Decisions taken in the 85th Meeting of the Genetic Engineering Approval Committee held on 28.5.2008

The 85th meeting of the Genetically Engineering Approval Committee (GEAC) was held on 28.5.2008 in Room No. 623 in the Ministry of Environment and Forests under the Chairmanship of Shri B. S. Parsheera, Additional Secretary, MoEF and Chairman, GEAC.

The deliberations of the GEAC in respect of Agenda Item 3 to 7 are as follows:

Agenda item No. 3: Action taken report.

1.0 The Member Secretary, GEAC informed the Committee that decisions taken in the GEAC meeting held on 2.5.2008 have been communicated to the applicants, State Government agencies and others, as applicable.

2.0 It was also noted that in accordance with the decision taken in the GEAC meeting held on 2.5.2008, the following hybrids were approved for commercial release in the Central / South zones by the Chairman, GEAC based on the report received from the Chairman, MEC:

1. PRCH 504 BG II by M/s Pravardhan Seeds Pvt. Ltd. in the Central Zone
2. NCEH 34 by M/s Nath Seeds Ltd in the Central zone.
3. ABCH-3483 Bt by M/s Amar Biotech Ltd. in the South Zone
4. VBCH 1501 BG II, VBCH 1503 BGII and VBCH 1505 BG II by M/s Vibha Agrotech Ltd. in the Central Zone.

Agenda Item No 4: Policy Issues

1.0 Before initiating discussion on the agenda items, Dr. P. M. Bhargava sought permission to make some general observations with regard to various issues relating to GEAC.

2.0 At the outset, Dr Bhargava expressed his appreciation for the tremendous co-operation and support provided to him by the members of the Committee and the GEAC Secretariat. He commended the Member Secretary, GEAC for the well recorded minutes of the meetings and the efficient work done by her.

3.0 While reiterating his earlier concerns on GM crops, he opined that there is substantial evidence which calls for a total review of India's experience with Bt cotton. He also called for a three to four year total moratorium on GM crops and their products on the grounds as perceived and illustrated by him as follows:

1. The GEAC is relying on biosafety studies (pollen flow, seed germination study, soil microbial studies, toxicity and allergenicity studies, etc., generated by the applicant which is an interested party. There is no mechanism to verify with the experimental and control groups, nor the data is reconfirmed by a third party. Therefore any study conducted by the applicant is of no value and is as good as not having been done.

2. Only acute toxicity studies have been conducted. Taking the example of, aflatoxin he emphasized the need for conducting chronic toxicity. He also pointed out that in the soil microbial studies, it is not enough to have the total number of organisms determined but the bacterial profile and the effect on soil micronutrients are far more important.

3. The pollen flow studies in Bt cotton and Bt Brinjal indicate that pollen flow does take place up to 10 m and 20 m, respectively. This means that in a two hectare farm, approximately one-third of the land will not be available for plantation. This alone, even on the basis of

unconfirmed studies of M/s Mahyco on pollen flow, should rule out the use of Bt cotton by small and marginal farmers representing 84% of our farming community.

4. No GM crop should be released unless appropriate and reliable DNA finger printing, proteomics analysis and studies on reproductive interference in at least three mammalian species have been done by an accredited and independent laboratory with established expertise in the field.

5. All toxicity studies must be done on the protein in the GMO (for example, appropriate extracts or whole parts of the plant). Toxicity studies done with the surrogate protein made, for example, in *E.coli*, should not be accepted.

6. There is a need for a full time testing and validation set up which has been appropriately licensed for staff, facilities, expertise and quality. Till such an independent system is set up which ensure objectivity and impartiality through an appropriate coding system, it would not seem proper to have any Bt cotton hybrid expressing even an approved event, released.

7. It would be appropriate to look at the current scenario in this regard for approval of ethical drugs before they are marketed openly. The approval process of release of GMOs in the environment must, obviously, be far more stringent as a drug, unlike a GMO (especially if it is a variety), can always be withdrawn from the market.

8. There must be a system of professionally trained people for monitoring just as there are FDA inspectors specially trained to check suitability for FDA approval. A system of accountability of the staff trained for this purpose must also be concurrently set up. The system should involve citizen groups, farmers' unions and governmental authorities. In the absence of a professional system, the present field trials are not being conducted and monitored in a proper and scientific manner. As an example, he cited the field trials of Bt okra in West Bengal. It was stated that the applicant has obtained the approval of the Panchayat but has conducted the trials without the prior approval of the State Biotechnology Coordination Committee (SBCC) and District Level Committee (DLC). It was further stated that the GEAC has approved the conduct of field trials in West Bengal, even though the State Government has objected to the same.

9. As of today, there is no GMO that has been released in the environment anywhere, for which we have all the above required information and for which all the tests have been done. Therefore India should adopt a cautious approach.

4.0 In conclusion, in view of the present scenario, he opined that he will not be able to support the proposals under agenda items 4, 5, 6 and 7 until an independent, competent and accredited organization of high public credibility is set up for this purpose, which may take a considerable time.

5.0 The Committee noted the observations and suggestions made by Dr. Bhargava. In response to Dr Bhargava's observations, the Committee reiterated the views expressed by the Members in the meeting held on 2.4.2008 (page 3 to 4, para 4.1.9). In addition the following views were also expressed by members of the GEAC:

1. The concept of testing toxicity and allergenicity is not new and is a common practice in the Pharma sector where the DCGI under the Drugs and Cosmetic, Act, 1940, accepts the data generated by the applicants. In all cases, the world over, accountability is introduced by the method of certification/ declaration by the applicants. Therefore, it will be unfair to mistrust the samples and data generated by the applicant, without any basis. In case of a wrong declaration, penal action can be taken under appropriate law.

2. In India, food safety studies are conducted in public institutions such as Indian Veterinary Research Institute, Izatnagar, National Diary Research Institute, Karnal, Indian Toxicological Research Institute, Lucknow, Avian Research Institute, Rae Bareilly, Central Fish Institute and Education, Mumbai, Rallies India Ltd, Bangalore etc., and their credibility, commitment and competence can not be suspected.

3. There are about 400 known allergens. When a new gene is introgressed into a plant species, it is tested in the first instance for known amino acid sequence which is similar to the known allergens. Further whether a single gene is toxic or non toxic is relative. Even in the case of alfalfa which has a history of known allergens is not toxic *per se.* It is the dose of a substance that makes it toxic or a remedy.

4. On the need for repeating the biosafety studies even though there is extensive scientific data and literature available globally, it was opined by one of the members that there seems to be a contradiction in the statement made by Dr. Bhargava. On one hand, we are not ready to accept the international data available but on the other hand we call for experts from abroad for training our scientific personnel or getting examined the data generated here.

5. While there is no dispute on the need for setting up an independent laboratory or raising the norms for regulatory approval, one has to be practical and realistic taking into consideration the national scenario. The expert member opined that by 'raising bars' as called for by Prof Bhargava, none of the antibiotics being currently prescribed will qualify as antibiotic. Therefore the question that needs to be debated is to what extent 'raising bars' would be acceptable under the present circumstances.

6. The adverse effect of Bt protein reported in the PNAS journal has been challenged by many scientists. About 40 scientists have written to the editor of the journal as the reference quoted by Dr Bhargava has many experimental flaws.

7. The representative of ICMR was in agreement with the views expressed by Dr. Bhargava on the chronic toxicity issue especially in GM foods which are to be use for long periods by human beings.

8. While members supported the suggestion for setting up an independent laboratory for verification of the sample provided by the applicant and validation of the biosafety data, they were unanimous in their view that they do not support a moratorium on GMOs. It was felt that strengthening the regulatory mechanism is a dynamic process and needs to be updated based on scientific facts, experience gained and national requirements.

9. On the issue of Bt okra field trials in West Bengal, it was clarified that the GEAC is the apex body for permitting the field trials of GM crops. The role of SBCC and DLCs is to ensure that the field trials are carried out in accordance with the prevailing biosafety guidelines and conditions stipulated by the GEAC. It was also clarified that the GEAC takes full cognizance of the views expressed by the state government. However, in respect of West Bengal, there have been no such objections from the state regarding the conduct of field trials with GM crops. The state government of West Bengal has only suggested that, in future, while approving the conduct of field trials the applicant may be directed to explore the possibility of conducting the trials in the state agricultural farms instead of long leased land acquired from farmers'.

6.0 After detailed deliberations, it was agreed that a separate brain storming session with the relevant stakeholders be convened under the aegis of the GEAC for review of the Bt cotton experience in India.

7.0 In light of the above deliberations, the following decisions were taken by the GEAC in respect of the agenda items listed below:

4.1 Draft Guidelines for the Conduct of Confined Field Trials of Regulated, Genetically Engineered Plants In India and Standard Operating Procedures (SOPs).

1.0 The draft guidelines for conduct of confined Field trials were adopted with the following amendments:

1. In section 5.5, 2nd sentence may be amended as "A single confined field trial may be comprised of one or more events of a single plant species that are subject to -------."

2. In section 7.1 last para to be amended as "Trial size and number of locations will be decided on a crop by crop basis". During the deliberations, it was pointed out by one of the members that in the three guidelines which are under consideration of the GEAC the word "Genetically Engineered Plants" have been used in place of genetically engineered crops and therefore there is a need to maintain uniformity in the text of the guidelines. After detailed deliberations it was agreed that the term "Genetically Engineered Plants / Crops" may be more appropriate.

3. In section 7.2 the following additions would be incorporated - "Monitoring should be ideally done by trained personnel and efforts would be made to impart training to a maximum number of people within a period of two years. To ensure accountability, the data of the monitoring team must be put in the public domain".

4.2 ICMR Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants in India.

1.0 The ICMR guidelines were adopted without any amendment. The Committee, however, requested Dr. Vasantha Muthuswamy, ICMR to look into the following suggestions made by Dr. Bhargava, which may be considered for suitably amending the Guidelines in due course:

1. The need for extensive DNA fingerprinting and proteomic study.
2. Study of possible interaction with the commonly used drugs (especially pro biotic interferences).
3. Reproductive interference.

4.3 Draft Protocols for Safety Assessment of Genetically Engineered Plants.

1.0 The protocols for safety assessment were adopted without any amendments.

Agenda Item No 5: Consideration of applications for Commercial release of Bt cotton hybrids expressing approved gene event

A. COMMERCIAL CULTIVATION FOR CENTRAL ZONE

Hybrids expressing Cry 1 Ac gene (MON 531 event)

5.1 Permission for commercialization of NCS 138 Bt expressing Cry *1 Ac* (MON 531 event) in the Central Zone by M/s Nuziveedu Seeds Ltd.

Hybrids expressing (Cry 1Ab -Cry 1Ac) "GFM Cry 1A" gene

5.2 Permission for commercialization of Monsoon Bt expressing (Cry 1Ab -Cry 1Ac) "GFM Cry 1A" gene) in the Central Zone by M/s Yashoda Hybrid Seeds Pvt. Ltd.

B. COMMERCIAL CULTIVATION FOR SOUTH ZONE

Hybrids expressing Cry 1 Ac gene (MON 531 event)

5.3 Permission for commercialization of NCS-906 Bt, NCS 907 Bt, NCS 908 Bt, NCS 909 Bt NCS 910 Bt *expressing* Cry 1 Ac (MON 531 event) in the South Zone by M/s Nuziveedu Seeds Ltd.

5.4 Permission for commercialization of Tulasi 9 Bt, Tulasi 45 Bt and Tulasi 118 Bt *expressing* Cry 1 Ac (MON 531 event) in the South Zone by M/s Tulasi Seeds Pvt. Ltd.

5.5 Permission for commercialization of ACH-1 Bt *expressing* Cry 1 Ac (MON 531 event) in the South Zone by M/s Ajeet Seeds.

1.0 The recommendations of SAU/MEC/RCGM/ICAR in respect of NCS 138 Bt expressing Cry *1 Ac* (MON 531 event), Monsoon Bt expressing (Cry 1Ab -Cry 1Ac) "GFM Cry 1A" gene) in the Central Zone and NCS-906 Bt, NCS 907 Bt, NCS 908 Bt, NCS 909 Bt NCS 910 Bt *expressing* Cry 1 Ac (MON 531 event), Tulasi 9 Bt, Tulasi 45 Bt and Tulasi 118 Bt *expressing* Cry 1 Ac (MON 531 event) and ACH-1 Bt *expressing* Cry 1 Ac (MON 531 event) in the South Zone were considered by the GEAC.

2.0 The Committee considered the recommendations of the MEC in its meeting held on 15.4.2008 and 29.4.2008 and by the RCGM in its meeting held on 22.4.2008 respectively. In light of the recommendations made by the MEC and the RCGM and taking into consideration the policy decision to adopt an event based approval mechanism for Bt cotton hybrids expressing approved events, the Committee approved the following hybrids for commercial release in Central and South zones.

1. Monsoon Bt expressing (Cry 1Ab -Cry 1Ac) "GFM Cry 1A" gene) developed by M/s Yashoda Hybrid Seeds Pvt. Ltd.
2. NCS-906 Bt, *expressing* Cry 1 Ac (MON 531 event) developed by M/s Nuziveedu Seeds Ltd.
3. NCS 907 Bt, *expressing* Cry 1 Ac (MON 531 event) developed by M/s Nuziveedu Seeds Ltd.
4. NCS 908 Bt *expressing* Cry 1 Ac (MON 531 event) developed by M/s Nuziveedu Seeds Ltd.
5. NCS 909 Bt *expressing* Cry 1 Ac (MON 531 event) developed by M/s Nuziveedu Seeds Ltd.
6. NCS 910 Bt *expressing* Cry 1 Ac (MON 531 event) developed by M/s Nuziveedu Seeds Ltd.
7. ACH-1 Bt *expressing* Cry 1 Ac (MON 531 event) developed by M/s Ajeet Seeds.

3.0 In respect of NCS 138 Bt expressing Cry *1 Ac* (MON 531 event) it was noted that MEC had recommended the hybrid for commercial release in its meeting held on 18.5.2007. However, it was not clear whether RCGM has recommended the hybrid for commercial release in the Central Zone. The Member Secretary, RCGM was requested to clarify whether the proposal has been recommended for commercial release by RCGM in the Central Zone. The Committee also authorized Chairman, GEAC to take a final view on the matter based on the facts submitted by the Member Secretary, RCGM.

4.0 In respect of Tulasi 9 Bt, Tulasi 45 Bt and Tulasi 118 Bt, the Member Secretary, GEAC informed that the Ministry has received a representation from M/s Mahyco regarding the illegal sale of BG II cotton hybrids in the State of Andhra Pradesh. It has been brought to the notice of the GEAC that M/s Tulasi seeds Pvt. Ltd is selling BG II hybrid expressing stacked gene (MON 15985 event) in the name of Tulasi 4 Bt. (Sri -4 Bt, TCHH-4 Bt) as BG I hybrid expressing Cry 1 Ac (MON 531 event) without the approval of GEAC. The packets of Tulasi 4 BG I were sent to CICR Nagpur, the referral laboratory notified under EPA, 1986 for verification. CICR has confirmed the presence of cry 2 Ab protein.

5.0 The Committee opined that the matter is of a serious nature and needs to be dealt with severely. The legal expert further opined in case of prima facie evidence, the approvals accorded by the GEAC may be revoked subject to further verification. After detailed deliberations, the Committee opined that a 'show cause notice' may be issued to M/s Tulasi Seeds Pvt. Ltd seeking explanation on the complaint received from M/s Mahyco and report of CICR within two weeks time. It was also

decided that until the matter has been resolved, no further approval would be granted to the Company. Accordingly, decision on Tulasi 4 Bt, Tulasi 45 Bt and Tulasi 118 Bt was deferred.

Agenda Item No 6: Consideration of Applications for MLRT/Strip Trials and Experimental Seed Production of transgenic crops expressing new genes/events during Kharif, 2008 as recommended by the MEC/RCGM.

6.1 Multi Location Research Trials (MLRT) of four transgenic stack cotton hybrids namely MRC Application submitted by M/s. Maharashtra Hybrid Seeds Co. Ltd., Maharashtra for permission to conduct 7017 BG-II RRF, MRC 7031 BG-II RRF, MRC 7041 BG-II RRF & MRC 7045 BG-II RRF containing staked *cry1Ac & cry2Ab* genes (MON 15985) & *CP4 EPSPS* Event (MON 88913) in North zone.

1.0 The Committee noted that the present request of the applicant is for permission to conduct MLRT of four transgenic BG II RRF cotton hybrids namely MRC 7017 BG-II RRF, MRC 7031 BG-II RRF, MRC 7041 BG-II RRF & MRC 7045 BG-II RRF containing staked *cry1Ac & cry2Ab* genes (MON 15985) & *CP4 EPSPS* Event (MON 88913) in North zone at six locations. The RCGM in its meeting held on 7.3.2008 has recommended MLRT with the above mentioned Bt cotton hybrids at five locations i.e. Punjab (Bhatinda, Muktsar), Haryana (Hisar and Sirsa) & Rajasthan (Sriganganagar) in North Zone during Kharif, 2008.

2.0 The Committee further noted that the GEAC had accorded permission for conducting MLRT in the South zones after the applicant had complied with the requirement of 200 m isolation distance, submission of a validated event specific protocol at an LOD of 0.01% and name of a lead scientist as directed in the Hon'ble Supreme Court directions dated 8.5.2007. Accordingly the applicant has conducted MLRT at 6 locations (Guntur, Ranga Reddy, Haveri, Dharwad, Coimbatore and Salem) in the South zone during Kharif 2007. The MLRT has been monitored by the MEC. Report of the MEC is awaited.

3.0 The GEAC having adopted an event based approval system, members were of the view that the present practice of hybrid by hybrid testing under MLRT for generating agronomic data is not necessary. The emphasis should be for generating biosafety data with respect to environmental risk assessment and health safety assessment. The Committee also endorsed the decision of the RCGM that MLRT for new gene events should be done maximum at two locations in each zone and with a maximum of two hybrids.

4.0 After detailed deliberation the Committee approved the conduct of confined field trials at two locations with two hybrids in the North Zone for the purpose of generating the following data:

1. To study the weed control efficacy of Glyphosate tolerant trait (MON 88913 Event) with application of Roundup formulation (MON 79770) on BG II RRF cotton hybrid and estimation of protein expression in various plant parts at fixed intervals.
2. To study the field efficacy against bollworm complex secondary lepidopteron pests and effect against non target organisms including soil micro flora and earthworms in BG II RRF cotton hybrids
3. Assess yield potential along with fibre quality traits of BG II RRF hybrids.'
4. To assess reaction of BG II RRF hybrid against Cotton Leaf Curl Virus disease.

5.0 It was also emphasized that MLRT should be undertaken by the applicant either in their own premises, research farms, SAU/ICAR farms. State agriculture farms or long leased land (min of 3 years lease).

6.2 Permission for conducting Experimental seed production of Bt Brinjal by M/s. Mahyco.

1.0 The Committee noted that the GEAC in its meeting held on 8.8.2007 had permitted experimental seed production of Bt brinjal in the research farms of IIVR/ICAR/SAU as per the protocol prescribed by Director IIVR. Dr. Mathura Rai, Director IIVR, Varanasi has informed vide his letter dated 13.9.2007 that the seed production of Bt brinjal may be assigned to the applicant due to non availability of land and skilled labour for seed production. The present request of the applicant is for conduct of experimental seed production at Jalna district, Maharashtra within their institutional research farm as per the protocol approved by IIVR. The Committee noted that the above matter was discussed in the GEAC meeting held on 2.4.2008 wherein it was opined that seed production being the propriety of the applicant, experimental seed production at Jalna may be permitted.

2.0 After detailed deliberations, the GEAC approved experimental seed production of Bt brinjal at Jalna under the supervision of Director Horticulture Research or Director Research of the State Agriculture University located in proximity to seed production area with a view to facilitate the monitoring and supervision mechanism.

6.3 Application submitted by M/s. Dow Agro Sciences India Pvt. Ltd., Mumbai for permission to conduct Multi Location Research Trials (MLRT) with 3 transgenic cotton hybrids expressing *cry1Ac* and *cry1F* proteins (WideStrike = Event 3006-210-23 and Event 281-24-236) at six locations in South zone during Kharif 2008.

1.0 The Committee noted that M/s Dow Agro Sciences India Pvt. Ltd. has developed WideStrike cotton (*Gossypium hirsuitum*, tetraploid, family Malvaceae) var. MXB-13 (Event 3006-210-23: Event 281-24-236) through genetic modification to express insecticidal proteins from Cry1Ac and Cry1F genes for controlling the lepidopteran insect pests. The development of widestrike cotton was initiated in 2005 and has been carried out by the applicant in accordance with the regulatory protocols approved by the RCGM. The present request is for conduct of MLRT of 8 wide strike cotton (WS 102, WS 103, WS 104, WS 105, WS 106, WS 107, WS 109 and WS 110) at 6 locations in South Zone.

2.0 The Committee also considered the recommendations made by the RCGM in its meeting held on 22.4.2008 wherein it was concluded that with the new event based approval system and field trials guidelines in place, the focus of MLRT should be on biosafety assessment rather than agronomic performance

3.0 In view of the observations made by the RCGM, the applicant has informed that the following environmental biosafety data would be generated while conducting MLRT with WideStrike during Kharif 2008:

- *Pollen Flow Study* .
- *Germination, aggressiveness and weediness* .
- *Soil Rhizosphere Studies*, including estimation of Bt protein concentration in Bt cotton and non Bt cotton soil/rhizosphere.
- *Effect on target & non-target organisms*, including beneficials.
- *Any other studies* recommended studies by RCGM/GEAC.

4.0 The Committee also noted that the applicant has complied with the LOD requirement of 0.01% in accordance with the Hon'ble Supreme Court directions.

5.0 After detailed deliberations, the GEAC approved the conduct of MLRT with 2 transgenic cotton hybrids expressing *cry1Ac* and *cry1F* proteins (WideStrike = Event 3006-210-23 and Event 281-24-236) at two locations in South zone during Kharif 2008.

6.4 Application submitted by M/s. Sungro Seeds Research Ltd., New Delhi for permission to conduct Multi Location Research Trials (MLRT) of 2 transgenic Cauliflower (*Brassica oleracea var botrytis*) hybrids namely SCF-1 Bt & SCF-3 Bt containing *cry1Ac* gene during Kharif 2008.

1.0 The Member Secretary, GEAC informed that the applicant has conducted experimental field trials of 10 Bt cauliflower hybrids in July, 2005 to assess the efficacy of the gene against the target pest. The MEC in its 22nd meeting held on 9.5.2006 had directed the applicant to repeat the trial during the next crop season and also include the hot spot locations in the trials. Since the results of the field trials are yet to be evaluated by the MEC, decision on the proposal was deferred.

Agenda item No 7: Other Items:

7.1 Permission for revalidation of Atal BG II expressing Cry 1Ac & Cry 2Ab genes (Mon 15985) for conduct of large Scale trials in the South Zone by M/s Monsanto Genetics India Pvt. Ltd.

1.0 In light of the policy decision to deregulate Bt cotton hybrids expressing approved events from biosafety angle, the Committee opined that large scale trials under GEAC would no longer be applicable and accordingly advised the applicant to follow the new procedure at Agenda Item 4.1 of 83rd meeting of GEAC held on 2.4.2008.

7.2 Request for commercial release Tulasi 4 Bt in the State of Orissa expressing Cry 1Ac (MON 531 event) for in the Central Zone by M/s Tulasi Seeds Pvt. Ltd.

1.0 Decision on the request of M/s. Tulasi Seeds Pvt. Ltd for commercial release Tulasi 4 Bt in the State of Orissa expressing Cry 1Ac (MON 531 even) was deferred until the matter pertaining to violation of Rules 1989 of the EPA 1986) is resolved.

7.3 Representation from Greenpeace regarding illegal GM food imports.

1.0 The Committee carefully examined the representation received from Greenpeace regarding the illegal import of GM food wherein it has been informed that Dorito's Cool Ranch Corn chip which is manufactured by Frito Lays Inc. for Pepsico USA., was detected with GM ingredients. On perusal of the analytical report from Eurofins (Gene Scan) submitted by the complainant it was noted that Corn chips have presence of Roundup Ready Soy in addition to MaxGard Maize (MON- 863) and roundup ready (NK-603) Maize. The Committee was of the view that there appears to be a discrepancy in the analytical report as it indicates the presence of round up ready soy in corn chips. It was agreed that this aspect needs to be clarified.

2.0 The Committee also noted, while the analytical report indicates the limit of detection (LOD) of the method is 0.01%, it does not indicate the percentage of GM content in the sample (whether it is 0.1%, 0.9%, 50% or 100%). After detailed deliberations it was decided in the first instance to seek clarifications from M/s Greenpeace on the above mentioned issues.

3.0 The Committee further agreed that illegal import of GM food in violation to the provisions of Rules, 1989 of EPA, 1986 and Notification No. 2(RE-2006)/ 2004-2009 dated 7.4.2006 para 18 is a matter of grave concern and needs to be tackled at the earliest. Views were expressed that there is an urgent need for issuing a Gazette Notification which makes it mandatory for import of GM food (processed or otherwise) to submit a mandatory declaration that the consignment does not contain GM matter. It was clarified that as per Notification No. 2(RE-2006)/ 2004-2009 dated 7.4.2006 issued by Ministry of Commerce, it is mandatory for all consignments containing product which have subjected to genetic modification to carry a declaration stating that the product is genetically modified. Further, the notification provides for penal action under the Foreign Trade (Development

and Regulation) Act, 1992 in case the consignment does not contain the declaration and later found to contain GM material. It was also agreed that while insisting on mandatory declaration, the threshold for the presence of GM also needs to be defined.

4.0 After detailed deliberations, it was decided a Sub committee comprising of inter ministerial representatives from Ministry of Health and Family Welfare, Ministry of Commerce, Ministry of Food Processing and Industry, Ministry of Environment and Forests and Department of Biotechnology would be constituted by MoEF to look into the above issue and suggest measures for strengthening the border security measures.

7.4 Request from National Seed Association of India regarding the testing of Bt cotton in State Agricultural Universities.

1.0 The GEAC considered the representation received from the National Seed Association of India (NSAI) informing that SAU/ICAR are reluctant to accept the Bt cotton entries for evaluation, as the notification is pending from the Government. As the notification empowering the State Department of Agriculture and SAUs to monitor and evaluate Bt cotton hybrids expressing approved events in cotton crop would take some more time and taking into consideration the seasonality involved, it was decided that ICAR and SAU may be requested to accept entries for testing the hybrids from Kharif, 2008 season. The Committee was also of the view that the SAU trials should be conducted as per the AICCIP procedure under the ICAR system for genotype evaluation.

7.5 Violation of the Rules 1989 and the EPA 1986 by M/s Tulasi Seeds Pvt. Ltd., on illegal sale of BG II cotton hybrids in the State of Andhra Pradesh.

1.0 Decision on the above agenda item may be seen at page 8-9, para 4.0 and 5.0 of agenda item 5.4.

7.6 Posting of Biosafety data on GEAC website.

1.0 The Committee noted that M/s Mahyco has recently submitted the entire biosafety data in electronic form to the GEAC wherein the applicant has classified the information into Confidential Business Information (CBI) and non CBI information. The Committee was of the view that none of the information classified under the CBI merits consideration under this category. The Committee requested the Member Secretary, GEAC to post the entire data on the GEAC website.

7.7 Recommendation of RCGM in respect of applications for conduct of MLRT/SAU trials/Experimental Seed Production of Bt cotton hybrids expressing approved events.

1.0 The Committee considered 68 applications from 19 companies recommended by the RCGM in the 66th meeting held on 27.5.2008 for conducting MLRT/Strip trials and limited seed production of Bt cotton hybrids expressing approved events in the Central and South zones.

2.0 The Committee conveyed its no objection to the proposals subject to strict compliance of the new event based approval procedure adopted by the GEAC. The Committee was also of the view that the SAU trials should be conducted as per the AICCIP procedure under the ICAR system for genotype evaluation.

The next GEAC meeting is scheduled for 25.6.2008.

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