



**COMMITTEE ON AGRICULTURE
(2013-2014)**

FIFTEENTH LOK SABHA

**MINISTRY OF AGRICULTURE
(DEPARTMENT OF AGRICULTURE AND COOPERATION)**

**CULTIVATION OF GENETICALLY MODIFIED FOOD CROPS – PROSPECTS
AND EFFECTS**

**{Action Taken by the Government on the Observations/
Recommendations contained in the Thirty-seventh Report
of the Committee on Agriculture (2011-2012)}**

FIFTY - NINTH REPORT



**LOK SABHA SECRETARIAT
NEW DELHI**

March 2014 / Phalguna, 1935 (Saka)

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Recommendations contained in the Thirty - seventh Report of the
Committee on Agriculture (2011-2012)**

Presented to Speaker	15.03.2014
Presented to Lok Sabha on2014
Laid on the Table of Rajya Sabha on2014



**LOK SABHA SECRETARIAT
NEW DELHI**

March 2014 / Phalguna, 1935 (Saka)

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*Not part of Cyclostyled version of the Report and will be appended in the Printed version of the Report.

(i)

COMPOSITION OF THE COMMITTEE ON AGRICULTURE (2013-14)

Shri Basudeb Acharia - Chairman

MEMBERS

LOK SABHA

2. Shri Narayansingh Amlabe
3. Shri Sanjay Singh Chauhan
4. Shri H.D. Devegowda
5. Smt. Ashwamedh Devi
6. *Shri L. Raja Gopal
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18. Shri Rajaiah Siricilla
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20. Dr. Vinay Kumar Pandey 'Vinnu'
21. Shri Hukumdeo Narayan Yadav

RAJYA SABHA

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26. Dr. K.V.P. Ramachandra Rao
27. Shri Parshottam Khodabhai Rupala
28. Shri Rajpal Singh Saini
29. Shri S. Thangavelu
30. Shri Shivanand Tiwari
31. Shri Darshan Singh Yadav

*Ceased to be the member of the Committee on his resignation form Lok Sabha on 19.02.2014.

SECRETARIAT

1. Shri A. Louis Martin - Joint Secretary
2. Shri C. Vanlalruata - Deputy Secretary

INTRODUCTION

I, the Chairman, Standing Committee on Agriculture (2013-2014) having been authorized by the Committee to submit the report on their behalf, present this Fifty-ninth Report on Action Taken by the Government on the Observations/Recommendations contained in the Thirty-seventh Report of the Committee on Cultivation of Genetically Modified Food Crops – Prospects and Effects pertaining to the Ministry of Agriculture (Department of Agriculture and Cooperation).

2. The Thirty-seventh Report of the Committee on Agriculture (2011-2012) on Cultivation of Genetically Modified Food Crops – Prospects and Effects pertaining to the Ministry of Agriculture (Department of Agriculture and Cooperation) was presented to Lok Sabha and laid on the Table of Rajya Sabha on 09 August, 2012. The Action Taken Replies on the Report were received on 30 November, 2012.

3. The Report was considered and adopted by the Committee at their Sitting held on 03 March, 2014.

4. An analysis of the Action Taken by the Government on the Observations/Recommendations contained in the Thirty-seventh Report of the Committee is given in **Appendix - II**.

NEW DELHI;
03 March, 2013
12 Phalgun, 1935 (Saka)

BASUDEB ACHARIA
Chairman,
Committee on Agriculture

CHAPTER - I

REPORT

This Report of the Committee on Agriculture deals with the action taken by the Government on the recommendations contained in the Thirty-seventh Report of the Committee on Agriculture (2012-2013) on 'Cultivation of Genetically Modified Food Crops - Prospects And Effects' of The Ministry of Agriculture (Department of Agriculture and Cooperation) was presented to the Lok Sabha and laid on the Table of Rajya Sabha on 09 August, 2012.

1.2 The Ministry of Agriculture (Department of Agriculture and Cooperation) have furnished Action Taken Replies in respect of all the 102 Observations / Recommendations contained in the Report. These have been categorized as under:-

(i) Observations / Recommendations that have been accepted by the Government:

Recommendation Para Nos. 1.21, 1.22, 1.23, 2.74, 2.75, 2.76, 2.80, 2.82, 2.87, 2.88, 2.92, 3.35, 3.36, 3.37, 3.38, 3.39, 3.43, 3.44, 4.28, 4.30, 4.31, 4.32, 4.33, 5.43, 5.44, 5.45, 5.54, 6.141, 6.142, 6.143, 6.150, 6.151, 6.152, 6.153, 6.154, 6.155, 6.156, 7.59, 7.71, and 8.115.

(Chapter II - Total 40)

(ii) Observations / Recommendations which the Committee do not desire to pursue in view of the Government's reply:

Recommendation Para Nos. 2.77, 3.45, 3.47, 4.29, 4.34, 5.47, 5.48, 5.55, 7.18 and 7.21. (Chapter III - Total 10)

(iii) Observations / Recommendations in respect of which action taken replies of the Government have not been accepted by the Committee:

Recommendation Para Nos. **1.20, 2.78, 2.79, 2.81, 2.83, 2.84, 2.85, 2.86, 3.40, 3.41, 3.42, 3.46, 3.48, 5.46, 5.49, 5.50, 5.52, 5.53, 5.56, 5.57, 5.58, 5.59, 6.144, 6.145, 6.146, 6.147, 7.19, 7.20, 7.60, 7.61, 7.75, 7.76, 8.116, 8.117, 8.118, 8.119, 8.120, 8.121, 8.122, 8.123, 8.124, 8.125, 8.126 and 8.127.** (Chapter IV - Total 44)

(iv) Observations / Recommendations in respect of which final replies of the Government are still awaited:

Recommendation Para Nos. 2.89, 2.90, 2.91, 5.51, 6.148, 6.149, 7.62 and 7.63.

(Chapter V - Total 08)

1.3 The Committee trust that utmost importance would be given to implementation of the Observations/Recommendations accepted by the Government. In cases, where it is not possible for the Department to implement the Recommendations in letter and spirit for any reason, the matter should be reported to the Committee with reasons for non-implementation. The Committee desire that further Action Taken Note on the Observations/Recommendations contained in Chapter-I and Final

Action Taken Replies to the Recommendations contained in Chapter-V of this Report be furnished to them within a period of three months.

1.4 The Committee will now deal with the action taken by the Government on some of the Recommendations in the succeeding paragraphs.

Regulatory Mechanism for Transgenics and Containment of Trials
(Recommendation Para No. 1.20, 3.40, 3.41, 3.42, 3.48, 5.46, 5.49, 5.52, 5.53, 6.144, 6.145, 6.147, 8.116, 8.117, 8.119 and 8.120)

1.5 The Committee are not satisfied with the replies furnished by the Government in respect of the above-mentioned recommendations. They therefore, reiterate their earlier recommendations and desire that further research and development on transgenics in agricultural crops should be done only in strict containment and field trials should not be undertaken till the Government puts in place all regulatory, monitoring, oversight, surveillance and other structures. The Committee note from press reports that the Minister for Environment and Forests has decided to allow field trials of transgenics which is contrary to the recommendations of the Committee in the Thirty-seventh report. The Committee strongly deprecate this.

Increase in Toxic Alkaloid in Bt. Brinjal
(Recommendation Para No. 2.78)

1.6 Dr. P.M. Bhargava had pointed out that the growing failures of Bt. cotton on the front of resistance to pests it was supposed to kill, increasing attacks of secondary pests, etc. prove that the technology is not sustainable. The death

of cattle and other livestock in Andhra after grazing on Bt. cotton fields also raised doubts about the safety of Bt. cotton as feed. The Committee desired to know how the regulatory mechanism had missed the 30 % increase in toxic alkaloid content in Bt. brinjal and approved it for environmental release, as all these developments could have devastating effects on environment and human and livestock health.

1.7 The Department have replied in their Action Taken Note that the observations of Dr. Bhargava on the growing failures of Bt. Cotton due to development of insect resistance is contrary to the field situations and appeared to be based on allegations made by some activists. They further stated that there are no reports of development of resistance to Bt. protein anywhere in the world so far under cultivated field conditions. All the reports are based on laboratory experiments for understanding the phenomena of resistance development and interpreting these laboratory observations in the context of field situation is not scientifically justified. The main purpose of Bt-cotton is to control bollworms. Bt cotton effectively controlled bollworms, thus preventing yield losses from an estimated damage of 30 to 60% each year in India thus far from 2002 to 2011. Increasing attacks of sucking pests are because of susceptible hybrids and not related to Bt. technology. It further stated that there is adequate scientific evidence to state that cry proteins have not been reported to be toxic to higher animals such as goats, sheep and cattle in any part of the world. The Andhra Pradesh State Department of Agriculture investigated the case of cattle/livestock and sheep mortality in the State due to grazing in Bt cotton fields and the

samples were found to contain high levels of nitrates, nitrites, hydrogen cyanide residues and organophosphates, which might have come from the soil, fertilizer or pesticides used in cotton cultivation and were the cause of animal deaths.

1.8 The Committee had desired to know how the regulatory mechanism had missed the 30% increase in toxic alkaloid in Bt. Brinjal and approved it for environmental release as all these developments could have devastating effects on environment and human and livestock health. The reply of the Government is silent on this point. The Committee would like to know the Government's response in this regard.

THOROUGH PROBE INTO THE BT. BRINJAL CASE
(Recommendation Para No. 2.79)

1.9 On the functioning of the extant regulatory mechanism Dr. P.M. Bhargava had revealed that co-chairman of GEAC, (Prof. Arjula Reddy) had stated that the tests asked for by Dr. Bhargava for assessing Bt. brinjal were not carried out and even the tests undertaken were performed badly and he was under tremendous pressure from industry, GEAC and from the Minister to approve Bt. brinjal. The Committee felt that this was indicative of collusion of the worst kind. The Committee, therefore, recommended a thorough probe into the Bt. brinjal matter from the beginning upto the imposing of moratorium on its commercialization by a team of eminent independent scientists and environmentalists.

1.10 In their Action Taken Note, the Department have stated that the allegation of Dr.P.M Bhargava has surfaced time and again. Ministry of Agriculture decided to get into the depth of this issue. Accordingly, both Dr. Bhargava and Dr. Arjula

R. Reddy were addressed asking them to clarify specific issues. Dr. P.M Bhargava was asked to give specific comments on the following two issues:-

- i) "in retrospect, the only conclusion is that he "succumbed". You are requested to kindly elaborate as to how this conclusion was arrived at.
- ii) "Knowing Monsanto's record and our own, it can be surmised as to how he was brought around"

In response to this letter Dr. Bhargava chose not to respond himself and asked someone else who sent a reply on the Anveshna letter head. For query No. i) Dr. Bhargava's reponse as indicated to DAC was that Oxford English Dictionary clearly gives the meaning of the word "succumb". For query No. ii) Dr. Bhargava responded by citing Monsanto's record for the last half-a-century and government records for dealing with GM crops. Dr. Bhargava mentioned that large number of scientific papers that have been published in well known scientific journals confirm this fact. Also Dr. Bhargava referred the Oxford Dictionary to explain the meaning of the word "surmise".

On the other hand Dr. Reddy gave a detailed response, in response to the following three points raised by DAC :

- i) "The Chairman of EC-II, Dr, Arjula Reddy....was making totally confidential call to tell me that eight of the tests that I had said should be done on Bt. Brinjal and with which he agreed, had not been done"
- ii) "Even in the case of tests that have been done, many have not been done satisfactorily and adequately"

- iii) “He was, however, under ‘tremendous pressure’ to clear the Bt. brinjal and had calls from Agriculture Minister, GEAC and industry”

The response of Dr. Reddy is reproduced below:

- i) “As Dr. P.M Bhargava himself claims that it was a totally confidential call, he breached it by making it public. Nevertheless, it was a normal conversation in which I said that the eight tests suggested by him were not done as those are not actually in the approved protocols by GEAC. It does not certainly mean that I have agreed for these tests. My intention of talking to him was to appraise him about the scientific aspects of several questions he usually raises at the GEAC meetings and it was in the back of my mind that he is going to raise these questions at the GEAC meeting any way. The GEAC discussions earlier also entered on the view that these tests are not expected to contribute significantly.
- ii) This statement is out of context. I said that I am seriously going through the draft report to see whether the tests data and interpretations were done properly .I said that some data were badly interpreted in draft text (sentences were rather awkward) which were corrected later and that took time I also said that I am also seeking clarifications on certain tests from the concerned Government laboratories such as NIN, Hyderabad.
- iii) I said I was under pressure as I was to meet the deadline of the forthcoming GEAC meeting and I already took a lot of time because of my pre-occupation with my official duties as the Vice Chancellor of a new University. There were no specific calls from Agricultural Minister nor from the industry for approval of Bt. Brinjal. Only calls were from the GEAC office to expedite the report as I was taking quite a long time in going through it.

It is unfortunate that he did not understand my intention of calling him and also did not take it in the right scientific perspective. In any event, I do not wish to dwell further on this matter. “

As can we see the above two responses received from Dr. Bhargava and Dr. Reddy, it is clear that the statement of Dr. Bhargava cannot be relied upon as it has been refuted by Dr. Reddy, the person who he has been quoting, often out of context.

1.11 What the Committee had sought was not a response from Dr. Bhargava and Dr. Reddy, but a through probe into the Bt. brinjal matter from the beginning upto the imposing of moratorium on its commercialization by a team of eminent independent scientists. This has not been done. The Committee therefore, reiterate their earlier recommendation of a thorough and independent probe into the Bt. brinjal matter from the beginning upto the imposing of moratorium on its commercialisation.

CHANGE IN THE ROLE OF GEAC
(Recommendation Para No. 2.81)

1.12 The Committee had noted that the demarcation of roles and responsibilities between Ministry of Environment and Forests (MoEF) and Genetic Engineering Approval Committee (GEAC) seemed to be hazy. While Rules 1989 are very clear and unambiguous about the authority of according approval for environmental and commercial release vesting with GEAC, the

information submitted to the Committee by MoEF and GEAC from time to time, for and in connection with the examination of the subject, conveyed an intent to obfuscate the matter. At some places, the authority of GEAC to accord approvals was truly reflected, at others it was couched as 'recommendation of GEAC to accord approval' and at still others it was stated that GEAC accorded approval for environmental release and had no role in commercialization of GM crops. The Committee, therefore, strongly felt that this uncertainty is not in the interest of the regulatory mechanism in place for such a sensitive matter. They, therefore, recommended the Government to come up with a detailed statement clarifying on all aspects of the matter so as to put the ongoing controversies to rest.

1.13 The Department in their Action Taken Note have submitted that as per Rules 1989, under the Environment Protection Act, 1986, regulatory powers for environmental release of Genetically Modified Organisms (GMOs) rest only with the GEAC. It has been further clarified that the commercial use of technology is subject to the laws, regulations and policies of line Ministries in the Central Government and State Governments, who are responsible for deployment of modern technologies in agriculture, healthcare, process industry, environment protection etc. suitable to societal and local needs.

It has been stated further that concurrent to the Parliamentary Committee deliberations, the Scientific Advisory Council to the Prime Minister (SAC-PM) has been discussing the matters related to biotechnology and agriculture and has recommended that "RCGM and GEAC should be the sole authority for

biosafety and bio- efficacy assessment of all recombinant products. Decision on commercial use of biotechnology produced crops should be taken by the Agriculture Ministries/Department of Central and State Governments as per existing policies and regulations on crops. For medical products, Central Drugs Standard Control Organization (CDSCO) of Ministry of Health and Family Welfare, Government of India would approve commercialization as of now”.

1.14 It is observed from the reply of the Government that GEAC will have only regulatory role. It will no longer have the role of according “approval of proposals relating to release of genetically engineered organisms and products in the environment including experiment field trials” as provided for in the Rules of 1989. The Committee in this connection note that the notification No. GSR 613(E) dated 16 July, 2010 has only amended the name of the “Genetic Engineering Approval Committee” into “Genetic Engineering Appraisal Committee” and not amended the role of the Committee. The words “approval of activities” and “approval of proposals” appearing in Rule No. 4(4) of 1989 rules still remain unamended. This would mean that the statutory power to accord approvals is still vested with the GEAC. The Committee expect the Government to look into this aspect and amend the relevant rules (7(1), 8, 10, 11, 12 and 13) suitably under intimation to the Committee.

ORGANIZATIONAL SETUP OF GEAC
(Recommendation Para No. 2.83)

1.15 The Committee noted that GEAC is chaired by a civil servant who also doubles up as Additional Secretary in the MoEF. The Vice-Chairman is also a civil servant and the Co-Chairman of GEAC, a nominee of DBT, is a biotechnologist. The Committee were not satisfied that ensuring environmental safety, health safety, food and feed safety of the entire Country from induction of GMOs has been left at the mercy of such a set-up for these many years. They, therefore, recommended that while reviewing the organizational set-up of GEAC, the Government should also keep this aspect in mind.

1.16 The Department in their Action Taken Note have stated that the composition of GEAC has been prescribed in Rules, 1989 notified under Environment Protection Act, 1986. The GEAC consists of both scientific experts as well as inter- ministerial representatives. Further, expert committees or sub- committees were constituted on a case by case basis providing the necessary support. The decision making process provides adequate opportunity to each member to express and record their views, if any. Besides, scientific evidence and data available on each case is also a key factor in decision making.

1.17 The Committee are aware of the composition of GEAC prescribed in the Rules 1989. The Committee feel that with the change in the role of GEAC from one of 'according approval' to 'appraising proposals', it would be in the fitness of things, if GEAC is headed by a technical expert rather than by a bureaucrat. The Committee hope that the Government will look into this aspect.

FORMULATION OF A POLICY REGARDING MARKER GENE TECHNOLOGY
(Recommendation Para Nos. 2.84, 2.85 And 2.86)

1.18 The Committee noted that Food and Agriculture Organization (FAO) or World Health Organization (WHO) expert panel, International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD) report and several other studies have recommended the use of anti-biotic resistant marker free genes technology while creating GMOs. According to such studies though the possibility of such a transfer is low but any transfer of such genes from Genetically Modified (GM) crops/commodities to cells of the body or to bacteria in the gastro-intestinal tract would be of concern. In our context, while GEAC has stuck to the argument that such possibilities are remote, most of the other ministries/departments whose views were sought by the Committee had shown a marked inclination for technologies without antibiotic resistant marker genes. Most of the independent scientists and other witnesses who appeared before the Committee also expressed their concern on use of anti-biotic resistant marker gene in developing GMOs.

1.19 An overwhelming majority of stakeholders who appeared before the Committee were in favour of use of anti-biotic marker resistant gene free technology. GEAC had, however, taken the stand that since technology for generating marker free technology is available, it is a matter of policy whether to allow GM crops with antibiotic resistance markers. They have also informed the Committee that they had noted this matter in its meeting held on 8 December, 2010 and had found that any decision to disallow release of GM

crops with antibiotic resistant genes would make almost all transgenic plants that are under consideration of GEAC or Review Committee on Genetic Manipulation (RCGM) ineligible for release.

1.20 The Committee expressed their extreme displeasure at the response of GEAC, which showed a complete lack of concern towards its role and responsibility and rather conveyed its strong inclination towards the benefit of industry. The Committee, therefore, recommended the Government to not leave such a crucial decision in the hands of GEAC but to come up with a clear-cut policy in this regard immediately.

1.21 The Department in their Action Taken Note have stated that there is ample scientific evidence that there is no significant, real world hazard associated with the markers that are commonly used. Regulatory decisions for plants containing one antibiotic resistance marker (*nptII*) have been issued in 15 countries including at least one from every continent. Decisions have been made for 12 species of plants representing more than 30 separate transformation events. This includes more than 200 food or feed safety decisions and 80 environmental safety decisions (for *nptII*). These have all agreed that the potential for harm from HGT of antibiotic resistance markers from these GE plants is negligible. Likewise, food and feed safety decisions have determined that the consumption of expressed proteins from antibiotic resistance markers does not present any risk to human or animal health and safety. Several international agencies, like International Food Biotechnology Council, FAO, WHO, US Food and Drug Administration (USFDA), European Food Safety

Authority (EFSA), etc. have deliberated on the issue and given statements with regard to safe use of antibiotic resistance markers.

The Department have stated further that in 2009, EFSA) requested the Panel on Genetically Modified Organisms and the Panel on Biological Hazards (BIOHAZ) to deliver a joint scientific opinion on the use of antibiotic resistance genes as marker genes in genetically modified plants. From all the evidence gathered, the two Panels came to the conclusion that “The current state of knowledge indicates that adverse effects on human health and the environment resulting from the transfer of these two antibiotic resistance genes from GM plants to bacteria, associated with use of GM plants are unlikely.”

It has been stated by the Department that in the global context, there is no ban on GM crops containing Antibiotic Resistance Marker (ARM) even in European Union (EU). Recognising new technologies available at proof of concept stage, the phasing out of ARM in GM crops has been considered by various countries as a future option. The GEAC decision dated December 8, 2011 is also on similar lines.

RCGM also reportedly opined that use of markers for antibiotic resistance is not an issue, since transfer of these genes from transgenic crops to bacteria living in the gut of humans and livestock is an extremely rare event under natural conditions and that antibiotic resistance genes are already found in some bacteria. Furthermore, none of the transgenic crops released for cultivation in the

past is marker-free, and no case of any transfer of marker gene or its toxic effect has ever been reported during the last 15 years of commercialization of crops.

1.22 Regarding the use of anti-biotic marker resistant gene free technology, the Department have stated that perception of stakeholders on possibility of transfer of ARM genes from GM crops to other organisms has no scientific evidence as explained in detail above.

1.23 The Department have stated further that the use of antibiotic marker gene has been the first generation technology with history of safe use as described above and therefore, even the public sector institutions employ these markers for development of GM crop varieties addressing problems of Indian agriculture.

1.24 The Committee are not inclined to agree with the views of the Government that possibility of transfer of antibiotic resistance marker genes from GM crops to other organisms has no scientific evidence. The Committee feel that there should be no compromise even remotely on human health and environment by the use of antibiotic-resistance marker in GM crops. It has been stated that since technology for generating marker gene technology is available, it is a matter of policy whether to allow GM crops with antibiotic resistance markers. The Committee urge that the Government should formulate a policy in this regard without delay keeping the human health and environment in view.

ROLE OF INSTITUTIONAL BIOSAFETY COMMITTEES (IBSC)
(Recommendation Para No. 3.43)

1.25 The 1989 Rules provides for the regulatory mechanism, which consists of six committees, (i) Genetic Engineering Appraisal Committee, (ii) Review Committee on Genetic Manipulation (RCGM), (iii) Recombinant DNA Advisory Committee (RDAC), (iv) State Biosafety Coordination Committees (SBCC), (v) District Level Committees (DLC) and (vi) Institutional Biosafety Committees (IBSC). While GEAC is at the apex body to accord approval for environmental release and commercial release, IBSC is where primary studies and assessments are undertaken and data generation takes place. This IBSC is within the company which intends to market the GMO product being worked upon. RCGM is the body to assess and evaluate the studies undertaken and data generated by IBSC. Recombinant DNA Advisory Committee (RDAC) is advisory in nature, while State Biosafety Coordination Committees (SBCC) and District Level Committees (DLC) are tasked with monitoring at State and district levels respectively.

1.26 The Department in their Action Taken Note have clarified the role of IBSC and stated that it is mandatory for any company/ organisation /institution involved in GMO research to set up an Institutional Biosafety Committee (IBSC) with a nominated external expert by the regulatory system. The mandate of IBSC is of a supervisory nature to ensure that research and development is carried out in a safe manner and regulatory compliance is strictly followed. Therefore on the contrary to statement in the report that “IBSC is where primary studies and assessments are undertaken and data generation takes place”, it may be clarified that IBSC does not generate safety data.

1.27 The Committee had nowhere mentioned that IBSC generates safety data. Hence, the clarification given by the Government “that IBSC does not generate safety data” is unwarranted.

CONFLICT OF INTEREST OF AGENCIES INVOLVED IN EXISTING REGULATING MECHANISM
(Recommendation Para No. 3.46)

1.28 The Committee had observed that GEAC is headed by a civil servant who also functions in another capacity in MoEF, the controlling authority of GEAC. The Co-Chairman of GEAC, though purportedly from outside is nominated by DBT, the promoter Department. The Vice-Chairman is again a civil servant and simultaneously discharging responsibilities in another role in MoEF. By its very composition, the Committee does not have regular existence and meets monthly, only when some decisions are to be taken. There is a serious dearth of scientists of eminence in sufficient number. Therefore, more or less the same set of people sit on both sides to develop technologies/products and also assess/evaluate and approve them as well.

1.29 The Department in their Action Taken Note have submitted that RDAC was set up by DBT in the early years to assist in framing of initial set of guidelines for biotechnology research. Due to diverse and specialized needs of various sectors, subsequently, various other mechanisms such as setting up of task forces, expert committees etc. have been used by various ministries to seek advice with respect to issues on GMOs in agriculture and healthcare.

Further, Biosafety assessment of GM crops is a multidisciplinary and scientific endeavour and so requires multiple kind of expertise. The important scientific subjects include molecular biology, agronomy, breeding, plant pathology, biochemistry, toxicology, etc. In the current, regulatory framework the safety assessment is carried out by statutory committees at three levels; institutional Biosafety Committees (IBSCs) at the institution level and the Review Committee on Genetic Manipulation (RCGM) and Genetically Engineered Appraisal Committee (GEAC) at the national level. Each application is examined critically by about 60 experts covering all the above disciplines, most of whom are external experts from public sector institutions and universities.

It may also be noted that Global Biotechnology Industry in Agriculture, Healthcare and Industrial applications is about US\$ 100 billion and Indian Biotech industry recorded a revenue of around US \$ 5 billion in 2012 with average growth rate of 21% per year. About US \$ 1 billion worth biotech pharmaceuticals are exported from India after regulatory and safety clearances from Indian regulatory system which includes RCGM and DCGI. Therefore, questioning the credibility and expertise available in the country on issues of safety assessment is not appropriate.

DBT and DST along with CSIR, ICAR and ICMR have invested heavily in human resource development and sufficient expertise is available in the country to take care of the regulatory functions. In addition, DBT and MoEF has organized series of training programmes and capacity building activities to create expertise in the safety assessment of GM crops.

About 600 universities, institutions and private sector laboratories with an estimated 3000 scientific and technical people are engaged in R&D and regulatory testing including research field trials. About 120 public sector universities / institutions and 320 private sector colleges and universities are engaged in biotechnology education.

1.30 Having noted the detailed submission of the Government, the Committee are constrained to note that the reply is silent on the question of the same set of people being involved in development of technologies/products and also in assessment, evaluation and approval. The Committee would like the Government to make changes in the composition of GEAC and other bodies so that the conflicting roles played by some of them are done away with.

PROCESS OF EXAMINING DOMESTIC LAWS
(Recommendation Para No. 4.32)

1.31 Nagoya – Kuala Lumpur Supplementary Protocol (N-KLSP) is meant to contribute to the conservation and sustainable use of biodiversity by providing international rules and procedures on liability and redress damage resulting from Living Modified Organisms (LMOs). The Committee were given to understand that as a party to the Supplementary Protocol, a special legislation, in the field of liability and redress for damage resulting from LMOs would be needed to meet the obligations under the Supplementary Protocol as also the proposed The Biotechnology Regulatory Authority of India (BRAI) Bill, 2010 do not address the

concept of damage and sufficient likelihood of LMOs and the response for measures including financial security to take preventive measures.

1.32 The Department in their Action Taken Note have stated that the MoEF has already signed the N-KLSP and initiated the process of examining the provisions before ratification. The Government had been going through a process of examining domestic laws to determine whether domestic rules and procedures already existed that address potential damage, as defined in Article 2 of the N-KLSP. If applicable rules exist, they should be carefully analyzed to ensure compliance with all aspects of the N-KLSP. Where rules do not exist or are insufficient or contrary to the N-KLSP, a comprehensive plan for amendment and/or creation of new legal instruments could be developed. This plan would address all aspects of referenced applicable domestic laws on both the mandatory and discretionary rules and procedures set forth in the N-KLSP.

1.33 The Committee note that the Government is going through a process of examining domestic laws to determine whether domestic rules and procedures already exist that address potential damage, as defined in Article 2 of the Nagoya-Kuala Lumpur Supplementary Protocol. The Committee desire that the whole process should be completed within a time frame under intimation to the Committee and if any gap is found, action to redress the same be taken without loss of time.

POST MARKETING SURVEILLANCE
(Recommendation Para Nos. 5.50, 7.61 and 8.124)

1.34 The IAASTD Report has concluded about the need for a systematic direction of agricultural knowledge, science and technology (AKST) including a rigorous rethinking of biotechnology and especially, modern biotechnology in the decades to come, effective long term environmental, health monitoring and surveillance programmes and training and education of farmers to identify emerging and comparative impacts on the environment and human health and to take timely counter measures. According to IAASTD Report, no regional long term environmental and health monitoring programmes had existed in the countries who are most concentrated with GM foods. Hence, long-term data on environmental implications of GM crop production are at best deductive or simply missing and speculative.

1.35 The Committee had desired to be apprised of the all action taken by the Government with regard to post marketing surveillance, health safety, food and feed safety of the cotton seed oil and other products like cotton cake extracted from Bt. cotton and whether the manufactures of the cotton seed oil and cotton cake derived from Bt. cotton have complied with all relevant laws and regulations laid down for production and marketing of products derived from transgenic materials.

1.36 The Committee also observed that the long term environment impact assessment and chronic toxicology studies of the effects of transgenic agriculture crops have not even been attempted till now. The Government had not yet taken a final call on labelling. There has been a complete lack of post market surveillance, as has been pointed out in one particular example of lacs

of tons of Bt. cotton seed oil having gone into the food chain during last ten years without anybody in the Government being aware or concerned about it.

1.37 The Department of Agriculture and Co-operation in their Action Taken Note have stated that the area under GM crops has been increasing exponentially since these were first commercialized in 1996, with more and more countries adopting the modern biotechnology. The global area under GM crops in 2011 has reached to 160 million hectares in 29 countries, thus indicating their acceptance globally. No product has ever been withdrawn by regulatory authorities in any country.

The Department have further stated that the IAASTD report has underestimated the potential of new technologies relative to existing technologies. Hence, rigorous rethinking of biotechnology and especially modern biotechnology as suggested to by the Committee seems out of place. Government is committed to continuously learn and evolve its regulatory procedures based on its home grown experience and scientific data generated worldwide. In addition, Government in accordance with its accepted policies is open to exploring all options that leads it towards food security, well being of farmers and making agriculture an economically viable proposition.

Regarding the issue of long term environmental and health monitoring programmes, the Department has clarified that the safety assessment of a GM crop encompasses two components *viz.* food and feed safety and environmental safety. Regulatory authorities undertake a detailed pre-release assessment on

both aspects before permitting their commercial cultivation. Regarding food and feed safety, the post release marketing of GM foods or any food in terms of safety aspects is not scientifically feasible. While post approval monitoring in case of drugs or any single chemicals produces useful sentinel data on drug safety and adverse effects, in such cases, people who provide a detailed history are taking a highly defined substance where there is already an idea of the types of adverse health effects that may be found. In contrast, any post market monitoring of GM foods would be of a population consuming different amounts at different times and in different ways amongst all other food intake, and with no particular health outcome in mind. The health effects observed may be vague, and may not be attributed to a particular cause. These factors make it unlikely that an adverse health effect due to any food or GM food could be detected above all the other health effects in the general population. In the light of above, regulatory authorities across the world focus on safety assessment before the food is placed on the market and the same is also reflected in the consensus documents by FAO, WHO, Codex Alimentarius, Organization for Economic Cooperation and Development (OECD) etc.

It has been stated further that the need for post-release environmental monitoring is determined on a case-by-case basis, taking into account familiarity with the plant species and trait. Bt cotton, with a history of safe use has been subjected to post release monitoring by Central Institute of Cotton Research with respect to monitoring of development of insect resistance in the target insect population.

Regarding the general surveillance of Genetically Engineered (GE) crops, it has been stated that while countries like USA, Canada and Australia have no specific requirements, an attempt was made by Brazil to enforce a general monitoring, in case of herbicide tolerant soybean, but even after four years of detailed field studies no harm was observed, as expected. In the light of this experience, Brazil has already modified its guidance and done away with the complex requirements.

1.38 It has been stated further that Bt. cotton has been in cultivation for the last 16 years with no report of any negative impact on health and environment. Even in the ICAR animal feeding trials on lamb, it was noted that the animal did not exhibit any detrimental effects attributable to Bt. cotton. This led to the conclusion that “feeding of Bt. cotton to lambs did not alter immunity status” as evidenced by increased RBC and decreased WBC in the gut of the lamb fed with Bt cotton seed. Similar studies published in international journals also support these conclusions. Further, long term studies for over 25 months based on cows feeding on Bt corn whole crop silage, kernels, whole-cobs also support these results (Ref: Steinke et al. 2010; Journal of Animal Physiology and Animal Nutrition)

1.39 The Committee had desired to be apprised of the steps taken by the Government regarding post marketing surveillance, health safety, food and feed safety of the cotton seed oil and other products like cotton cake extracted from Bt. Cotton and whether the manufactures of the cotton seed oil and cotton cake derived from Bt. Cotton have complied with all relevant

laws and regulations laid down for production and marketing of products derived from transgenic materials. In response, the Government have inter-alia stated that the post release marketing of GM foods or any food in terms of safety aspects is not scientifically feasible. It has been stated that “any post market monitoring of GM foods would be of a population consuming different amounts at different times and in different ways amongst all other food intake, and with no particular health outcome in mind. The health effects observed may be vague, and may not be attributed to a particular cause. These factors make it unlikely that an adverse health effect due to any food or GM food could be detected above all the other health effects in the general population”. The Committee do not agree with this view. The Committee feel that it is a question of evolving a system of collecting and monitoring reports from health centers about novel cases involving GM food consumption and attempting to study the pattern regarding health effects for appropriate remedial action. The Committee would appreciate intimation of steps taken in this regard.

Conservation of Biodiversity
(Recommendation Para No. 5.51)

1.40 The Committee observed that while there is awareness and appreciation of the various findings contained in IAASTD Report and a lot of preparatory action is available in documents, purposeful and definitive action towards adopting and implementing sustainable and environment friendly practices and technologies in agriculture and allied sectors which will conserve biodiversity and

also ensure safety of human and livestock health had not been initiated in right measures.

1.41 The Department of Agriculture and Co-operation in their Action Taken Note have stated that the National Agriculture Research System (NARS) with its extensive network of research institutions along with State Agriculture Universities (SAUs) have been continuously working towards identifying suitable technologies and developing sustainable and environmental friendly practices in agriculture. Several initiatives such as Task force, constitution of expert committees, framing of policy guidelines are a continuous process and these update as well as guide the proposed agenda. Indigenous recommendations for making agriculture more competitive as well as sustainable are more comfortable rather than drawing conclusions from IASTTD, which has only provided sweeping generalised statements. In fact, the Independent Evaluation Group, a unit within the World Bank group in its Global Programme Review has noted that IASTTD had limited representations of farmers and those closest to them. There was predominance of international Non-Government Organizations (NGOs) over national and local NGOs and therefore local knowledge representation was found to be inadequate.

1.42 The Committee had pointed out that purposeful and definitive action towards adopting and implementing sustainable and environment friendly practices and technologies in agriculture and allied sectors which will conserve biodiversity and also ensure safety of human health and livestock health is unfortunately yet to be initiated. The Government in their reply

have not indicated what specific initiatives have been initiated in this regard. The Committee would await information in this regard.

Merits and Demerits of GM Crops
(Recommendation Para No. 5.56)

1.43 GEAC had approved the commercial release of Bt. Brinjal as the apex regulatory body for the purpose in the Country. The same agency has been holding the judgment on the merits and demerits of GM crops, in general, and Bt. Brinjal in particular, which is a clear case of conflict of interest. The Committee, therefore, recommended that evaluation of various reports on this matter should be done by some other agency such as Council for Scientific and Industrial Research (CSIR), since they not only have sufficient expertise in this regard but also have minimum conflict of interest amongst the various public sector scientific institutions. The Committee also felt that the examination of various reports had to be expedited and results conveyed to them at the earliest so that a final view in the matter is facilitated without any further delay.

1.45 The Department in their Action Taken Note have stated that the GEAC is a statutory body under Rule 1989 for according approval for environmental release of GMOs. The GEAC is well represented by CSIR. DG, CSIR is a statutory member of the GEAC as also its nominee.

1.46 The Committee had recommended, among other things that the examination of various reports on the merits and demerits of GM crops in General and Bt. Brinjal in particular has to be expedited and results conveyed to them at the earliest. There is nothing in the reply of the Government to indicate whether examination of various reports has been completed and what is the outcome of its examination. The Committee would appreciate a detailed reply in this regard.

Evaluation of Environmental Risks
(Recommendation Para No. 5.57 and 5.58)

1.47 The Committee had noted that the Report of Prof. David A. Andow on Bt. Brinjal is a scientific evaluation of the scope and adequacy of environmental risk assessment of transgenic EE-1 Bt. Brinjal. The Report has criticized GEAC for setting a narrow scope for environmental risk assessment of Bt. Brinjal due to which the assessment of Bt. Brinjal by Expert Committee–II was not adequate. Amongst the possible environmental risks that have not been adequately evaluated include risks to local varieties and wild relatives, risk to biological diversity and risk of resistance evolution in Brinjal fruit and shoot borer.

1.48 The Department in their Action Taken Note have stated that the information generated on GM crops from discovery to market involves three important aspects i.e. biosafety assessment on scientific basis, bioefficacy of targeted genetic intervention and other technology transcending issues such as farming conditions, socioeconomic analysis etc. The reports referred to by the petitioners quoted large mix of all these issues lacking clarity and with theoretical

and non-pragmatic approach. The Committee's report itself states that several stakeholders who are against transgenic crops have cited this report. The environmental safety assessment by GEAC is in line with international approaches and Indian regulatory requirements. The risks mentioned by the Committee have been adequately covered in EC-II report.

1.49 The Committee had pointed out, among other things, that amongst the possible environmental risks that have not been adequately evaluated include risks to local varieties and wild relatives, risk to biological diversity and risk of resistance evolution in brinjal fruit and shoot borer. The Government have not responded to these specific concerns of the Committee. The Committee desire on expeditious evaluation of these risks and intimation of results thereof.

Expeditious Evaluation of Reports
(Recommendation Para No. 5.59)

1.50 In the opinion of the Committee, Bt. Brinjal, unlike Bt. cotton is a food crop and it would have been the first such endeavour in India of a technology on whose safety and sustainability the last word is yet to be heard. Further, the contents of the report are still under examination as post moratorium follow-up. The Committee were of the opinion that since the matter pertains to human health, any amount of time and money spent on any number of studies and analyses to evaluate the product is justified. Mere referring to best global practices and internationally laid down norms would not suffice. The Committee, therefore, recommended that the Government should get all the reports

evaluated and examined by any agency other than GEAC like CSIR, etc., strictly in national interest on the basis of scientific merits.

1.51 The Department in their Action Taken Note have stated that the regulatory guidance and evaluations are the result of a long period of consultations and consensus building based on participation of large number of subject specific experts and other stakeholders at both national and international level. Published literature from peer reviewed journals is taken into account while deliberating on various issues.

1.52 The Committee reiterate their earlier recommendation regarding expeditious evaluation of the reports by an agency other than GEAC and would like to be apprised of the outcome of the evaluation.

DECISION MAKING PROCESS IN COMMERCIAL RELEASE OF Bt. COTTON (Recommendation Para No. 6.146)

1.53 Though Bt. Cotton is a cash crop which in no way would have contributed to the food security of the country, yet lakhs and lakhs of hectares of land have got diverted to Bt. Cotton cultivation because of misconception about its potential, leading to reduction of area of cultivation of several food crops during these years and thus jeopardizing the country's food security to that extent. Also, due to the popularity of Bt. Cotton, countless number of traditional varieties of cotton have been wiped out. The same fate would have befallen our traditional varieties of brinjal had the moratorium not been placed on the commercialization of Bt. Brinjal. Taking a very serious note of this matter, the Committee had

recommended that an in-depth probe may be carried out to track the decision making involved in commercial release of Bt. Cotton right from the initial stage.

1.54 The Ministry of Agriculture in their Action Taken Note have submitted that it would be to take a narrow view to link increased acreage under cotton to jeopardising food security. Relying on figures of increased foodgrain production it can be seen that India has made considerable increase in food grain production and the year 2010-2011 accounted for record food production of 244.78 million tones, as per final estimates of the Department of Economics and Statistics under the Ministry of Agriculture.

Further it is clarified that total acreage under cotton crop remained almost same all these years. The area under cotton crop in India was 8.9 million hectares during 1997-98 and 9.2 million hectares during 2008-09. The productivity increased from 302 kg/ha in 1997-98 to 591 kg/ha in 2008-09. Therefore, there has been no negative effect of cultivation of Bt cotton on the food security in the country

DAC has played a responsible role and attaches great importance to NPF 2007, which is why it endorsed release of Bt. Brinjal. Brinjal cultivation consumes maximum quantity of pesticides after cotton. As indicated in section 6.145, experience of cotton itself shows that we could prevent-12,738 tons of pesticides getting released annually into the environment. Before the introduction of Bt cotton, insecticide quantity applied on cotton was the highest relative to other cultivated crops. By the mid 1990s Indian cotton farmers were spending

>43% of the variable costs of cotton production on insecticides, around 80% of that being for bollworm control and in particular *Helicoverpa* control. Insecticide use on cotton was 50% of all insecticide use in the country and as a result cotton production was being rendered uneconomic in many regions of the country. The area under cotton in the country has increased in recent years as compared to the coverage of 2008-09 as farmers in the new regions are coming forward to this crop for remunerative price and higher net income especially as compared to Jowar, Bajra, upland rice and other crops. Recognizing, this trend DAC has taken adequate measures to promote intercropping food crops with cotton to maintain the area and sustainability of food grains production to some extent.

Farmers also cultivate non-food crops as they have other uses for man, like cotton, which provides clothing. Any technology, including Bt. Cotton if enhances the productivity of the crop with reduced use of chemicals, the ultimate beneficiary will be the farmers in terms of realisation of higher income. Therefore, there appears nothing wrong in commercial cultivation of Bt cotton, though as stated in the earlier para, Bt cotton adoption was a reflection of farmers' free will in choosing a technology, which he feels is right for him.

1.55 The Committee had, inter-alia, pointed out that countless number of traditional varieties in natural form of cotton have been wiped out and recommended that an in-depth probe may be carried out to track the decision making involved in commercial release of Bt. cotton from the initial stage. There is no response from the Government on these points. The Committee reiterate that as already recommended, an in-depth probe

be conducted into the matter without further delay and the Committee be informed of the outcome.

Special Medicinal Properties in Traditional Brinjal
(Recommendation Para No. 6.150)

1.56 The Committee had conveyed their unhappiness over the failure of the Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy) to bring the matters regarding with their advice on Bt. Brinjal not being heeded by Ministry of Environment and Forests, their representation in GEAC being staggered to subsequent years, etc. to the appropriate authorities meant to sort out such inter-ministerial issues. The Committee had further desired a detailed explanation from GEAC as to what action they had taken on the serious reservations expressed by Department of AYUSH in regard to commercialisation of Bt. Brinjal and other plants having medicinal properties. The Committee had also desired a detailed explanation from Ministry of Environment and Forests on their refusal to co-opt the representatives of Department of AYUSH on GEAC right away when Bt. brinjal had been approved for commercial release and several other crops having medicinal properties are already being assessed for approval by Review Committee on Genetic Manipulation (RCGM)/GEAC.

1.57 The Department in their Action Taken Note have stated that the representatives of the Department of AYUSH (Ayurveda, Unani and Medicinal Plant Board) in the meeting of the GEAC with experts on 27.4.2011 opined that

their concern is limited to the fact that brinjal had a special medicinal advantage in traditional system of medicine. They had suggested that compositional comparative analysis of both traditional brinjal and Bt. Brinjal to ascertain the alteration, if any, in the bioactivities, nutritional and medicinal values. It had been further recommended by AYUSH that such studies may be conducted in public sector institutions such as Central Drug Research Institute (CDRI), Lucknow, National Institute of Nutrition (NIN), Indian Institute of Integrated Medicine (IIM) and others. In response to the above observations, Department of AYUSH had been requested to provide the information based on which appropriate follow-up action to identify and estimate such components in the Bt. Brinjal under consideration will be carried out as additional components of compositional equivalence studies.

1.58 It appears from the reply of the Government that neither the Department of AYUSH nor the GEAC is serious about expeditiously addressing the concerns of the former regarding the issue of special medicinal properties in traditional brinjal and Bt. Brinjal. There is nothing in the reply to show as to when AYUSH was requested to give details of information to enable compositional comparative analysis and whether the requisite information has since been furnished by them to undertake studies by Central Drug Research Institute, Lucknow, National Institute of Nutrition, Indian Institute of Integrated Medicine. The Committee desire this information and would also like to be apprised of the outcome of the aforesaid studies, if already completed.

Food Safety and Standards Authority of India (FSSAI)
(Recommendation Para Nos. 6.154, 6.156 and 8.123)

1.59 The Committee in their Twelfth Report (Fourteenth Lok Sabha), presented to the Parliament on 20 April, 2005 had laid stress on the need for a single regulatory body and an integrated food law to obviate the confusion created by the multiplicity of laws. The Committee had noted that the Food Safety and Standards Act was enacted on 24 August, 2006. However, the mechanism to enforce it was badly delayed and the Authority came into being only on 5 September, 2008. Due to teething troubles the Authority could start functioning only from January, February, 2009. The Committee had noted that FSSAI had been allocated sums of Rs. 8.00 crore, Rs. 21.00 crore and Rs. 32.37 crore respectively in the first three fiscals of their existence viz. 2008-09, 2009-10 and 2010-11. The FSS Act, 2006 has come into force w.e.f. 5 August, 2011 and the Authority has been functioning without any worthwhile infrastructure and manpower at the Central and State levels to enforce the Act. All work pertaining to strengthening of FSSAI Headquarters; development of science based standards; food testing facilities; surveillance mechanism at both Central and State levels have been being badly delayed because of paucity of funds. The Food Safety and Standards Regulations which were published in November, 2010 for inviting public comments had not been finalized. The database for the Risk based food clearance system had not been developed. Food Testing Laboratories network was in shambles, accreditation procedure for referral labs have not been devised.

1.60 The Committee had exhorted the Government to allocate requisite funds to the Authority on priority basis.

1.61 The Department in their Action Taken Note have stated that the FSSAI and the Ministry of Health and Family Welfare are fully apprised of this situation and during 12th plan adequate financial support and expansion plans have been proposed.

1.62 The Department have stated further that like any other science, in GM technology too, new issues emerge for which a continuous system of learning, evolving is needed. The Government is fully aware of this and acting upon making systems updated. Protection of Plant Varieties & Farmers' Rights Authority (PPV&FRA) and National Biodiversity Authority (NBA), have made significant achievements even though the legislations have been a new area.

1.63 The Committee had pointed out the shortcomings in the functioning of Food Safety and Standards Authority of India (FSSAI) due to paucity of funds, inordinate delay in finalisation of Food Safety and Standards regulations, delay in development of data base for the Risk based food clearance system and delay in devising accreditation procedure for referral labs. The Government appears to have drawn satisfaction by simply stating that FSSAI and the Ministry of Health and Family Welfare are fully apprised of this situation and during 12th plan adequate financial support and expansion plans have been proposed. The Committee would like to be informed of the details of financial support and expansion plans during the

12th plan and whether Food Safety and Standards have since been finalised and if not, reasons for delay. The Committee would also desire to be informed of the status of development of database for the Risk based food clearance system and accreditation procedure for referral labs.

ABSENCE OF MONITORING MECHANISM
(Recommendation Para No. 6.155)

1.64 In the opinion of the Committee, the Government should have realized the magnitude of the task to be performed by FSSAI. Apart from regulating local food and food products, the Authority has to ensure food safety of food items imported into the Country. Imports in India are permitted through 255 entry points. These include 82 custom ports, 32 customs airports, 132 land customs stations and 9 foreign port offices, sub foreign post offices. During 2007-08 and 2008-09, 76 lakh metric tonnes of food items were imported into the Country. For the Committee, the most worrying aspect in the matter had been the admission of the representative of Directorate General of Foreign Trade before the Committee during oral evidence that there were absolutely no monitoring of the food items being imported into the Country.

1.65 The Department in their Action Taken Note have stated that the FSSAI and the Ministry of Health and Family Welfare are fully apprised of this situation and

during 12th plan adequate financial support and expansion plans have been proposed.

1.66 The Committee take a serious view that there is no response from the Government on the question of absence of monitoring mechanism regarding safety of food items imported into the Country. Failure of Food Safety and Standards Authority of India (FSSAI) in this regard, which has been in existence for the last five years, is glaring. The Committee would like to know what steps have been proposed and how soon will these be implemented to ensure safety of food items imported into India.

FIELD TRIALS OF TRANSGENIC CROPS IN VARIOUS STATES
(Recommendation Para Nos. 7.19 & 7.20)

1.67 In regard to field trials of transgenic crops, the Committee had observed that while some States like Kerala and Uttarakhand have decided to keep their State totally GM free, others like Bihar, Madhya Pradesh and Rajasthan have disallowed field trials, while Maharashtra, Tamil Nadu, Karnataka, Andhra Pradesh, West Bengal, Punjab and Haryana have allowed field trials and Himachal Pradesh will take a view on Bt. Brinjal once all trials are completed and Government of India have taken a decision in the matter.

1.68 In their Action Taken Note, the Department have stated that the decisions on banning or other wise of field trials of GM crops should be guided by a well reasoned scientific decision and guidelines operational under the existing regulatory frame work. The regulatory framework already provide for constitution of State Biotechnology Advisory Committees chaired by Chief Secretary with line

ministries/departments as members. The whole issue is that many states listed have not constituted such committees or where constituted have not been functional to address issues related to GMOs. Using Ad-hoc and reactive mechanisms guided by emotions and impulses is not an appropriate approach to prevent or agree to the conduct of field trials when the existing regulations, under an act of Parliament, are not complied with. The states need to analyse the issue of GM crops on scientific basis. As indicated in section 7.18, the SAC-PM report has also suggested measures for resolving these issues

It may be reiterated that the evaluation of plant performance (suitability to a condition of production) in the natural environment is a key component of crop development, and GM crops are no exception. Field studies enable researchers to evaluate environmental safety of GM plants and collect bio safety data required for necessary regulatory authorization and in addition promotion of plant materials, such as seed and forage. These are produced using small confined field trials and collected to perform compositional analysis and other testing necessary to demonstrate food safety. Green house study cannot be performed at a scale sufficient to comply with these regulatory requirements. Without this field data, researchers cannot make scientifically tenable predication about the performance of plants in the field or about the environmental safety of the plant.

The issue of permitting field trials is entirely a science based issue. GOI is of the view that field trials are done as per safe practices as alluded above and accordingly the states shall have no objection in conduct of such trials in due course.

1.69 The Government have stated that the issue of permitting field trials is entirely a science based issue and field trials are done as per safe practices and accordingly States have no objection in conduct of such trials in due course. Also, decisions on banning or otherwise of field trials of transgenics should be guided by a well reasoned scientific decision and guidelines operational under the existing regulatory frame work. However, the Committee are of the strong view that unless and until a comprehensive, transparent, effective and professional regulatory system is in place, there exists no scope for field trials of transgenics. They, therefore, reiterate that a comprehensive and effective monitoring mechanism for transgenics crops is put in place at the earliest, before any field trials are undertaken.

**Check on GM Processed Food
(Recommendation Para No. 7.60)**

1.70 There had been no check on GM processed food and other items coming from outside the Country or being produced here viz. cotton seed oil produced from Bt. cotton. To compound this inaction further, the Government had been entrusting this responsibility to the proposed BRAI. In the opinion of the Committee the delay in bringing GM food and products, had not been a simple act of oversight or a genuine inability to do the needful and needed to be thoroughly investigated and responsibility for this callous neglect of health safety be fixed at the earliest. The Committee desired to be apprised of the results of the investigation and the action taken in pursuance thereof.

1.71 The Department in their Action Taken Note have stated that the issue of regulations on labelling of transgenic food products is complex and sensitive matter in terms of trade, farming practices from land to markets, export and import and challenges of implementation being an inter-ministerial matter. It requires techno-economic feasibility study on a large scale including implication on price of food and affordability due to additional cost. Studies published in Australia, India (from JNU policy research group) and Philippines have shown that consumer has to bear additional cost (a minimum of 10%) in case GM labelling is introduced. In many countries where labelling regulations are in place, the implementation and monitoring is highly challenging task and has shown mixed results.

1.72 The Committee had pointed out that there is no check on GM processed food and other items coming from outside the Country or being produced here viz. Cotton seed oil produced from Bt. Cotton in the Country. The Committee also opined that the delay in bringing imported GM food and products, thereof, is not a simple act of oversight or a genuine inability to do the needful and needs to be thoroughly investigated and responsibility for this callous neglect of health safety be fixed at the earliest. The Committee are dismayed to note that the Government have not given any response to this recommendation of the Committee. The Committee reiterate their earlier recommendation and urge the Government to investigate the matter without further loss of time under intimation to them.

ALLEGATION OF BIO-PIRACY
(Recommendation Para Nos. 7.75 And 7.76)

1.73 A report appeared in media about a case of 2010 pertaining to alleged misappropriation of local brinjal varieties by M/s Mahyco and others. Allegations about continued inaction of the Authority in respect of this case were also reported in the media. The Committee had sought a detailed explanation from the National Biodiversity Authority in the matter. According to NBA on the basis of a complaint alleging biopiracy by Monsanto and its corporate in development of Bt. Brinjal, the Authority had began investigating the matter with the help of Karnataka State Biodiversity Board. Information and inputs from the institutions and agencies involved in the development of said Bt. Brinjal material were procured and legal assessment of the same had been undertaken considering the elements and extent of violation of the provisions of Biological Diversity Act. Between August and October, 2011 further information had been sought from the agencies involved in the development of this material. NBA had also informed the Committee that a subsequent application of M/s Monsanto Holding Private Limited for accessing onion material developed by Indian Institute of Horticulture Research, ICAR, Bengaluru had not being cleared.

1.74 The Committee were not convinced by the dilatory response of NBA on whether the Company in question had obtained any local biological resource for and in connection with development of Bt. Brinjal without prior approval of NBA and violated Section 3 of Biological Diversity Act, 2002. The delayed conclusion on this simple issue shows the NBA in a poor light. It would have been worth

mentioning that during this period, i.e. from 11 November, 2010 to 11 August, 2011, Chairman, GEAC had been also holding the charge of Chairman, NBA. The Committee had not only desired a thorough inquiry in the matter of delay in decision making on a case of this magnitude but also had recommended that the NBA should decide upon this case without any further delay.

1.75 The Department in their Action Taken Note have stated that NBA has been in the process of resolving the issue as per the provisions of the Biological Diversity Act, 2002.

1.76 The Committee had desired that the inquiry regarding alleged bio-piracy by a company in development of Bt. Brinjal be completed and a decision taken regarding the case, without delay. It appears from the reply of the Government that the inquiry is yet to be completed. The Committee fail to understand why the inquiry could not be taken to logical conclusion during the last three years. They reiterate that the matter be resolved without any further loss of time.

EFFECTS OF TRANSGENIC CROPS ON ENVIRONMENT, HUMANS AND LIVESTOCK

(Recommendation Para No. 8.118)

1.77 The Committee critically analyzed the evidence for and against transgenic agriculture crops and had not limited their analysis to pure science. Some of the most compelling concerns factored in by the Committee include, India's rich bio-diversity and agriculture which provide sustenance to almost 70% of the rural populace, more than 70% of India's farmers being small and marginal farmers for

whom agriculture is not a commercial venture, but a way of life and a means of survival, the irretrievability of side effects of transgenic crops on the environment, human and animal health, etc.

1.78 The Ministry of Agriculture in their Action Taken Note submitted that the Environment and Production Technology Division, International Food Policy Research Institute (IFPRI) a CGIAR institute undertook a study in October 2008 on “Bt Cotton and Farmer Suicides in India” to review the evidence on the alleged resurgence of farmer suicides in India and the potential relationship between the adoption of Bt cotton and suicides among Indian farmers. It is shown that “media hype around farmer suicides, fueled by civil society organizations and reaching the highest political spheres in India and elsewhere, there is no evidence in available data of a “resurgence” of farmer suicide in India in the last five years” The report “provide a comprehensive review of available evidence on the effects of Bt cotton in India and find that Bt cotton technology has been very effective overall. Using macro data on productivity and a synthetic review of results from micro-level studies, it is shown that on an average Bt cotton has had a significant positive effect on cotton productivity in India, raising farmers’ income via an increase in yields and a reduction in pesticide use. Overall, analysis shows that, without a doubt, Bt cotton is not a necessary or sufficient condition for the occurrence of farmer suicides or agrarian crisis. Therefore, it should not be blamed for the resurgence of farmer suicides in the field. In contrast, other factors have almost certainly played an indispensable role

in these cases, especially the insufficient or risky credit systems with no formal or informal support and the wide availability of toxic pesticides.”

Study reports of Planning commission and DAC detailed elsewhere in this submission also explain the agrarian crisis in the same context

Thus, it is now time to unshackle our farmers from undertaking agriculture for survival, to making it as an economically viable option for livelihood. To maximise returns on his inputs and labour, since India is rainfed and water for irrigation on premium, new technologies and GM crops assume greater significance. Rather, the very reasons that are being cited for stopping transgenic research crops and release are the very reasons why India should adopt it.

1.79 The committee are not satisfied with the reply of the Government. The reply is conspicuous by its silence on the concerns expressed by the Committee about the side effects of transgenic crops on the environment, human and animal health and on our bio-diversity. The Committee would await the Government’s response on the concerns expressed by them.

REFORMS IN CURRENT REGULATORY SYSTEM
(Recommendation Para No. 8.121)

1.80 The Internal Bio-Safety Committee functions in the promoter company and performs all basic assessments and evaluations of a transgenic product being developed by that very company. It also generates data on the basis of which RCGM and GEAC base their evaluation. This mechanism does not

inspire confidence for obvious reasons. The Department of Biotechnology which is mandated with the promotion of bio-technology in the Country, funds various transgenics research projects and activities both in public, as well as, private sector companies. This funding is of a significant order. The transgenic products created through these projects and activities are then assessed and evaluated by an adjunct of Department of Biotechnology (DBT) viz. RCGM. On top of it, the final approval for environmental/commercial release is granted by GEAC which is co- chaired by a DBT nominee. With the Chairman of GEAC as well as the Vice Chairman being civil servants, it is not very difficult to appreciate the primacy of DBT nominated Co-chair in GEAC in the decision making process. The Committee, in spite of DBT's protestations to the contrary, had strong reasons to agree with the opinion of several stakeholders that in a regulatory set-up where the promoter has an overwhelming say and presence in the regulatory mechanism, an element of subjectivity in assessment and evaluation is unavoidable. The entire system, therefore, reflected a pro-DBT/pro-industry tilt which has best avoided. Apart from this major shortcoming, the Committee's examination had revealed that the extant system has been grossly inadequate and antiquated to face the typical challenges a population intensive, agrarian economy like India poses when the question of introduction of such modern technologies in agriculture sector crops up.

1.81 The Department have stated in their Action Taken Note that the matter has been under discussion for sometime in the Scientific Advisory Panel of the Prime Minister (SAC-PM).The following recommendations of SAC-PM in its meeting

held on 9th October 2012 on Agriculture Biotechnology were being considered to address the issues :

1) The current regulatory system for recombinant products administered under Rules (1989) of EPA Act, 1986 should be reformed till BRAI is in place.

(i) RCGM and GEAC should be the sole authority for biosafety and bio-efficacy assessment of all recombinant products. Decision on commercial use of biotechnology produced crops should be taken by the Agriculture Ministries/ Department of Central and State Governments as per existing policies and regulations on crops. For medical products Central Drugs Standard Control Organization (CDSCO) of Ministry of Health and Family Welfare, Government of India would approve commercialization as of now.

(ii) High Level dialogue with State Governments to streamline clearances for conduct of multi- location “Confined field trials” – a scientific pre-requisite in all countries for meaningful decision making on approvals or otherwise.

(iii) A Biotechnology Regulatory Secretariat with high level of scientific and technical trained manpower should be established to support RCGM and GEAC.

(iv) GEAC and RCGM should have full time Chairpersons. The Chairman of GEAC, may be of Special Secretary Status for 3 year period and

RCGM one level lower. Chairman of RCGM be the Co- chair in GEAC and not the expert nominee of Department of Biotechnology. For greater synergy at least three members should be common between RCGM and GEAC.

(v) The public needs to be informed of every decision.”

The Department further stated that the Institutional Biosafety Committee (referred as Internal Bio-Safety Committee) is not responsible for assessment and evaluation of transgenic products being developed by a particular company. The responsibilities of IBSC are clearly defined and its role is basically to ensure that organization is conducting guidelines.

1.82 The Committee are glad to note that reforms in the current regulatory system are being considered in pursuance of the concerns expressed by the Committee. The Committee desire that the proposed changes should be implemented without delay.

ABSENCE OF LIABILITY CLAUSE
(Recommendation Para No. 8.122)

1.83 The Committee were worried about the absence of any liability clause or mechanism in the system which could compensate the poor farmers and the consumers in the eventuality of crop loss and harm to bio-diversity health, environment, etc. With the various crop insurance schemes also not being of much help to a majority of farmers any prospective losses to the farmers due to cultivation of transgenic agricultural crops would have a crippling effects on

their fortunes as they are already under severe agrarian crisis for years together now.

1.84 Department in their Action Taken Note have submitted that after wide ranging stakeholders discussions and elaborate inter-ministerial consultations, the Biotechnology Regulatory Authority of India (BRAI) Bill had been prepared and submitted to Parliament for introduction. SAC-PM has been of the view that “The Bill pending with Parliament, i.e. BRAI, 2012, should be debated with open mind. It would be appropriate if administrative organization could be Cabinet Secretariat because of the involvement of multiple ministries. The Bill when examined by appropriate Parliamentary Committee would be opened up for wider debate and discussions for shaping the draft legislation into a model regulatory framework.” All concerned departments/ministries had agreed with these views as the Bill also took into consideration the collaborative and coordinated mechanisms across different existing legislations and authorities. The BRAI Bill had provided for constitution of pan-government Inter ministerial Governing Board with 15 Ministries/ Departments/Agencies/ Authorities as an umbrella mechanism to provide oversight on cross cutting mandates and polices.

1.85 The Committee had, *inter-alia*, highlighted the absence of any liability clause or mechanism in the system which could compensate the poor farmers and the consumers in the eventuality of crop loss and harm to bio-diversity health, environment, etc. The Committee further pointed out that with the various crop insurance schemes also not being of much help to a majority of farmers any prospective losses to the farmers due to cultivation

of transgenic agricultural crops would have crippling effects on their fortunes, as they are already under severe agrarian crisis for years together now. The Government's reply has not given any response on this very crucial point. The Committee urge the Government to take appropriate action in this regard under intimation to the Committee.

ETHICAL DIMENSIONS OF TRANSGENICS
(Recommendation Para No. 8.125)

1.86 The Committee observed that on a major issue that had escaped the attention of the Government during all these years has been question of ethics. In the extant social-cultural milieu, a serious thought has been required to be given to the ethical dimensions of transgenics in agricultural crops. Even a miniscule degree of insensitivity on this matter could lead to avoidable discontent which apart from causing societal tensions would also have grave socio economic repercussions.

1.87 The Department in their Action Taken Note have clarified that the GM crops are assessed for safety and efficacy. Efficacy means that whether the biotechnology intervention made in a particular crop is providing additional benefit as claimed by the developer. The effectiveness of a GM crop under given agro-climatic condition is assessed by elaborate confined field trials by taking care of all biosafety measures as per Standard Operating Procedures (SOPs). Since, the regulatory frame work approves for commercial use only those technologies which go through these stringent tests are approved. Therefore, the issue of socio economic repercussions does not arise. Further, all the

information is also made available to the farmer by developer at the time of sale and finally it is farmer's choice that determines the adoption.

1.88 The Committee had pointed out that a serious thought requires to be given to the ethical dimensions of transgenics in agricultural crops. The Government's reply is completely silent on the ethical issue and speaks only about safety and efficiency of GM crops. The question relates to appropriateness of modifying the genetic structure of naturally endowed with plants. The Committee would await the Government's response in this regard.

CULTIVATION OF Bt. COTTON COMPOUNDING THE MISERIES OF THE SMALL AND MARGINAL FARMERS.
(Recommendation Para No. 8.126)

1.89 The Committee during the course of their study visit held extensive interactions with farmers and had observed that there had been no significant socio-economic benefits accruing to farmers due to introduction of Bt. Cotton. On the contrary, being a capital intensive agriculture practice, the indebtedness of the farmer had grown massively, thus exposing them to greater risks. Thus, Bt. Cotton cultivation had only added to the miseries of small and marginal farmers who constitute more than 70% of tillers in India.

1.90 The Ministry in their Action Taken Note stated that it is unfortunate to attribute the problems to Bt. Cotton. Bt cotton-effectively controlled bollworms preventing yield losses from an estimated damage of 30% to 60% during 2002 to 2011 period. Yields are estimated to have increased at least by 30% due to

effective protection from bollworm damage. All India average yield, which was 189 kg lint per ha in 2001 increased to 491 kg lint/ha in 2011. About 9400 M tonnes of insecticides were used for bollworm control in 2001, which reduced to only 222 M tonnes in 2011. The per ha income of the farmers, which was ` 7058/- in 2000 increased to `16125/- in 2010 under rainfed conditions and from ` 15370/- in 2000 to ` 25000/- in 2010 under irrigated conditions. Increase in income of farmers have definitely increased the capacity of the farmers to invest in their well being and hence improved their socio-economic status.

1.91 The Government's claim of farmers' income having increased on account of cultivation of Bt. cotton is not borne out by farmers who interacted with the Committee during their study visit. The first hand experience gained by the Committee is ample proof to show that the miseries of farmers have compounded since the time they started cultivating Bt. Cotton. The Committee would like the Government to appreciate the ground reality and not to thrust commercial cultivation of Bt. cotton on farmers.

REGULATORY MECHANISM FOR TRANSGENICS
(Recommendation Para No. 8.127)

1.92 The Committee observed that while the introduction of transgenics in India had extensively benefitted the industry, yet the trickle down for the poor farmers was not visible at all. They had, therefore, recommended that till all concerns voiced by the Committee are fully addressed and decisive action is taken by the Government with promptitude to put in place all regulatory, monitoring,

oversight, surveillance and other structures, further research and development on transgenics in agricultural crops should be done in strict containment and field trials under any garb should be discontinued forthwith.

1.93 In their Action Taken Note, the Department have submitted that this recommendation is contrary to the recommendation that there is a need for generating data on long term impacts on biodiversity and human health.

There is a mix-up in the recommendations for field trials and commercial release. Parameters that need to be taken into consideration for taking a decision on field trials are different from that of a decision on commercial release. Field trials are integral part of research and development and therefore decision on field trials are based on scientific facts. However, decision on commercial release may go beyond scientific facts to include need, socioeconomics, public perception, corporate rivalry and political will; all of which fall beyond the scope of the purpose for which field trials are meant. Biosafety research cannot be conducted in glass house as the safety efficacy and performance of GM crop would vary depending on the host environment, host crop and inserted gene.

Bt cotton was commercially released in other countries and has a robust record of safety and performance for about sixteen years. The situation in India has been no different. Globally, India is the second largest exporter of cotton. In spite of the controversy regarding Bt cotton, the ground reality is that Bt cotton has been beneficial to farmers as none of the State Government have requested for withdrawal of the approval granted for Bt cotton.

The discontinuation of field trials undermine the existing two decade global experience and is completely arbitrary and without basis in the context of confined experimental field trials. Discontinuation of GM crops field trials has serious implications. It will virtually stop the attempts of public sector institutions to test and introduce GM crop varieties that can be inexpensive, reusable – seeds, and cost effective. Such a move will discourage and demotivate the; public sector GM crops research. Discontinuation of field trials will also discourage all other technology providers, from introducing competitive GM crop events in cotton, thus reinsuring the monopoly of the existing technology provider. The move will also deprive farmers of useful GM crops with new genes and enforce them to repeatedly use the same gene events thus rendering the existing genes and Bt, cotton unsustainable soon.

1.94 The Government's reply does not appreciate the ground realities mentioned by the Committee and does not inspire any degree of confidence in the Committee to change their well considered opinion on the subject. They, therefore, reiterate their earlier recommendation that further research and development on transgenics in agricultural crops should be done only in strict containment and field trials should not be undertaken till the Government puts in place all regulatory, monitoring, oversight, surveillance and other structures.

**NEW DELHI;
03 March, 2013
12 Phalguna, 1935 (Saka)**

**BASUDEB ACHARIA
*Chairman,
Committee on Agriculture***

COMMITTEE ON AGRICULTURE

(2013-14)

MINUTES OF THE TWENTIETH SITTING OF THE COMMITTEE

The Committee sat on Monday, the 03 March, 2014 from 1100 hours to 1130 hours in Committee Room 'E', Parliament House Annexe, New Delhi.

PRESENT

Shri Basudeb Acharia - Chairman

MEMBERS

LOK SABHA

2. **Shri Sanjay Singh Chauhan**
3. **Smt. Ashwamedh Devi**
4. **Shri Premdas Katheria**
5. **Smt. Botcha Jhansi Lakshmi**
6. **Sardar Sukhdev Singh Libra**
7. **Shri Rajaiah Siricilla**
8. **Shri Patel Kisanbhai V.**
9. **Dr. Vinay Kumar Pandey 'Vinnu'**
10. **Shri Hukumdeo Narayan Yadav**

RAJYA SABHA

11. **Smt. Mohsina Kidwai**
12. **Dr. K.V.P. Ramchandra Rao**
13. **Shri Rajpal Singh Saini**
14. **Shri S. Thangavelu**
15. **Shri Shivanand Tiwari**

SECRETARIAT

1. **Shri A. Louis Martin** - **Joint Secretary**
2. **Smt. Abha Singh Yaduvanshi** - **Director**
3. **Shri T.H. Rao** - **Additional Director**
4. **Shri C. Vanlalruata** - **Deputy Secretary**

APPENDIX-II

(Vide Para 4 of Introduction of the Report)

ANALYSIS OF ACTION TAKEN BY GOVERNMENT ON THE THIRTY-SEVENTH REPORT OF COMMITTEE ON AGRICULTURE (2013-14) ON CULTIVATION OF GENETICALLY MODIFIED FOOD CROPS- PROSPECTS AND EFFECTS OF MINISTRY OF AGRICULTURE (DEPARTMENT OF AGRICULTURE AND COOPERATION)

(i)	Total number of Recommendations	102
(ii)	Recommendations/Observations which have been Accepted by the Government Para Nos. 1.21, 1.22, 1.23, 2.74, 2.75, 2.76, 2.80, 2.82, 2.87, 2.88, 2.92, 3.35, 3.36, 3.37, 3.38, 3.39, 3.43, 3.44, 4.28, 4.30, 4.31, 4.32, 4.33, 5.43, 5.44, 5.45, 5.54, 6.141, 6.142, 6.143, 6.150, 6.151, 6.152, 6.153, 6.154, 6.155, 6.156, 7.59, 7.71 and 8.115.	
	Total	40
	Percentage	39.21 %
(iii)	Recommendations/Observations which the Committee Do not desire to pursue in view of the Government's replies Para No. 2.77, 3.45, 3.47, 4.29, 4.34, 5.47, 5.48, 5.55, 7.18 and 7.21	
	Total	10
	Percentage	9.80 %
(iv)	Recommendations/Observations in respect of which replies of the Government have not been accepted by the Committee Para Nos. 1.20, 2.78, 2.79, 2.81, 2.83, 2.84, 2.85, 2.86, 3.40, 3.41, 3.42, 3.46, 3.48, 5.46, 5.49, 5.50, 5.52, 5.53, 5.56, 5.57, 5.58, 5.59, 6.144, 6.145, 6.146, 6.147, 7.19, 7.20, 7.60, 7.61, 7.75, 7.76, 8.116, 8.117, 8.118, 8.119, 8.120, 8.121, 8.122, 8.123, 8.124, 8.125, 8.126 and 8.127.	
	Total	44
	Percentage	43.14 %
(v)	Recommendations/Observations in respect of which Final replies of the Government are still awaited Para Nos. 2.89, 2.90, 2.91, 5.51, 6.148, 6.149, 7.62 and 7.63	
	Total	08
	Percentage	7.85 %