krishidhan seeds Ltd.

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7.9 Renewal of GEAC permission for commercial cultivation of ACH-11-2 BGII cotton hybrid *expressing cry 1A*c & cry 2 Ab genes (Mon-15985 event) in Central zone developed by M/s Ajeet seeds Ltd.

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7.10 Renewal of GEAC permission for commercial cultivation of KDCHH-441 BGII cotton hybrid *expressing cry 1A*c & cry 2 Ab genes (Mon-15985 event) in Central zone developed by M/s Krishidhan seeds Ltd.

1.0 The Committee considered the request from M/s J. K. Agri Genetics Ltd, M/s. Nuziveedu Seeds Pvt. Ld., M/s. Prabhat Agri biotech Ltd, M/s. Tulasi Seeds Pvt. Ltd., M/s. Ajeet seeds Ltd, M/s. Monsanto Holding Pvt Ltd., M/s Rasi Seeds and M/s. Krishidhan seeds Ltd., for renewal of GEAC permission for commercial cultivation of JKAL -1947 Bt, JK-Varun Bt, JKCH-99 Bt and JK Durga Bt *expressing cry 1A*c gene (event 1); NCS-138 Bt, NCS-913, NCS-913 Bt, PCH-2171, PCH-2270 Tulasi -4 Bt , Tulasi- 117 Bt, Tulasi -9, ACH-33-1, ACH-155-1 Brahma BG, RCH-377 Bt, RCH-111, RCHB-708 Bt, KDCHH 9810 Bt, KDCHH 9632 Bt, KDCHH-9821 Bt, expressing cry 1Ac (MON 531 event) and ACH-11-2 BGII and KDCHH-441 BGII *expressing cry 1A*c & Cry 2 Ab genes (Mon-15985 event) in the North, Central and South Zones respectively.

2.0 The Member Secretary, GEAC informed the Committee that the proposals at agenda items 7.1 to 7.10 were approved for commercial release in the North, Central and South zones for a period of three years subject to compliance of certain conditions in its meeting held in April/May, 2006. As the validity of GEAC approval expires in April / May, 2009, the respective companies have submitted their applications for renewal of the GEAC permission in accordance to Rule 13 (2) of Rules 1989.

3.0 After detailed deliberations, the GEAC agreed to renew permission for commercial cultivation of Bt cotton hybrids namely JKAL -1947 Bt, JK-Varun Bt, JKCH-99 Bt and JK Durga Bt *expressing cry 1A*c gene (event 1); NCS-138 Bt, NCS-913, NCS-913 Bt, PCH-2171, PCH-2270 Tulasi -4 Bt , Tulasi-117 Bt, Tulasi -9, ACH-33-1, ACH-155-1 Brahma BG, RCH-377 Bt, RCH-111, RCHB-708 Bt, KDCHH 9810 Bt, KDCHH 9632 Bt, KDCHH-9821 Bt, expressing cry 1Ac (MON 531 event) and ACH-11-2 BGII and KDCHH-441 BGII *expressing cry 1A*c & Cry 2 Ab genes (Mon-15985 event) in the North, Central and South Zones respectively as requested by the applicants on the following grounds:

- It was decided in the 75th GEAC meeting held on 14.3.2007 that renewal of GEAC permission after the second renewal may not be necessary as the hybrids are usually phased out after a period of four to five years with the entry of new and better hybrids / technology.

- The GEAC in its 91st meeting held on 14.1.2009 has adopted a new procedure under the 'event based approval mechanism' in respect of Bt. cotton hybrids expressing approved events.

- The GEAC has not received any adverse reporting on the performance of the above listed hybrids from the State Department of Agriculture / State Agricultural Universities.

4.0 During the deliberations, it was further noted that renewal of GEAC permission for Bt cotton hybrids expressing approved events may not be applicable in future in light of the new procedure recently adopted by the GEAC. The Committee further agreed to the suggestion that Chairman GEAC

may be authorized to consider routine cases of requests for renewal of GEAC approval for Bt cotton hybrids expressing approved events and take decision on the matter.

Agenda Item No 8: Other Items.

8.1 Permission for revalidation of GEAC approval for manufacture and marketing of FMD (Foot and Mouth Disease) vaccine by M/s Brilliant Bio Pharma Ltd.

8.1.1 M/s Brilliant Bio Pharma Ltd. has requested for revalidation of the GEAC approval for manufacture and marketing of FMD (Foot and Mouth Disease) Vaccine.

8.1.2 The Committee noted that the GEAC in its 38th meeting held on 27.11.2003 had accorded approval for manufacture and marketing of FMD vaccine by M/s Brilliant Bio Pharma Ltd for a period of 4 years. In accordance with the provisions of rules 1989 13(2), the GEAC agreed to revalidate the GEAC permission dated 5.1.2004.

8.1.3 The Committee also considered the need for continued renewal of GEAC permission for r-Pharma proposals as the mandate of post market surveillance, if any, falls under the mandate of DCGI. The Member Secretary, GEAC informed the Committee that MoEF has recently initiated the review of 'Rules 1989' notified under the E(P)A, 1986 to further streamline the regulatory process. As part of this initiative a 'Working Group' has been constituted under the chairmanship of Shri A. K. Goyal, Joint Secretary, MoEF. After detailed deliberations, the Committee requested the 'Working Group' to examine the issue of renewal also.

Agenda Item No 9: Any other matter with the permission of the Chair.

9.1 Preparation of Phase –II Capacity Building Project on Biosafety.

9.1.1 The Member Secretary, GEAC informed the Committee that MoEF has initiated a 'Capacity Building Project on Biosafety (Phase-II)' under GEF – UNEP assistance subsequent to the completion of phase I capacity building project under WB-GEF in June 2007. The GEF Council in its October, 2008 meeting has approved the Phase-II proposal based on the information submitted in the Project Identification Form (PIF). The objective of the Phase-II proposal is to strengthen the biosafety management system in India. The current project also responds to the commitment under Article 22 of the Cartagena Protocol on Biosafety to provide support for capacity building for the effective implementation of the CPB.

9.1.2 In accordance with the GEF Council approval, MoEF is in the process of preparing a 'Full Scale Project (FSP)'. After a brief discussion on the matter, Members agreed to provide inputs for preparation of FSP. However it was suggested that the Ministry may adopt a consultative approach involving relevant stakeholders including national and international expertise. It was further noted by the Committee, that preparation of FSP involves compilation of extensive information and documentation as well as rigorous follow-up for which MoEF may appoint a consultant like BCIL to facilitate the preparation of FSP in a timely manner.

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