Decisions taken in the 97th Meeting of the Genetic Engineering Approval Committee (GEAC) held on 14.10.2009.

The 97th meeting of the GEAC was held on 14.10.2009 in the Ministry of Environment and Forests (MoEF) under the chairmanship of Shri B S Parsheera, Special Secretary, MoEF and Chairman, GEAC.

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

Agenda item No. 4: Policy issue

4.1 Report of the Expert Committee on Bt Brinjal and consideration of the proposal for environmental release of Bt Brinjal event EE-I developed by M/s Mahyco, TNAU Coimbatore and UAS Dharwad.

4.1.1 Bt Brinjal event EE1 has been developed on a Public Private Partnership mode under the aegis of Agriculture Biotechnology Support Project from Cornell University wherein the Bt technology available with M/s Mahyco has been transferred to Tamil Nadu Agriculture University, Coimbatore, University of Agricultural Sciences, Dharwad and Indian Institute of Vegetable Research, Varanasi free of cost. As part of this collaboration, the technology has also been transferred to University of Agriculture in Philippines and Bangladesh.

4.1.2 Bt brinjal contains cry1Ac gene isolated from *Bacillus thuringiensis* tolerant to the fruit and shoot borer, one of the major pests which attack the brinjal crop throughout its life cycle. The development of Bt Brinjal was initiated in 2000. Bt brinjal has been evaluated for its efficacy and safety as per the protocols and procedures prescribed under the Rules 1989 and relevant biosafety guidelines.

4.1.3 The RCGM in its meeting held on 25-4-2006 considered in detail the data generated by M/s Mahyco to establish the efficacy and safety of the inserted gene. The RCGM concluded that Bt brinjal is affected in controlling target pests, save to environment, non toxic in toxicity and animal feeding tests, non- allergenic and has potential to benefit the farmers. RCGM recommended that GEAC may consider granting approval for conduct of large scale field trials on Bt. Brinjal as per the protocols submitted by the applicant.

4.1.4 Based on the recommendations of the RCGM and the Expert Committee (EC-I) constituted by the GEAC in 2006 under the chairmanship of Dr Deepak Pental, vice Chancellor of Delhi University, the GEAC permitted the conduct of large scale trials of Bt brinjal for two seasons under the direct supervision of Indian Institute of Vegetable (IIVR), Varanasi and other biosafety related studies by M/s Mahyco to generate additional information in 2007. The GEAC has received the final reports from IIVR and M/s Mahyco. During the interim period, the GEAC had received several representations concerning risks to human health and environment arising from Bt brinjal based on the views of some international experts.

4.1.5 To review the findings of the LST and other studies on Bt brinjal as well as address the concerns expressed in the representations, the Ministry had constituted an 'Expert Committee' (EC-II) under the chairmanship of Prof. Arjula R. Reddy, vice chancellor, Yogi Vemana University, Hyderabad and Co-chairman, GEAC in accordance with the decision taken in the GEAC meeting held on 14.1.2009 with the following terms of reference:

- to review the findings of the data generated during the large scale trials;
- to review the biosafety data of Bt brinjal in light of the available scientific evidence, reports from international/national experts and representations from NGOs and other stakeholders;
- to make appropriate recommendations for consideration of the GEAC based on the above review.

4.1.6 Member Secretary, GEAC informed that in accordance with the mandate given by the GEAC, the EC-II in its meetings held on July 30, 2009 and August 31, 2009, reviewed the findings of the data generated during the LST, biosafety data of Bt brinjal provided by the developer, studies conducted by various institutions outsourced by the developers, published literature, reports from international/national groups and representations from NGOs and other stakeholders. The report of the Expert Committee was placed for consideration of the GEAC.

4.1.7 Before initiating discussions on the findings of the report, the Chairman GEAC invited Prof Arjula Reddy, Chairman of the Expert Committee to present the report. The Committee noted that the report has extensively covered the following points:

1. Review of status of regulatory compliance

i. Approvals taken by M/s Mahyco.

ii. Compliance with the "Revised guidelines for research in transgenic plants & guidelines for toxicity and allergenicity evaluation of transgenic seeds, plants and plant parts, 1998".

iii. Compliance with regulatory conditions stipulated by GEAC in the permit letter for large scale trials, 2007

iv. Compliance with the Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered (GE) Plants, 2008

2. Review of Bt brinjal Event EE-1 safety assessment dossier

i. Nature and effect of gene modification

ii. Environmental safety

iii. Food and feed safety

3. Review of efficacy and agronomic performance

4. Consideration of issues raised by NGOs, national and international groups

4.1.8 The GEAC extensively deliberated on the findings of the Expert Committee and the basis for the following conclusions:

- Damage by fruit and shoot borer (FSB) is a major problem in brinjal production and there is an urgent need to have alternate strategies in place to control the same. The current practices of extensive use of chemical pesticides besides being expensive and unsustainable are also harmful to health and the environment.
- The RCGM had considered and examined the biosafety data generated by the applicant and concluded that Bt brinjal is effective in controlling target pests, safe to the environment, non-toxic as determined by toxicity and animal feeding tests, non- allergenic and has potential to benefit the farmers.
- The EC-I had recommended the conduct of large scale trials of Bt brinjal event EE-1 at 10-11 locations subject to certain conditions for reconfirmation of some biosafety data generated by M/s Mahyco. The status of compliance of conditions recommended by EC-I and stipulated by GEAC for large scale field trials indicate that there has been compliance with the prescribed conditions in most of the cases. Wherever there was a deviation, the same had the approval of GEAC. The results of the LST as well as biosafety studies conducted by IIVR and M/s Mahyco were in conformity with earlier information submitted by the applicant and available literature.

- The data generated by the applicant with reference to food and feed safety assessment is complying with the "Guidelines for the safety assessment of foods derived from GE plant, 2008".
- The three genes introgressed by M/s Mahyco into Bt brinjal event EE-1 i.e. *cry1Ac*, *nptII* and *aad* gene have been extensively studied by researchers and evaluated and approved by regulatory agencies worldwide in products such as Bt maize, Bt potato and Bt cotton. All the inserted genes and regulatory sequences (promoters and enhancers) have a history of safe use in view of their inherent characteristics/properties. Further, the expression of *cry1Ac* gene is consistent during the entire life of the crop, and the levels of Cry1Ac protein are sufficient for effective control of FSB in various agro-climatic conditions. This demonstrates that the insect resistance trait is stably integrated in the brinjal genome and there is no evidence or likelihood of genetic instability.
- The protein encoded by the *cry1Ac* gene incorporated in Bt brinjal event EE-1 is 99.4% identical to native *cry1Ac* from *Bacillus thuringiensis* sub species *kurstaki*, and 100% identical to the one expressed in Bt cotton event MON-531 approved in India.
- Environmental safety assessment studies on Bt brinjal event EE-1 demonstrated that introgression of *cry1Ac* gene has in no way affected outcrossing potential and weediness characteristics of *S. melongena.* There was no adverse impact on non target organisms including beneficial organisms and soil microflora. Further, no accumulation and persistence of Bt protein in the soil was observed.
- S. *melongena* and its wild relatives including S. *incanum* have co-existed in nature for millenia. No instances of natural inter-specific hybridization with wild species have been reported for cultivated brinjal. The crossability studies have been repeated by IIVR and it has been reported that crossing was not possible with representative wild relatives except *S. incanum* where limited crossing could be achieved through assisted pollination.
- The *cry1Ac* gene used in Bt brinjal event EE-1 confers no advantage to recipient plants in terms of aggressiveness or growth characteristics. Therefore, even if gene flow occurs in exceptional circumstances, it will not confer any fitness advantage to wild species because insect pests such as *Leucindes orbonalis* (FSB) are rarely found on them. FSB is a lepidopteron pest that prefers brinjal exclusively, and Cry1Ac provides protection only against FSB. Since no lepidopteron pests are prevalent on *Solanum* wild species, the matter of fitness advantage does not arise.
- The food and feed safety assessment of Bt brinjal event EE-1 demonstrates that the expressed Bt protein is highly specific to lepidopteran pests and is neither toxic nor allergenic to human and animals.
- Cry1Ac protein rapidly degrades (in 30 seconds) in simulated gastric and intestinal fluids and is not detectable even in short term digestibility studies.
- The detailed compositional analysis consisting of proximate (protein, fat, ash, fibre, carbohydrate, moisture, calories), amino acid, fatty acid, minerals (calcium, copper, iron, magnesium, manganese, phosphorus, potassium, sodium, selenium and zinc), vitamins (vitamin c, thiamin, riboflavin, niacin, vitamin B6, folic acid, Beta carotene, vitamin A, lycopene, vitamin E and vitamin K) and lipids demonstrates that Bt brinjal event EE-1 is substantially equivalent to its non transgenic counterpart.
- Cry1Ac protein being heat labile is rapidly degraded upon cooking. Highly specific and sensitive ELISA tests conducted for the presence of Cry1Ac protein have confirmed that Cry1Ac protein is not present in any cooked form of brinjal containing event EE-1.
- Variations in the observations regarding the response of animals during the toxicity/feeding studies are commonly noticed in dynamic biological systems. Interpretation of data on safety studies are never done in isolation but as a meaningful holistic evaluation of the entire toxicological data. In the present case, it was observed that experimental observations are within the normal physiological ranges and statistically insignificant. Therefore, the studies

conducted and inference drawn that no significant differences were observed between the animals fed with Bt brinjal *vis-à-vis* control non-Bt counterpart is valid.

- Chronic toxicity studies are warranted only if any toxic effects are observed in acute or sub-chronic studies. Since no toxic effects were seen in acute and sub-chronic studies, there is no need and justification for any chronic or long term studies for evaluating the safety of Bt brinjal event EE-1.
- Cry1Ac protein has a history of safe use for human and animal consumption as GM crops containing Cry proteins including Cry1Ac protein have been consumed by millions of people for over two decades without any adverse effects reported in the published scientific literature.
- The cumulative results of more than 50 field trials demonstrate that Cry1Ac protein provides effective protection to brinjal crop from the FSB resulting in enhanced economic benefits accrued from higher marketable yield and lower usage of pesticide sprays.
- The guidelines and protocols prescribed by RCGM and GEAC are in line with the internationally accepted norms prescribed by OECD, FAO, WHO, Codex Alimentarius, etc.. The applicant has fully complied with the Indian regulatory requirements. Several studies recommended by Dr. P.M. Bhargava have no relevance and are not applicable in the present case, as discussed in Annexure-1 of the Expert Committee report.

4.1.9 The GEAC also took into considerations the following recommendations made by the Expert Committee:

1. Bt brinjal event EE-1 is safe for environmental release in India.
2. Benefits from Bt brinjal event EE-1 far outweigh the perceived and projected risks.
3. In accordance with the event based approval mechanism, the GEAC may consider approving all the Bt brinjal hybrids and varieties containing event EE-1.
4. Bt brinjal event EE-1 has been extensively tested for its biosafety and no additional studies/review are necessary.

4.1.10 Subsequent to the presentation of the report of the Expert Committee and deliberations, the Chairman GEAC invited the members and special invitees to give their views on the findings of the Expert Committee regarding the safety and efficacy of Bt brinjal. The views expressed by the members/ special invitees are summarized below:

Dr Swapan Kumar Dutta, Deputy Director General, ICAR: The biosafety document and data is well document and fully adequate to conclude that Bt brinjal is safe for environmental release. The Expert Committee report has scientifically clarified all the concerns regarding the safety of Bt brinjal.

Dr B M Khadi, Pr. Scientist & Head, RS, University of Agriculture Science, Dharwad.

Accepting the findings and recommendations of the Expert Committee, he opined that Bt brinjal will significantly benefit the farmers.

Dr. P. Ananda Kumar, Project Director, National Research Centre on Plant Biotechnology (NRCPB), IARI, New Delhi.

Bt technology (Cry 1 Ac gene and nptII gene) in GM crops has a safe history of more than 15 years. Bt technology has been successfully deployed in maize and potatoes and is consumed by millions of people. Bt sprays have been used for nearly 70 years. Accepting the findings and recommendations of the Expert Committee, he opined that the Bt brinjal has been adequately tested for its safety and efficacy. Brinjal requires minimum of 25-30 pesticide sprays in one season. With the adoption of Bt

brinjal, the pesticide requirement would decrease and the marketable yield would increase which would be good for farmers both economically and from health point of view.

Dr. Lalitha R. Gowda, Central Food Technology and Research Institute (CFTRI), Mysore.

Fully accepted the report and recommendations of the Expert Committee on the safety of Bt brinjal for environmental release.

Dr. M. N. Murthy, Institute of Economic Growth, Delhi University, New Delhi

Biosafety studies have been well done to remove most of the uncertainties and the progress is satisfactory from the scientific point of view. However, he opined that socio-economic studies are also important. It was informed that *ex ante* assessment of socio-economic benefits of Bt brinjal has been initiated by NCAP with the financial support of MoEF. However the mandate of the GEAC is limited to biosafety assessment.

Dr. Ramesh Sonti, Scientist Centre for Cellular & Molecular Biology, Hyderabad

In response to queries raised by Dr Sonti, the following clarifications were provided:

- The *aad* gene is part of the introduced insert and is driven by a bacterial promoter and hence no protein will be synthesized
- Hybrid gene has been used in the safety assessment
- Reports of sheep death from Warangal cannot be attributed to grazing on Bt cotton
- Natural hybridization between S. *melongena* and its wild relatives including S. *incanum* is not reported.

He further opined that the issue of organic farming though a philosophical issue, may require some attention by the appropriate agencies.

He further opined that the vector that was used for gene modification did not seem appropriate because unnecessary gene like the *aad* gene and more DNA than necessary has been transferred to brinjal genome and therefore he cannot support the release of this line. Other experts reiterated that *aad* gene protein is not expressed in plant parts as it is driven by a bacterial promoter. Also, the construct used in this case was the same used in MON 531 which was earlier approved in cotton. The Committee further opined that the safety assessment has been conducted on the final product.

Dr. K. Satyanarayana Scientist Indian Council of Medical Research, New Delhi.

Fully accepted the report and recommendations of the Expert Committee on the safety of Bt brinjal for environmental release.

Shri D. S. Mishra, Assistant Commissioner (seeds), Ministry of Agriculture

The testing of Bt brinjal has been going on for a long time and adequate measures and studies have been conducted to establish the safety and benefits of Bt brinjal. ICAR is the think tank of Ministry of Agriculture and therefore he would support the views of DDG-ICAR. During commercialization of Bt brinjal, some studies on socio-economics should be entrusted to assess the long terms benefits to farmers.

Shri S. P. Sahani , AD, Drug Controller General of India, New Delhi

Food coming into the environment should be based on appropriate regulatory mechanism. Approval should be given in the first instance only for two years and post release surveillance should be carried out. During this period long term chronic toxicity should be carried out. It was clarified by Director NIN, that long term toxicity is warranted only if the sub chronic studies show some adverse impact.

As the cry 1 Ac gene used in Bt brinjal has a safe history and based on the data from sub-chronic studies conducted with Bt brinjal, such long term chronic studies are not necessary.

Shri S. B. Dongre, Director (F&VP) Food Safety and Standards Authority of India (FSSA), New Delhi

He informed that FSSA is in the process of putting necessary framework in place for regulating the GM processed foods and until such time the FSSA supports the mechanism put in place by the GEAC under Rules 1989 and decisions taken therein by the GEAC.

Dr B. Sesikaran, National Institute of Nutrition (NIN), Hyderabad

He informed that toxicity, allergenicity and nutritional studies conducted with Bt brinjal are adequate to conclude that it is safe for human consumption. He further reiterated that chronic toxicity study is not warranted in this case as Bt technology has a history of safe use. On the demand for additional studies he argued that all tests have been conducted as per the international prescribed procedures and protocols. As technology develops and baseline data for validation becomes available, it would be appropriately integrated into the regulatory system in future on a case by case basis.

Dr P M Bhargava, Special Invitee

Dr Bhargava opined that he does not support the recommendations of the Expert Committee on the following grounds:

- Brinjal is a widely consumed food in India.
- It is not proper to accept international guidelines for safety assessment. Biosafety assessment should be based on national guidelines which take into consideration new insights and evidences.
- In matters of such importance, independent verification should be mandatory.
- More time is needed to review the Expert Committee document. He opined that a minimum of one month should be given followed by a debate in which international experts who have commented on the Bt brinjal data should be invited.
- There is a disagreement in the primary data
- There are several gaps in the safety assessment
- Analysis of the safety data is not correct

He further opined that he is not against GM crops but cannot support the proposal as the safety assessment in his view is not complete. Dr Bhargava also attributed the issue of sheep death in Warangal and farmers suicide in Vidharba to Bt cotton cultivation. He opined that the GEAC should also take into consideration the reliability of MNCs especially Monsanto who has a notorious track record. Referring to the recent report from Ms Mira Shanker, Hon'ble Indian Ambassador to the US, he informed that M/s Dow Agro Genetics is one of the company listed in the report.

The Committee was of the view that issues related to Bt brinjal safety assessment is not new to any of the members and has been deliberated in the GEAC several times. Due responses to Dr Bhargava's views have also provided during the deliberations. The biosafety data, report of the first Expert Committee and minutes of the GEAC meeting are in the public domain since 2006. Therefore the Committee did not accept the request for deferring the discussion on the Expert Committee report. The Committee also noted that Dr Bhargava has time and again raised similar issues to which the Expert Committee has responded adequately. The Committee did not support Dr Bhargava's view that the biosafety assessment is inadequate. The Committee also noted that Dr Bhargava is not a member of the GEAC but a special invitee as per the directions of the Hon'ble Supreme Court. In accordance with the directions, Dr Bhargava was given a full opportunity to express his views. After extensive deliberations, the GEAC decided to record the dissent note made by Dr Bhargava.

Dr. K K Tripathi, Advisor, Department of Biotechnology, New Delhi.

He informed that the regulatory process is a dynamic one and biosafety guidelines are regularly updated taking into consideration the development of novel products and experiences with the commercially released products. He further opined that Bt technology has a history of safe use, each and every concern raised by Dr Bhargava and the NGOs have been addressesed by the Expert Committee. Accepting the findings and recommendations of the Expert Committee, he opined that Bt brinjal is safe for animal and human use and environmental release and will significantly benefit the farmers.

Shri A. K. Goyal, Joint Secretary, MoEF and Vice Chairman, GEAC.

He agreed with the report and recommendations of the Expert Committee on the safety of Bt brinjal for environmental release. He opined that detailed scientific discussions have taken place. Except for Dr Bhargava and Dr Sonti, all members have agreed with the recommendations of the Expert Committee. He also supported the views of Dr Murthy on the need to conduct socio-economic analysis. However, this study should be taken up post commercialization to get a clear picture on the benefits to farmers and acceptance by the consumers. There is also a need to clarify the doubts of the general public in the form of responses by Frequently Asked Questions (FAQs) on the website of the MoEF.

Dr. R. Warrier, Director, MoEF & Member Secretary, GEAC.

Accepted the report and recommendations of the Expert Committee on the safety of Bt brinjal for environmental release.

4.1.11 After hearing the views of all members and special invitees, the GEAC concluded that the report of the Expert Committee is acceptable to all members with some minor editorial corrections except Dr P M Bhargava. In the case of Dr Ramesh Sonti, there was no objection on the adequacy of the safety assessment and findings of the Expert committee. His concern was that an inappropriate vector has been used in the Bt brinjal introgression. The GEAC opined that the *cry1Ac* gene incorporated in Bt brinjal event EE-1 is 100% identical to the one expressed in Bt cotton event MON-531 approved in India and globally. The Committee took note of the dissent note made by Dr Bhargava and Dr Sonti.

4.1.12 The Committee also noted that three experts namely Dr C M Gupta, former Director Central Drug Research Institute, Dr Vasantha Muthuswamy former BMS, AIIMS, New Delhi and Dr. Uday Kumar, Emeritus Scientist, UAS Dharwad who were unable to participate in the meeting, have conveyed their acceptance of the Expert Committee report on safety and efficacy of Bt brinjal vide e-mails.

4.1.13 After detailed deliberations and taking into consideration the findings of the review by three high level technical committees namely the RCGM and two Expert Committees constituted by the GEAC in 2006 and 2009, the GEAC concluded that Bt Brinjal is safe for environmental release. Since this decision of the GEAC will have major policy implications, the GEAC decided to forward the recommendations and report of the Expert Committee on the safety and efficacy of Bt brinjal event EEI to the Government for a final view. It was also agreed that the report of the Expert Committee would be made available in the public domain by posting on the MoEF website at the earliest.

4.2 Report of the Sub-committee constituted by the GEAC to examine the "Guidance document for information/data generation and documentation for safety assessment of GE Plants" during BRL-I and II trials.

Due to paucity of time, it was decided to defer discussion on this agenda item. At the request of Dr P M Bhargava, the Committee agreed to consider this item in the December GEAC meeting.

4.3 Stocktaking assessment of GM crops which are under various stages of field testing.

Due to paucity of time, it was decided to defer discussion on this agenda item to the next GEAC meeting.

Agenda item No. 5: Consideration of applications confined field trials of transgenic crops expressing new genes/events for event selection /BRL-I /BRL-II as recommended by the RCGM.

5.1 Permission to conduct event selection trial (confined field trial) on 49 Bt rice events containing *cry1Ca, cry1Ab and bar* genes at Crop Development Centre, Patancheru during Rabi 2009-2010. by M/s. Bayer Biosciences Pvt. Ltd., Gurgaon.

5.1.1 The Committee considered the request from M/s. Bayer Biosciences Pvt. Ltd., Gurgaon is to conduct 'Elite Event Selection Trials' on 49 Bt rice events namely RICE1502-RICE1509, RICE1511, RICE1515, RICE1526, RICE1528, RICE1530-RICE1532, RICE1551, RICE1552, RICE1555, RICE1557, RICE1558, RICE1576, RICE1577, RICE1590, RICE2111-RICE2114, RICE2117, RICE2118, RICE2120, RICE3101, RICE3102, RICE3105-RICE3110, RICE3116-RICE3118, RICE3120-RICE3126, RICE3129 and RICE3130 containing cry1Ca, cry1Ab and bar genes. The trials will be conducted at the Crop Development Centre, Patancheru during Rabi 2009-2010.

5.1.2 The RCGM has recommended the proposal in its meeting held on 22.9.2009.

5.1.3 The Committee conveyed its 'no objection' to the proposal.

5.2 Permission to conduct second year Biosafety Research Level-1 (BRL-1) trials on corn hybrids namely Hishell and 900M Gold containing stacked *cry2Ab2* and *cry1A.105* (Event MON 89034) & *CP4EPSPS* genes (NK603) under confined conditions within the SAUs during Rabi 2009 by M/s Monsanto India Ltd., New Delhi.

5.2.1 The Committee noted that the GEAC in its meetings held on 12.11.2008 and 10.6.2009 had approved the conduct of BRL-I of the above mentioned two corn hybrids expressing stacked events MON 89034 and NK603 at three SAUs during Rabi 2008 and at six SAUs during Kharif 2009 for generating biosafety data. The present request is for conducting second year BRL-I during Rabi 2009.

5.2.2 The RCGM in its meeting held on 22.9.2009 has recommended the conduct of second year BRL-I on corn hybrids namely Hishell and 900M Gold at three locations where the trial was conducted earlier i.e. Rajendra Agricultural University, Samastipur (Bihar); Mahatma Phule Krishi Vidyapeeth, Rahuri (Maharashtra);and Tamil Nadu Agricultural University, Coimbatore (Tamil Nadu); during Rabi 2009.

5.2.3 The Committee conveyed its 'no objection' to the proposal.

5.3 Permission to carry out confined field trial for event selection with RB-transgenic potato at CPRI Campus, Modipuram by Central Potato Research Institute (CPRI), Shimla.

5.3.1 The Committee noted that the GEAC in its meeting held on 12.11.2008 had approved the conduct of event selection with RB- transgenic potato clones expressing RB gene conferring resistance to late blight disease at Modipuram campus during October 2008 to January 2009. Subsequently in the GEAC meeting held on 13.5.2009, the request for change in location from CPRI, Modipuram to CPRI, Shimla was approved by the GEAC.

5.3.2 The present request is for renewal of the earlier permission as the trials could not be initiated during Kharif 2009. RCGM in its meeting held on 22.9.2009 has recommended the proposal for event selection with RB-transgenic potato at CPRI Campus, Modipuram during winter season of 2009-10 before mid-October.

5.3.3 The Committee conveyed its 'no objection' to the proposal.

Agenda Item No 6: Consideration of applications pertaining to pharmaceuticals

6.1 Permission to manufacture and marketing of (i) Haemorrhagic Septicaemia Vaccine (Gel or oil Adjuvanted) ; (ii) Haemorrhagic Septicaemia and Blackquarter combined Gel or Oil Adjuvant vaccine containing the organism Pasteurella multocida P52 by M/s Intervet India Pvt. Ltd.

6.1.1 The Committee examined the proposal and it was noted that proposal does not fall under the purview of Rules 1989 as per Gazette notification GSR 616 (E) dated 20.9.2006 issued by the MoEF as neither the process nor end product contains LMO.

6.2 Permission for Manufacture and marketing of the live /inactivated vaccines and immune diagnostics in India by M/s Globion India Private Ltd, Secundrabad.

6.2.1 The Committee examined the proposal and it was noted that proposal does not fall under the purview of Rules 1989 as per Gazette notification GSR 616 (E) dated 20.9.2006 issued by the MoEF as neither the process nor end product contains LMO.

Agenda Item No 7: Other items

7.1 Export of BGII RRF cotton hybrids (15 numbers) to Pakistan from India by M/s Monsanto.

7.1.1 Due to paucity of time, it was decided to defer discussion on this agenda item to the next GEAC meeting.

7.2 Representation from M/s. Bayer Biosciences Pvt. Ltd., Hyderabad informing that M/s Greenpeace has raided the field trials of Bt Rice containing *cry1Ab, cry1Ca* and *bar* genes in Chinakanjaria village near Hyderabad.

7.2.1 Due to paucity of time, it was decided to defer discussion on this agenda item to the next GEAC meeting.

7.3 Representation from M/s Monsanto and Ms. Aruna Rodrigues on the illegal sale of herbicide tolerant (HT) cotton seeds in the country.

7.3.1 Due to paucity of time, it was decided to defer discussion on this agenda item to the next GEAC meeting.

The next meeting of the GEAC is scheduled for 9.12.2009

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