



**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 on

Laid on the Table of Rajya Sabha on



LOK SABHA SECRETARIAT

NEW DELHI

March 2014 / Phalguna, 1935 (Saka)

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(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
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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.

(iii)

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 (2011-12) 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 Nos. 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.

1.44 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.

1.45 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 Nos. 5.57 and 5.58)**

1.46 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.

1.47 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.

1.48 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)

1.49 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.

1.50 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.

1.51 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)

1.52 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.

1.53 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.

1.54 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)

1.55 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.

1.56 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.

1.57 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)**

1.58 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.

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

1.60 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.

1.61 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.

1.62 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)

1.63 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.

1.64 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.

1.65 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)

1.66 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.

1.67 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.

1.68 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)**

1.69 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.

1.70 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.

1.71 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)**

1.72 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.

1.73 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.

1.74 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.

1.75 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)**

1.76 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.

1.77 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.

1.78 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)

1.79 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.

1.80 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 prerequisite 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.

1.81 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)

1.82 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.

1.83 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.

1.84 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 biodiversity 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)**

1.85 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.

1.86 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.

1.87 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)

1.88 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.

1.89 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.

1.90 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)

1.91 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.

1.92 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.

1.93 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.

CHAPTER-II

OBSERVATIONS/RECOMMENDATIONS WHICH HAVE BEEN ACCEPTED BY THE GOVERNMENT

Policies and Strategies in Agriculture and Allied Sectors to be Sustainable for Growth and Prosperity of the Farming Community (Recommendation Para No. 1.21)

There is, therefore, a pressing need for policies and strategies in agriculture and allied sectors which not only ensure food security of the nation, but are sustainable and have in built deliverable components for the growth and prosperity of the farming community. It is also imperative that while devising such policies and strategies the Government does not lose track of the fact that 70% of our farmers are small and marginal ones. As the second most populous Country in the world, with a growing economy ushering in its wake newer dietary habits and nutrition norms, a shrinking cultivable area, a predominantly rainfed agriculture, the task is indeed enormous.

Reply of the Government

Advances made in agricultural research and development activities have benefitted all categories of the farming community in India which is amply demonstrated with the facts that the country not only achieved self sufficiency in agricultural production, maintains huge buffer stock of food grain and exports some commodities at times.

Growth of agriculture sector depends on a number of factors comprising the natural resources endowments especially land, soil quality, water, climate and biodiversity, infrastructure development, investment and human efforts to effectively and efficiently use the various resources. Since agriculture is a state subject, performance of the agriculture sector in India largely depends on what

occurs at the states level in terms of seed distribution, extension and training of farmers, pricing of inputs, policies etc.

For meeting the growing demand of food, feed and fiber technologies and extension approaches need to continuously evolve to make Indian Agriculture competitive. The Ministry of Agriculture is implementing various programmes such as the National Food Security Mission (NFSM), Rashtriya Krishi Vikas Yojana(RKVY), National Horticulture Mission (NHM), etc. with a view to increase agriculture production, productivity and income of the farmers and the priority is always accorded to small and marginal farmers.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Promise held by Biotechnology in Ensuring Sustainable Growth in Agriculture and Allied Sectors
(Recommendation Para No. 1.22)

In the considered opinion of the Committee biotechnology holds a lot of promise in fructification of the above-cited goals. Several of conventional biotechnologies *viz.* plant breeding techniques, tissue-culture, cultivation practices, fermentation, etc. have significantly contributed in making agriculture what it is today. The Committee note that for some years now transgenics or genetical engineering is being put forward as the appropriate technology for taking care of several ills besetting the agriculture sector and the farming community. It is also stated that this technology is environment friendly and, therefore, sustainable. Affordability is another parameter on which policy makers and farming communities world over are being convinced to go for this nascent technology. The Committee further note that in India, transgenics in agriculture were introduced exactly a decade back with the commercial cultivation of Bt. Cotton which is a commercial crop. With the introduction of Bt. Cotton, farmers have taken to cotton cultivation in a big way. Accordingly, the area under cotton

cultivation in the Country has gone up from 24000 ha in 2002 to 8.4 million ha at present. Apart from production, productivity has also increased with the cultivation of the transgenic cotton. The Committee also take note of the claim of the Government that input costs have also gone down due to cultivation of transgenic cotton as it requires less pesticides, etc.

Reply of the Government

Development of Bt cotton hybrids and their adoption by farmers globally, is the land mark achievement similar to the discovery and exploitation of dwarfing genes in wheat and rice and development of hybrid vigour in maize and pearl millet, contributing towards revolution in achieving higher production and productivity in these crops.

Bt cotton was released during 2002-03 initially for Central and South Zone States and in 2005-06 for North zone. The Bt technologies proved to minimize the damages caused by boll worm, reduced pesticide use, increased production, yield and net income of the farmers. As a result, the adoption of Bt hybrids took a faster rate and within a short span of time, area under Bt cotton, which was 29,000 ha in 2002-03 (0.38% of total cotton area) increased to 111.39 lakh ha in 2011-12 (91.47% of total cotton area).

Since the introduction of Bt cotton in farmers' fields in 2002, there has been near doubling of cotton production from 158 lakh bales in 2001-02 to 356 lakh bales in 2011-12. This increase in cotton production has mainly been attributable to increase in cotton productivity from 308 kg/ha in 2001-02 to 496 kg/ha in 2011-12 due to introduction of Bt cotton in India. On the other hand, world wide area under GM crops has been increasing at fast pace every year for the last 16 years, with remarkable 94 fold growth since the commercialization began in 1996. Nearly 14 million farmers have grown GM crops in 25 countries in 2009. It is estimated that about 16.7 million farmers from 29 countries planted

GM crops in 160 million hectare land in 2011. India has become the fourth largest adopter of biotech crop in the world, displacing Canada, in 2008. At present, a number of different GM crops for insect resistance, herbicide tolerance, altered oil composition, virus resistance etc. are under commercial cultivation worldwide.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Pros and Cons of Introduction of Genetical Modification/Transgenics in our Food Crops
(Recommendation Para No. 1.23)

Notwithstanding the claims of the Government, the policy makers and some other stakeholders about the various advantages of transgenics in agriculture sector, the Committee also take note of the various concerns voiced in the International Assessment of Agriculture, Science and Technology for Development Report commissioned by the United Nations about some of the shortcomings and negative aspects of use of transgenics/genetical engineering in the agriculture and allied sectors. The technical, social, legal, economic, cultural and performance related controversies surrounding transgenics in agriculture, as pointed out in IAASTD report, should not be completely overlooked, more so, when India is a signatory to it. The apprehensions expressed in the report about the sustainability and productivity of GMOs in different settings; the doubts about detected benefits of GMOs extending to most agro-eco systems or sustaining in long term; the conclusion that neither costs nor benefits are currently perceived to be equally shared, with the poor tending to receive more of the costs than benefits all point towards a need for a revisit to the decision of the Government to go for transgenics in agriculture sector. This is all the more necessary in the light of Prime Minister's exhortion on 3 March, 2010 at the Indian Science Congress about full utilisation of modern biotechnology for ensuring food security but without compromising a bit on safety and regulatory aspects. The present examination of the Committee, as the

succeeding chapters will bear out, is an objective assessment of the pros and cons of introduction of genetical modification/transgenics in our food crops which happened to be not only the mainstay of our agriculture sector but also the bedrock of our food security.

Reply of the Government

While referring to the benefits and concerns of GM crops, the committee has referred to IAASTD report. It may be noted that IAASTD report is not a consensus report and fraught with controversies. The IAASTD was created in 2002 to address global problems of agriculture and food security. The advisory bureau comprised of representatives from government, consumer groups, industry and NGOs such as Green Peace. Although, the panel was launched with high expectations, there were serious disagreements between the stakeholders. This also led to broadening of the purview beyond food production to include social justice and the environment. The discussion on GM crops was also highly polarized with groups speaking for and against GM crops with no resolution in sight. This led to walkout by industry representatives, academics and some NGOs. Some of the key agricultural producers countries declined to endorse the final synthesis report.

In view of the above, it is not appropriate to base the agricultural policies only on the basis of IAASTD report. It is important to note that the potential of GM crops to improve crop productivity, increase crop adaptation to climatic stresses such as drought, and mitigate greenhouse gas emissions has been recognized by many national and international bodies, including the United Nations Food and Agriculture Organization, and was addressed in the World Development Reports in 2008 and 2010.

1. <http://www.fao.org/docrep/meeting/019/al295e.pdf>

2. World Bank. (2008). World Development Report 2008: Agriculture for Development. World Bank, Washington, D.C. http://siteresources.worldbank.org/INTWDR2008/Resources/WDR_00_book.pdf
3. World Bank. (2010). World Development Report 2010: Development and Climate Change. World Bank, Washington, D.C. <http://siteresources.worldbank.org/INTWDR2010/Resources/5287678-1226014527953/WDR10-Full-Text.pdf>

Government of India is committed to the safe use of GM crops and accordingly has established a regulatory system way back in 1989 to regulate the use of GM technology. There have been several pro active measures involving multidisciplinary stakeholders for strengthening the governance, management and scientific risk assessment processes in view of newer scientific developments and regulatory challenges.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Present Regulation of Genetically Modified Organisms and Products (Recommendation Para No. 2.74)

The Committee note that as on date genetically modified organisms and products, thereof, including genetically modified crops are regulated under the 'Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro Organisms/Genetically Engineered Organisms or Cells' notified by the Ministry of Environment and Forests on 5 December, 1989. These Rules also called Rules 89 have been framed under the 'Environment (Protection) Act, 1986. The Rules intend to ensure sound application of biotechnology, making it possible to accrue benefits arising from modern biotechnology, while minimizing the risks to environment and human health. These Rules are supplemented by various guidelines issued from time to time to keep pace with international practices and developments in the field of biotechnology.

Reply of the Government

Statement of facts.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Composition of Regulatory Mechanism for Transgenics **(Recommendation Para No. 2.75)**

The Committee further note that the regulatory mechanism to enforce these rules consists of six committees. The chain begins with the Institutional Bio-Safety Committee, which is established under the institution engaged in GMO research for oversight and to interface with Review Committee on Genetic Manipulation (RCGM). RCGM functions under the Department of Biotechnology and is mandated with the responsibility of monitoring and regulating safety related aspects of ongoing research projects and activities including small scale field trials. There is a recombinant DNA Advisory Committee (RDAC) which is of an advisory nature and which recommends suitable and appropriate safety regulations in recombinant research, use and applications from time to time. The Genetic Engineering Appraisal Committee (GEAC) previously known as Genetic Engineering Approval Committee is the apex body to accord approval of activities involving large scale use of hazardous micro-organisms and recombinants in research and industrial production from environmental angle. More importantly it is also mandated with the authority for approving release of genetically engineered organism and products into the environment including experimental field trials. GEAC functions under the Ministry of Environment and Forests. Then there are State Biotechnology Coordination Committees (SBCCs) who are mandated with the power of State level monitoring. SBCCs also have powers to inspect, investigate and take punitive action in case of violations. The last tier of the regulatory mechanism are the District Level Committees (DLCs) who are tasked with the role of monitoring the safety regulations in installations engaged in the use of

GMOs/hazardous microorganisms and their applications in the environment. Apart from these six Committees, the Committee note there is a Monitoring-cum-Evaluation Committee which monitors the compliance of regulatory procedures during field trials of GM crops.

Reply of the Government

The para refers to statement of facts regarding the current regulatory framework. However, it may be clarified that

“RCGM **does not** function under the Department of Biotechnology (DBT). It is a statutory committee set up as per Rules,1989 notified under Environment (Protection) Act, 1986. RCGM **is not** under administrative control of DBT, which only services RCGM in terms of infrastructure and human resource.”

RCGM **does not** report to Secretary, DBT directly or indirectly. No official of DBT has any influence on the functioning of RCGM. **It directly reports to GEAC.**

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Procedure for Assessment and Evaluation of GM Crops before Granting Approval **(Recommendation Para No. 2.76)**

The procedure in vogue preceding approval is that the company involved in development of GM crop undertakes in containment, several biosafety assessment including environmental safety, food and feed safety assessments. This is followed by Bio- safety Research Trials in two stages BRL-I and BRL-II which require prior approval of RCGM and GEAC respectively. Approval for environmental release is accorded by GEAC after taking into consideration the findings of bio-safety and agronomic studies as well as recommendations of RCGM, ICAR and MEC. Finally commercial release is permitted by GEAC for

only those transgenic crops which are found to be safe for human consumption as well as the environment. Committee note that the Government have also put a strict regimen in place at all stages of assessment and evaluation procedure.

Reply of the Government

It may be clarified that the process is applicable to products developed by not just the 'company' as stated but to all organizations including public sector academic and research institutions and private sector.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Renaming of Genetic Approval Committee as Genetic Engineering Appraisal Committee **(Recommendation Para No. 2.80)**

The Committee find that the Bt. brinjal controversy also led to renaming of Genetic Engineering Approval Committee as Genetic Engineering Appraisal Committee. The Ministry of Environment and Forests issued a notification on 16 July, 2010 effecting the change. The notification which was published in the Gazette of India dated 22 July, 2010, inexplicably does not mention any reasons for the renaming nor does it mention any change in the role and responsibility and the mandate of GEAC. On a query of the Committee, the Government has justified the change on the ground that the old name gave GEAC the aura of being the approval agency and the new one would suggest that it is meant to appraise the safety of GMO. To another query of the Committee the Government have also clarified that there is no change in the mandate of GEAC due to rechristening. The Committee are, however, not satisfied with the apparently contradictory stands taken by the Government in the matter. As per Rules 89, GEAC is the apex approval body in the regulatory mechanism for GMOs related matters. How the Government has then chosen to rename it

with a view to convey that it is doing appraisal only defies logic. They, therefore, expect a detailed clarification from MoEF in the matter including the inputs and decision making leading to the issue of Notification No. GSR 613(E) dated 16 July, 2010.

Reply of the Government

The decision to rename GEAC was taken by the then Minister for Environment & Forests Shri Jairam Ramesh, in the Decision Document dated 9th February 2010 while imposing moratorium on Bt Brinjal. The decision of the Minister to change the name of GEAC from 'approval' to 'appraisal' is reflected in Para 30, last line of the decision document, which reads as

“Meanwhile, I also intend to change the name of the Genetic Engineering Approval Committee to Genetic Engineering Appraisal Committee”.

Accordingly, MoEF issued the Gazette Notification No. GSR 613(E) dated 16 July, 2010.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Review of Organizational set-up of GEAC and Review Committee on Genetic Manipulation (RCGM) **(Recommendation Para No. 2.82)**

The Committee note with concern that both GEAC and RCGM who are in existence for several years now and are mandated with very very sensitive functions have no organizational set-up and infrastructure worth mentioning. Due to these severe and debilitating impediments, both the agencies have to depend on a Committee based approach, which in the opinion of the Committee, is not the most optimal way of functioning for agencies tasked with such sensitive responsibilities. The Committee are in full agreement with GEAC that the ever evolving dynamics of modern biotechnology cannot be kept fully tracked of with the Committee based review approach and a more robust and dedicated review

mechanism is urgently called for. The Committee, therefore, recommend that an immediate review of the organizational set-up and infrastructure of GEAC and RCGM be got done by the Government and necessary augmentation, both in terms of men and material be carried out immediately and without linking it to the proposed omnibus regulatory authority that may still take years to come into existence.

Reply of the Government

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. **(Annexure-I)**. 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. Composition and expertise of the IBSC and RCGM is placed at **Annexure-II**.

Regarding the committee approach, it may be noted that in many countries the risk assessment expertise lay in academic and other public sector research institutions. Accordingly most of the countries couple in-house expertise in the regulatory agency with expert advisory committees for development of policies and guidelines as well as for case by case decision making.

MoEF and DBT provides administrative support to the committee for its operations, for which the manpower and infrastructure requirements are in place.

Further, pending BRAI Bill 2012 in the Parliament, proactive steps have been taken to strengthen required support system for RCGM and GEAC. As mentioned above, a recent review by SAC-PM has already suggested certain measures, which shall be implemented at an early date.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Conflict of Interest in Genetic Engineering Appraisal Committee (GEAC)
(Recommendation Para No. 2.87)

While making enquiries in the light of some media reports of conflict of interest in GEAC, the Committee have come to know that GEAC has laid down a criteria to address the conflict of issue matters in December, 2010. After the said media report the ambit of conflict of interest criteria has been extended to apart from a member of GEAC to his/her spouse or children. The Committee feel that considering the slew of activities that GEAC is concerned with, the present conflict of interest criteria would not suffice. The situation demands a delinking of interest groups/individuals from the decision making tiers of the regulatory mechanism without the regulatory mechanism being deprived of the professional inputs of the groups/individuals in question. The Committee would like the Government to come up with their well considered views on this vexed issue.

Reply of the Government

Recognising this constraint, a mechanism to avoid conflict of interest has been put in place by the GEAC. As per the prescribed conflict of interest criteria, professionals/individuals who are members of the GEAC but also involved in the development of a specific GM crop expressing a specific trait is not allowed to participate in the review/decision making process when the

concerned application is discussed. The conflict of interest criteria is also triggered if the spouse or children of a member are involved. This is as per the international practice.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Controversy Surrounding Development of BN Bt. and Bt. NHH 44
(Recommendation Para No. 2.88)

During the course of the examination of the Subject the Committee were seized of controversy surrounding the development of BN Bt variety and Bt NHH 44 hybrid cotton variants by University of Agricultural Science, Dharwad. CICR, Pune is also involved closely with the project. It was reported in the media on 30 December, 2011 that these two variants were found to be carrying genes from the original patented product of a multinational. The Committee sought explanation of concerned players including ICAR, DBT and MoEF. It transpires that the gene construct for the event was provided to UAS Dharwad by National Research Centre on Plant Biotechnology. UAS Dharwad carried out the genetic transformation of the cotton variety Bikaneri Narma using this cry1AC gene construct. CICR was involved in undertaking and coordinating RCGM and GEAC regulatory trials as well as generation of bio-safety data. The presence of the controversial gene was, however, according to ICAR, not detected either in southern analysis carried out by NRCPB when they confirmed gene integration and copy number or by M/s Avesthagen, who characterized the BN Bt event in 2006-07. GEAC approved commercial cultivation of BN Bt variety on 2 May, 2008 and hybrid Bt NHH 44 on 13 May, 2009. In September – October, 2009 representatives of M/s Mahyco – Monsanto met ICAR officials and pointed out the presence of Monsanto gene and event, MON 531 in BN Bt and Bt NHH 44 seeds. On 10 December, 2010 ICAR decided to stop production of seeds of these two variants. It was also decided that production could only be restarted, after complete purification for uniformity and homozygosity of cry1AC gene BNLA106 original event. UAS, Dharwad was entrusted with this task.

CICR, who had applied to Protection of Plant Variety and Farmers Rights Protection Authority in May, 2009 for commercialization, withdrew its application from the Authority on 3 August, 2011. The permission was granted by the Authority on 16 January, 2012. UAS Dharwad and NRCPB are working on purification of BN Bt as of now. ICAR has also decided to set-up an expert Committee consisting of experts from outside ICAR to look into the entire issue and advise further course of action.

Reply of the Government

The expert committee has submitted its report to the ICAR. The ICAR is examining the report in light of the evidences supporting the observations of the committee report.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Inadequate Present Regulatory Mechanism (Recommendation Para No. 2.92)

Having gone through the voluminous evidence gathered by them the Committee can safely conclude that all is not well with the regulatory mechanism put in place by the Government for oversight of cutting edge technology as sensitive as GMOs and products thereof. Firstly, GEAC being an entity created under rules rather than an Act of Parliament deprives it of the status, powers and more importantly autonomy and independence that a statutory regulator ought to have. The enforceability of Rules, albeit made under some Act only, does not have as much definitiveness and clarity as under an Act. Furthermore, unlike an Act, there is a lot of scope for varied interpretation of Rules as also flexibility to implement them. The confusion about the recommendatory/approving authority of GEAC whether due to genuine confusion or deliberate; the confession of the Co-Chairman of GEAC, the only

technocrat in the top three positions of GEAC, about minister/GEAC/industry pressuring him to favour a bad technology; the various acts of omission and commission of GEAC that have been documented in various chapters of this Report, all go on to cement the view of the Committee that the regulatory mechanism definitely requires the protection and support of an Act of the Parliament which leaves no scope for ambiguity or complacency. The problem, however, is that the Government has inordinately dithered in bringing an appropriate bio-safety friendly legislation in the matter before the Parliament. Nonetheless, the Committee feel that the failure of the Government to bring a legislation on the subject till now should not in any way prevent or pre-empt the monitoring, oversight and evaluation of the extant regulatory system by the Parliament and its entities. Given the fact that the two major constituents of the present regulatory system *viz.* GEAC and RCGM are under the Ministry of Environment and Forests and the Department of Biotechnology respectively and both MoEF and DBT are under the jurisdiction of the Department- related Parliamentary Standing Committee on Science and Technology, Environment and Forests. The Committee request their sister Committee to take up GEAC and RCGM for an indepth and comprehensive examination at their earliest convenience.

Reply of the Government

It may be clarified that existing regulatory mechanism for GMOs is working adequately.

Globally all regulatory frameworks comprise of Acts, rules and regulations, decrees, or guidelines, etc. that support and empowers the administrative and institutional mechanisms for decision making to approve or reject a GM crop. For example existing Statutory instruments are utilized in USA, Canada, Argentina and Philippines and new laws were passed to specifically address gene technology in Australia, South Africa, Japan, Malaysia and at regional level by European Union.

In fact India has been one of the earliest countries to implement such regulatory measures under the Environment Protection Act, 1986 and Rules 1989 to address safety issues emerging from global developments and beginning of biotechnology research in India. Therefore the Government of India has always been on the forefront to ensure safe use of newer technologies including GM technologies. Further, several initiatives have been taken up subsequently to ensure that regulatory system is geared up to meet newer developments in research in biotechnology. The Ministry of Agriculture had set up a Task Force on Application of Agriculture Biotechnology in 2002, which submitted its report in 2004. MoEF had also set up a Task Force on Recombinant Pharma in 2005. In addition, both RCGM and GEAC continuously review and update the guidelines through consultative process and harmonising with international best practices.

However, in view of the future challenges of increased complexities of biotech product development involving second and third generation technologies and array of converging technologies for preparedness in future as directed by the Government of India and the above referred task forces, the Department of Biotechnology, Ministry of Science & Technology has been entrusted to act as the nodal agency to facilitate establishment "National Biotechnology Regulatory Authority" (NBRA) through an act of parliament. Accordingly, a consultative group of experts have prepared draft organization plan of NBRA and the proposed Bill. Both the draft documents were put in public domain for review and comments. Several consultative meetings were held with concerned stakeholders representing farmers and consumer's organizations, industry, legal experts, media and academia/ scientists from research institutions/ universities. State Governments were also consulted for their feedback. An Interdisciplinary and Inter-ministerial Advisory Committee was also constituted to oversee and advise on all matters related to drafting, reviewing the comments of experts and stakeholders as well as preparing final documents. The governmental process of inter-ministerial consultation has been completed including the finalization of bill by Union Ministry of Law & Justice. Thus, NBRA became the "Biotechnology

Regulatory Authority of India” (BRAI) in the process and the BRAI Bill, 2012 to empower the same, has been submitted to Parliament for introduction in Lok Sabha.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Regulatory Mechanisms for Release of GM Crops in other Countries
(Recommendation Para No. 3.35)

The Committee have examined the regulatory mechanisms for release of GM crops and other products in some of the countries. The issue of GMOs and genetically modified micro organisms in the European Union States were initially being addressed under the Directive 90/220/EC (since 1990) until a new framework under the Directive 2001/18/EC replaced it on 17 April, 2001. Basically the Regulatory System in EU States consists of a step by step approval process on a case by case assessment of risk to human health and environment before any GMOs or product thereof or a product containing GMOs is released into the environment or placed in the market. The procedure involves notification to the competent authority in the member State where the GMOs will be field tested/marketed. The assessment report of the competent authority is, thereafter, forwarded to the EU Commission and competent authority of all member States. With a view to reach agreement general public is also provided an opportunity to express their views. The review process culminates with the competent authority providing consent for marketing of the GMOs for a period not exceeding ten years. The EU Directive mandatorily requires the labeling of such products to include the words ‘this product contains genetically modified organisms’. Some of the salient features of the EU directive include phasing out of antibiotic resistant genes; requirement to trace the GMO at all stages to market; taking into consideration ethical aspects when reviewing GMO.

Reply of the Government

Statement of facts.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Bio-Safety Guidelines in China **(Recommendation Para No. 3.36)**

In case of China, their first Biosafety Guidelines were worked out in December, 1993 by the State Science and Technology Commission. Under these guidelines the responsibility for biosafety of various products vests with the relevant administrative department. With a view to strengthen the safety and management of genetically modified products China has also framed rules on GMOs in 2002. A notable feature of all these rules is that all genetically modified products are required to be labeled in China.

Reply of the Government

Statement of facts.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Regulatory Mechanism for Bio-technology Products in China **(Recommendation Para No. 3.37)**

In Canada, the regulatory mechanism for biotechnology products consists of Canadian Food Inspection Agency (CFIA), Health Canada and Environment Canada. The CFIA is responsible for regulating import, environmental release, variety registration and use of plants with novel traits in livestock feeds. An assessment of human health safety of foods is mandated

with Health Canada. The administration of new substances notifications/regulations and for performing environmental risk assessment of toxic substances, including organisms and micro-organism that may have been derived from biotechnology are responsibility of Environment Canada. These three agencies derive their authority atleast from ten legislations for the purpose of regulating biotechnology products. The Committee also note that another agency for fisheries and oceans with a view to regulate potential environmental release of transgenics aquatic organisms is under development in Canada. In Canada genetically modified plants or foods are typically referred to plants with novel traits and novel foods. Under the Canadian regulatory system all agricultural commodities and food products whether produced using conventional technologies or modern biotechnologies are covered under the same Act.

Reply of the Government

Statement of facts.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
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Regulatory Mechanism for Genetically Modified Organisms (GMOs) and Products in United States of America (USA) **(Recommendation Para No. 3.38)**

As in the case of Canada, the US regulatory system for GMOs and products, thereof, involves three different Government Agencies viz. United States Agriculture Department (USDA), US Food and Drug Administration (FDA) and US Environmental Protection Agency (EPA). The jurisdiction of USDA extends to plant pests, plants and veterinary biologics. The FDA is responsible for food, feed, food additives, veterinary drugs, human drugs and medical devices. Similarly, EPA has the jurisdiction over the microbial and plants

pesticides, new uses of existing pesticides and novel micro-organisms. While in the case of several products these agencies have exclusive jurisdiction, some products are regulated by more than one agency e.g. pesticidal plants. The Committee also find that in case of USA no new law was enacted for regulation of GMOs or products, thereof, *albeit*, suitable provisions have been made in the existing laws. However unlike in Canada, products developed using genetic engineering are subjected to much higher degree of scrutiny as compared to those derived through traditional methods. All the three agencies are vested with the powers to order immediate recall from the market of any product, if any new and valid data indicates involves a question of safety for consumer or environment.

Reply of the Government

Statement of facts.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Regulatory Mechanism in Japan **(Recommendation Para No. 3.39)**

Japan follows a number of voluntary guidelines administered through four different Agencies of the Government. The Ministry of Science and Technology oversees laboratory level work, the Ministry of International Trade and Industry takes care of industrial applications, the Ministry of Agriculture, Forestry's and Fisheries oversees the safety of animal food, feed and environmental release of GMOs and the Department of Health and Welfare is responsible for food and food additives produced by recombinant DNA technology.

Reply of the Government

Statement of facts.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Role of Institutional Bio-safety Committees (IBSC) **(Recommendation Para No. 3.43)**

As has been stated previously in this Report the regulatory mechanism in India derives its authority from Rules 1989 and the guidelines and regulations made thereunder from time to time. As the Rules 1989 were drafted more than two decades ago based on the then prevalent global best practices modifications have been carried out from time to time to keep the regulatory mechanism update and in tune with latest developments. The regulatory mechanism, as stated previously, 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 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. RDAC is advisory in nature, while SBCC and DLC are tasked with monitoring at State and district levels respectively.

Reply of the Government

Some clarifications may be noted regarding role of IBSC.

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.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.27 of Chapter of this Report.

Institutional Bio-safety Committee (IBSC) being the Weakest Link in the Regulatory Framework (Recommendation Para No. 3.44)

From the evidence placed before the Committee and their interaction with eminent scientists and experts IBSC is the weakest link in the chain. Modern bio-technology research and development are mostly in the private sector. The capital intensive nature of the R&D in this sector and the compelling need to make such ventures commercially profitable at the earliest opportunity, is the driving force for the private sector institutions to get their product in market at the soonest. Similarly the charm of patent and IPR is too strong a motivation for not only the private sector, but public sector as well, for quick commercialization of such products.

Reply of the Government

IBSC is the only statutory committee which operates from the institution in the private and public sector laboratories working on GM technology across the country and is a vital link for compliance of safety regulations. It has a first-hand view on the availability of the relevant infrastructure and manpower for undertaking the proposed activities by any organization. The external nominated expert in each IBSC shares his/her observations directly with RCGM. As per the guidelines stipulated by RCGM, the presence of nominated external expert is a must for each meeting of IBSC. RCGM does not accept the minutes of the meeting unless they are signed by the RCGM nominee, in addition to the Chairperson and members of the committee including a medical officer. It may be noted that there are about 500 IBSCs registered so far in covering basic research, agriculture and healthcare applications. IBSCs have nothing to do with the IPRs or publications and are completely dedicated for the mandate of safety assessment. It is therefore not acceptable to say that IBSCs clear projects due to pressure of developer in gaining name and fame due to quicker gains from IPR and commercialisation.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

International Conventions **(Recommendation Para No. 4.28)**

The Committee have taken note of various international conventions which have in some way or the other a significant bearing on the subject and related matters.

Reply of the Government

Noted.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Cartagena Protocol on Biosafety (CPB) **(Recommendation Para No. 4.30)**

The Cartagena Protocol on Biosafety (CPB) which India acceded to on 17 January, 2003 exhorts the signatories to contribute to ensuring adequate level of protection in the field of safe transfer, handling and use of LMOs resulting from modern biotechnology that may have adverse affects on the conservation and sustainable use of biodiversity, taking also into account risks to human health and specifically focusing on trans boundary movements. The Committee find that unfortunately even after the adoption of the Protocol, several critical issues such as risk assessment, liability and redress, documentation and identification of LMOs for food, feed and processing are still being discussed. Thus, globally the progress in the implementation of protocol is slow due to complexity of the issues involved and lack of capacity.

Reply of the Government

It is standard procedure in international treaties for issues covered by those treaties to be further negotiated during the years following entry into force. The CPB is no exception to this rule, and Parties continue to discuss implementation of its provisions in regular meetings of the Parties. These continued implementation discussions are not necessarily due to the complexity of issues; they are simply part of the on-going process of treaty implementation. The level of capacity of Parties in any international treaty will always vary drastically, and the process of treaty implementation is intended to allow those

Parties with greater capacity to provide assistance in treaty implementation to those with less capacity.

In the case of CPB, there are numerous instances, in fact, where the Parties issued clear guidance on CPB provisions early after entry into force, and those decisions still stand today. For example, at their second meeting, Parties agreed to detailed guidance on implementation of paragraph 2 of Article 18, which addresses documentation requirements for shipments of LMOs for contained use intended for intentional introduction into the environment. Parties considered this guidance at their fourth and sixth meetings, acknowledging each time that the guidance was working well and need not be revised as a result.

Additionally, Parties completed their negotiations on liability and redress in 2010 when they finalized the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress (N-KL SP). With the completion of the N-KL SP, Parties finalized rules on damage to the conservation and sustainable use of biological diversity resulting from LMOs that find their origin in transboundary movement. Implementation discussions of N-KL SP will continue, as in any international treaty, but its completion was a significant step forward for Parties to conclude outstanding concerns regarding Article 27 of the CPB.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

The Nagoya Protocol
(Recommendation Para No. 4.31)

The Nagoya Protocol on access and benefit sharing in which India has made significant contributions, lays down fair and equitable sharing of resources arising from utilization of genetic resources. The Nagoya Protocol is expected to address the concerns of biodiversity rich countries like India relating to misappropriation of genetic resources and associated traditional knowledge and

lead to a more balanced implementation of CBD. The domestic regulatory framework on access and benefit sharing is already in existence in India in the form of Biological Diversity Act and Rules.

Reply of the Government

Statement of facts.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Process of Examining Domestic Laws **(Recommendation Para No. 4.32)**

Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress in the context of CPB is of special importance to India. Being a megadiverse country, which is also centre of origin/diversity to several crops, the Supplementary Protocol 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 LMOs. The Committee 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 need to been acted to meet the obligations under the Supplementary Protocol as Environment (Protection) Act1986 and Rules 1989 as also the proposed BRAI Bill do not address the concept of damage and sufficient likelihood of LMOs and the response for measures including financial security to take preventive measures.

Reply of the Government

MoEF has already signed the N-KL SP and initiated the process of examining the provisions before ratification. 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 N-KL SP. If applicable rules exist, they shall be carefully analyzed to ensure compliance with all aspects of the N-KL SP. Where rules do not exist, or are insufficient or contrary to the N-KL SP, a comprehensive plan for amendment and/or creation of new legal instruments could be developed. This plan will address all aspects of referenced applicable domestic laws on both the mandatory and discretionary rules and procedures set forth in the N-KL SP.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.33 of Chapter of this Report.

The World Trade Organisation Agreement **(Recommendation Para No. 4.33)**

The World Trade Organisation Agreement on Application of Sanitary and Phytosanitary Measures is related to procedures of risk analysis of plant, health regulations which should be based on science, applied only to the extent necessary and not discriminate between countries with similar conditions. This apart the guidelines for pests risks analysis ensure that of restriction in trade are based on the assessment of risks and are not arbitrary or discriminate against any exporting country with the same pest status.

Reply of the Government

Statement of facts.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Studies and Reports on the Subject by various Stakeholders
(Recommendation Para No. 5.43)

The Committee were furnished with several studies and reports on the subject by various stakeholders. The Committee would like to dwell upon a few of them which have significant contextual bearing on Indian agriculture sector.

Reply of the Government

No comments.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Report of International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD)
(Recommendation Para No. 5.44)

First and foremost the Committee take note of International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD) Report – Agriculture at a Crossroads. The Report is a painstaking, indepth and accurate assessment of agricultural knowledge, science and technology (AKST). Compiled by 400 experts after working on the project for four years the Report contains several recommendations which are very germane to Indian agriculture sector.

Reply of the Government

The IAASTD study was initiated in 2002 by the World Bank and the Food and Agriculture Organization of the United Nations (FAO) as a global consultative process to determine whether an international assessment of agricultural knowledge, science and technology was needed.

The first part of the report covers a wide range of issues relating to reduction of hunger and poverty, improvement of rural livelihoods and human health, equitable, socially, environmentally and economically sustainable development. The second part of the report deals with cross cutting themes which include bio-energy, biotechnology, climate change, human health, natural resource management, trade and market, traditional and local knowledge, community based innovation, and women in agriculture. The report suggested strategies like Integrated Pest Management, organic agriculture and conservation agriculture for achieving sustainable agriculture.

Government of India recognises importance of the issues related to bio-energy, biotechnology, improvement of rural livelihoods, poverty alleviation, food security and health care issues, in context of conservation and sustainable use of biological diversity. In matters related to sustainable agriculture, Ministry of Agriculture follows the policy guidelines of National Policy of Farmers with major goals such as improving economic viability of farming, conserving land, water biodiversity and genetic resources to provide quality inputs for farming, strengthening bio-security of crops, and creating sustainable rural livelihoods etc., which are also the objectives of the schemes implemented by Government of India.

An independent evaluation group within the World Bank (Global Programme Review Vol 44, No.2) has critically analysed the IASTTD report and arrived at the following conclusion with respect of effectiveness of the report :

“The IAASTD was a useful experience at the nexus of politics and science. However, agricultural technology, with its complexity, diversity and politics, proved to be a bridge too far. The process itself was instructive and there is much useful information in the reports” further the review concludes that, “ for the substantial resources used, the program (IAASTD) did not offer sufficient new knowledge or conceptual frameworks for decision makers. It gave conflicting

messages, and, for a 50 year time span, it under-estimated the potential of new technologies relative to existing technologies. Attributable impact (of the IAASTD report] at the international level has so far been modest at best, and at the national level and below, negligible.”

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Findings of the Report of IAASTD
(Recommendation Para No. 5.45)

The Report has devoted an exclusive theme on biotechnology with particular reference to modern biotechnology that includes genetic engineering/transgenics. While supporting the use of modern biotechnology to some extent in the pharma and human health sector, the Report has expressed its serious reservations about the application of modern biotechnology including transgenics in agriculture sector. A major finding of the Report is that while modern biotechnologies used in containment have proved advantageous *viz.* industrial enzymes, they have yet to prove their efficacy, safety and sustainability outside containment such as genetically modified crops. Furthermore, the Report has expressed serious concerns about the adequacy of efficacy and safety testing or regulatory framework of testing GMOs; suitability of GMOs for addressing the needs of most farmers while not harming others, at least within some existing IPR and liability framework; ability of modern biotechnology to make significant contributions to the resilience of small and subsistence agricultural systems, etc. The Committee during their Study Visit in February – March, 2012 extensively travelled in rural areas of Vidharbha to have a first hand assessment of the worst agrarian crisis affecting the region. From what they saw during the Study Visit, they are in concurrence with the findings of IAASTD Report. They are also in agreement with the question raised in IAASTD Report as to whether detected benefits of GMOs will extend to most agro ecosystems or

be sustained in the long run as resistances developed to herbicides and insecticides.

Reply of the Government

The section on biotechnology with particular reference to modern biotechnology has been one of the contentious issues while formulating the IAASTD report. The Standing Committee in addition has quoted selective statements to justify the suggested action. In fact, the countries at the forefront of biotechnology and embracing agricultural biotechnology in a big way viz. USA, Canada and Australia have expressed their serious reservations on these recommendations. It may also be noted that the concerns expressed regarding adequacy of safety testing or regulatory framework of testing GMOs have led to efforts by various countries in improving their regulatory framework and triggered the formulation of additional guidance and capacity building activities by agencies like FAO, UNEP and World Bank. There is no example of any country, having predominance of agriculture, putting ban on conduct of field trials or open field research of GM crops, as a follow up of recommendations of IAASTD.

Several studies have been conducted on Vidarbha region. In the year 2010, DAC brought out "Report on Integrated Development of Agriculture in Vidarbha Region. The DAC report analyzed that there is general agreement among academicians and researchers that the incidence of farmers' suicides can be traced back to a deeper agrarian crisis. While failure of village as a social community and growing disintegration of the joint family which earlier acted as a protective and supportive social structure may have a significant contribution to the incidence of farmers' suicides, the context of such crisis can be in the form of increasing input cost, decreasing farm profitability, volatile commodity prices, growing risks in rainfed and dryland farming, degradation, depletion of natural resources, indebtedness, social and personal reasons etc. Due to scarcity of irrigation and lack of micro-nutrients in the soil, the productivity of cotton in this

region is one of the lowest in India. Moreover, dependency on rain and adoption of Bt cotton which is more sensitive to shortage of water has made cotton cultivation a high risk – high cost cultivation system.

The Indira Gandhi Institute for Development Research, Mumbai, which investigated the agrarian crisis in Maharashtra, reported indebtedness as one of the major drivers for suicide. It also brought out that the role of agricultural input dealers, the possibility of informal debts being much higher than the formal debt and feeling of helplessness that one is trapped in perpetual debt etc. are some of the primary causes of farmers' suicides.

A fact finding report of Planning Commission (2006) also pointed out that while Bt cotton does quite well in irrigated conditions, as in Vidarbha region. However, it does not do as well in rainfed conditions. Besides, the farm practices followed were questionable as there was "inadvertent mix up" of different quality of seeds in an attempt to fully sow the land under cotton. Farmers often mix Bt cotton seeds with other hybrid or local cotton seeds thereby resulting in poor quality of products and lesser price realization. Hence rather than faulting GM technology, the resilience of small and medium farmers can be built up by various initiatives that Government and particularly Ministry of Agriculture have been undertaking. DAC in its report on integrated development of Vidarbha has suggested numerous measures, significant being schematic interventions (NFSM, RKVY, RADP), need for convergence of various schemes and undertaking new interventions such as community based livelihood support system (CBLSS), development of protective irrigation, rainfed area development in soybean, pulses, cereal belt and establishing custom hiring centres for agricultural machinery and implements through self help groups (SHGs). Currently, irrigation component has been undertaken as a special scheme under RKVY. The present year allocation is Rs. 300 crores. Proposed 12th Plan allocation for integrated irrigation development is Rs. 3250 crores.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
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Recommendations of the Six Academies to be Studied
(Recommendation Para No. 5.54)

Similarly, CSIR have opined that the six academies have arrived to some recommendation which requires due deliberation. India has rich biodiversity and agroclimatic zones; detailed studies are required now to arrive at a policy decision. The Committee note that Ministry of Environment and Forests as a follow-up to the moratorium on Bt brinjal had received several reports from both national and international experts on the merits and demerits of GM crops in general and Bt brinjal in particular and GEAC in consultation with eminent experts and scientific is examining alongwith other reports, the contents of this report as well.

Reply of the Government

Noted.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Involvement of various Agencies in Agriculture and Allied Activities
(Recommendation Para No. 6.141)

The Committee note that research and development and extension services in agriculture sector in the Government domain is the responsibility of National Agricultural Research System headed by Department of Agricultural Research and Education/Indian Council of Agricultural Research. The policy matters rest with Department of Agriculture and Cooperation. The Department of

Biotechnology in the Ministry of Science and Technology are the promoter Department of biotechnology including transgenics/genetical engineering in agricultural crops. Genetic Engineering Appraisal Committee under Ministry of Environment and Forests is the apex regulator which has the authority to accord approval for environmental/commercial release of transgenic agricultural crops. Some laboratories under institutions like Department of Science and Technology, Department of Scientific and Industrial Research/Council of Scientific and Industrial Research, also undertake research and development activity in the field.

Reply of the Government

Statement of facts.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

System of Concurrent and Continuous Oversight of Agricultural Produce (Recommendation Para No. 6.142)

Apart from these R&D, regulatory and promotional structures, any agricultural produce as it moves upwards with value addition in the food chain, moves into oversight, monitoring, evaluation and assessment and regulatory domains of several other agencies of the Government for assessment of its safety, quality, etc. This system of concurrent and continuous oversight is essential since food is a basic necessity of the mankind. Furthermore, the methods and technologies adopted for producing the food also have a profound and lasting impact, both positive and negative, not only on human and livestock health but also on environment, bio-diversity, bio- safety and sustainability. In this connection the Committee note that the Government of India (Allocation of Business) Rules, 1961 (as modified from time to time) have laid down clear cut instructions for all ministries/departments of the Government about what all is their individual role and responsibility in the scheme of

governance. The Committee analysed and evaluated the performance of some of the ministries/departments/agencies in the context of what was expected of them with regard to the introduction of transgenics agricultural crops more specifically food crops in India and matters incidental to it. The Committee note that the Department of Agriculture and Cooperation is the nodal Department for agriculture and cooperation. The National Policy on Farmers, 2007 which is based on the recommendation of the National Commission of Farmers is to be implemented under its aegis. Under the NPF 2007, DAC is vested with the task of protecting and improving land, water, biodiversity and genetic resources, developing support services including provision for seeds, irrigation, power, machinery, fertilizers, implements and credit at affordable prices. The Policy also lays emphasis on paying explicit attention to sustainable rural livelihoods. NPF 2007 also specifies that efforts shall be made to conserve as well as to develop bio-resources to ensure their sustainable use with equitable sharing of benefits. The Committee note that the Protection of Plant Varieties and Farmers' Right Act, 2001 and Biological Diversity Act, 2002 have been enacted to achieve some of these objectives.

Reply of the Government

Statement of facts.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
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National Policy on Farmers, 2007 **(Recommendation Para No. 6.143)**

The Committee further note that NPF 2007 elaborates importance of science and technology as the key drivers of change in farm operations and outputs and application of frontier technologies viz. Biotechnology, ICT, renewable energy technologies, space applications and nano technology for

improving productivity in agriculture. All this, however, has to be done with extreme caution and without compromising on bio-diversity, environment, human and livestock health.

Reply of the Government

Statement of facts

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

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

The Committee while appreciating the candid admission of the Department of AYUSH before them would like to convey their unhappiness over the Department's failure to bring all these matters viz. 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 further desire 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 also desire 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 RCGM/GEAC.

Reply of the Government

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 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 was 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, Dept of AYUSH was requested to provide the following 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:

- Nature of medicinal properties of brinjal
- The specific varieties which have been documented in literature to have such properties
- the active ingredients /ingredient which have such properties
- Their chemical nature, mode of action, clinical indications etc. if information is documented
- The standardized methodology to measure these components and/or their active/inactive metabolites which could act as fingerprints for identification.
- The methodology for estimation as accepted based on their sensitivity and specificity limits of detection etc.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.57 of Chapter of this Report.

Responsibility of the Department of Commerce **(Recommendation Para No. 6.151)**

The Department of Commerce are entrusted with the responsibility of attending to policy matters relating to international trade in goods and services including agreements with other countries/various international trade body but excluding agreements relating to wheat, sugar, jute and cotton. The Committee note India exported agricultural products worth Rs. 89523 crore during the year 2009-10. From the data submitted by the Government to Committee it is observed that exports of agricultural products have shown a continuously rising trend in the last decade. A major chunk of our exports have been of rice mostly basmati. EU is one of the important importers alongwith several Middle East countries. The Department of Commerce admitted before the Committee that exports of transgenic crops will depend upon international acceptance to transgenic food and food products. The Department also stated that there may be no real demand for GM crops when the emphasis is on organic production. It needs to be pointed out that the Department of Commerce are also a member of GEAC. From the inputs provided by the Department, the Committee feel that cultivation of genetically modified food crops will have a debilitating effect on the export of agricultural products. EU already has a strict regime for not permitting import of genetically modified crops. With the awareness about the safety and other concerns about transgenic crops taking centre stage now, there is a strong possibility of several other countries following suit. The volume of global trade in GM food and food products being of the order of a paltry US dollar 4 billion speaks volumes about the acceptability of

GM products. The Committee, therefore, strongly feel that the negative impact of genetically modified crops on the country's agricultural exports is another important aspect that needs to be factored in while taking a decision in regard to introduction of genetically modified crops. The Committee desire the considered views of the Government in the matter.

Reply of the Government

The Department of Commerce (DOC) favours the stand that export policy for agriculture produce should always be open and stable in long term. To the extent that GM food grains are found safe, commercially viable and are in compliance with domestic and International policies on the subject and remunerative to the farmers and enhances yields productivity of the crops, DOC is of the view that international trade in such products can take place. This will also depend upon International acceptance to the GM food and food products.

It may be further clarified that EU has a tolerance level of 0.9% for adventitious presence of GM product in non GM consignments. Similarly many countries have such threshold levels. Thus there is no absolute ban as stated in the report in EU as evidenced by large imports of GM crop derived oil seed cakes, etc. provided the consignments are properly labelled as per EU prescription.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

National Biodiversity Authority of India **(Recommendation Para No. 6.152)**

The National Biodiversity Authority of India (NBA) administers the Biological Diversity Act, 2002. The Committee note the aims and objectives of

NBA are reaffirming the sovereign rights over its biological resources of India; preventing misappropriation of bio-resources and or associated knowledge; protecting biodiversity in general in a holistic manner; regulating use of biological resources; ensuring sustainable utilization and equitable benefit sharing; providing legal recognition and support to the bio-resources and associated traditional knowledge. Amongst the various powers conferred on NBA to achieve the above-mentioned aims and objectives, NBA is vested with the power to advise the Government on matters relating to conservation of biodiversity, sustainable use of its components and equitable sharing of benefit arising out of utilization of biological resources. Being a highly specialized scientific body which has quasi-judicial powers, the Chairperson of NBA as per the Act shall be an eminent person having adequate knowledge and expertise in the conservation and sustainable use of biological diversity and in matters relating to equitable sharing of benefits. The Authority had its first Chairman appointed on 1 October, 2003. The present Chairman who is an eminent geneticist is the seventh Chairman of the Authority. It is indeed a matter of regret that out of these seven Chairmen of this very important body only three were regular/full time Chairmen. Of the remaining four, two were from Indian Administrative Service and the other two from Indian Forest Service, who all held the charge of the Chairman additionally. To what extent the authority would have been able to achieve its hallowed aims and objectives during last nine years plus of its existence with such a pathetic situation at the helm of its affairs is a moot point.

Reply of the Government

Noted .

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Strengthening of National Biodiversity Authority (NBA) in terms of Scientific, Technical and Legal Human Resource
(Recommendation Para No. 6.153)

The Committee regret to note further that NBA which has been mandated with the responsibility of safeguarding the biodiversity of one of the richest country in terms of biodiversity, functions from a rented accommodation in Chennai. As regards the manpower at its disposal the less said the better. Leaving aside the administrative components, personal staff, etc. apart from the Chairman, there is only one technical officer in position and lone advisor for legal matters. In all, this high sounding Authority has a total sanctioned strength of 16 with 14 positions occupied as on date. From the manpower and wherewithal at the disposal of NBA, the Committee can very well gauge out the seriousness of the Government towards this very important responsibility of theirs. The Committee wonder, as to how NBA with such rudimentary existence would be able to ensure India's interest in the context of Nagoya Protocol on access and benefit sharing. The Committee, therefore, recommend that with most of the international conventions and protocols increasingly revolving around biodiversity and related matters it is but imperative that the National Biodiversity Authority should be sufficiently strengthened with scientific, technical and legal human resource of best quality so that the Country's rich biodiversity is adequately safeguarded. The Committee, as an alternative, would also like the Government to explore the possibility of amalgamating the mandate of NBA with the proposed Bio-Safety Authority when it comes into being so that the multiplicity of authorities and the resultant working at cross purposes is avoided. The Committee would like to have a definite roadmap in this regard from the Government within three months of presentation of this Report to the Parliament.

Reply of the Government

- As mentioned in section 6.144, as a Party to the CBD, India was one of the first few countries to have enacted a legislation in 2002, the Biological

Diversity Act, to give effect to the provisions of the CBD, including those relating to ABS.

- ABS issues are still emerging and evolving. There are many grey areas which the world is grappling with, and there is no set model in the world that can be followed. We are learning by doing things.
- Biological Diversity Act is a path-breaking and progressive legislation, and NBA is an important statutory body. In the last nearly seven years of its existence, the NBA has done some credible work, however, there is much more that needs to be done.
- Strengthening the implementation of this Act is a priority. This would *inter alia* require substantial financial support to the state and local level bodies, as well as enhancing awareness and capacity building. The MOEF has proposed proactive measures for the same including increasing manpower and infrastructure.

Prima facie, the objectives of Biological Diversity Act and the Biosafety regulation are quite different, and so are the mandates of NBA and the GEAC. Therefore, working at cross purposes and amalgamation does not arise.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Food Safety And Standards Authority of India (FSSAI)
(Recommendation Para No. 6.154)

With a view to regulate food multiple regulations have been enacted in India from time to time. The Committee, therefore, in their Twelfth Report (Fourteenth Lok Sabha) which was 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 and problems created by the multiplicity of laws. The Committee notes 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 are surprised to note that FSSAI which has been given an omnibus mandate in food sector regulation has 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 is functioning without any worthwhile infrastructure and manpower at the Central and State levels to enforce the Act which is a very worrying situation. All work pertaining to strengthening of FSSAI Headquarters; development of science based standards; food testing facilities; surveillance mechanism both Central and State levels are being badly delayed because of paucity of funds. The Food Safety and Standards Regulations which were published way back on 20 November, 2010 for inviting public comments are yet to be finalized. The data base for the Risk based food clearance system is still being developed. Food Testing Laboratories network is in shambles, accreditation procedure for referral labs is not yet devised.

Reply of the Government

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.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.62 of Chapter of this Report.

Absence of Monitoring Mechanism
(Recommendation Para No. 6.155)

In the opinion of the Committee the Government should realize 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 is the admission of the representative of Directorate General of Foreign Trade before the Committee during Oral-Evidence that there was absolutely no monitoring of the food items being imported into the Country.

Reply of the Government

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.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.65 of Chapter of this Report.

Food Safety and Standards Authority of India (FSSAI)
(Recommendation Para No. 6.156)

The Committee had asked the Authority to spell out their requirements of finances for the projected activities. The Authority have projected a requirement of Rs. 4557.00 crore for the entire Twelfth Five Year Plan. The Committee exhort the Government to allocate the requisite funds to the Authority on priority basis, as unless the edifice is built, it will not be possible for it to function optimally, a possibility the Country can ill afford in the food sector.

Reply of the Government

Noted.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.62 of Chapter of this Report.

Handling of Regulation and Labelling of Transgenic Food Products by the Government
(Recommendation Para No. 7.59)

The handling of the twin issues of regulation and labeling of transgenic food products by the Government speaks volumes about their casual attitude towards such sensitive and important matters. As per Rule 11 of Rules 89, the food stuffs, ingredients in food stuffs and additives including processing aids containing or consisting of GMOs could not be produced, sold, imported or used without the approval of GEAC. However, MoEF on 23 August, 2007 exempted all

these categories from Rule 11 if the end product was not an LMO. This according to the Government was done as only Living Modified Organism have property to propagate and pose risk to environment; the Task Force on recombinant pharma under Dr. R.A. Mashelkar, former DG, CSIR and the Task Force on Agriculture Biotechnology under Prof. M.S. Swaminathan, have recommended that GEAC should be involved only in the regulation of LMOs to avoid regulatory overlap; FSSAI Act had a special provision for dealing with GM food and food products and to address health concerns/risks in line with codex guidelines.

Reply of the Government

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.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Potential of Transgenic Food Crops to ensure Country's Food Security (Recommendation Para No. 7.71)

A major argument extended in favour of transgenic food crops by DAC before the Committee is their potential to ensure Country's food security in coming years due to increase in population. The Committee, therefore, analysed the food production and availability scenario during last decade along with

population trends. The foodgrains production during the last decade has more than kept pace with the growth in population. The total foodgrains production rose from 197 odd million tonnes in 2000-2001 to 241 million tonnes in 2010-11. The production of fruits has gone up steeply from 430 lakh tonnes to 759 lakh tonnes during this decade. Similarly, the production of vegetables has also shown a significant rise from 886.22 lakh tonnes to 1376.32 lakh tonnes. Throughout this decade barring a year or so India has been a net exporter of food grains and vegetables. The rise in food grains and fruits and vegetable production has continued in spite of two major droughts during this decade. The toil of the farmer and the significant contribution of the agricultural scientists have ensured that food security is not a problem. In the opinion of the Committee the problem today is in no measure comparable to the ship to mouth situation of early sixties as today we are only faced with a serious deceleration in availability of food. In spite of sufficient production and more than double the amount of buffer norms food stocks with the Government there is a huge disparity in availability of food. A large majority does not have access to food due to extreme poverty while colossal amounts of food grains, fruits and vegetables are being lost during post harvest storage. As Secretary, Department of Agriculture & Cooperation confessed before the Committee that a saving of 10% in post harvest crops losses would mean 23 million tonnes of extra food grains. Primarily faulty procurement policy, mismanagement of stocks, lack of adequate and proper storage, hoarding and lopsided distribution, massive leakages in the public distribution delivery system, etc. are more responsible for the present worrisome situation. If these shortcomings and problems are attended to along with liberal financial assistance to agriculture and allied sectors, proactive measures are initiated to arrest the decreasing trend in cultivable area and farmer friendly and sustainable agricultural practices are put in use, there would not be any compelling need for adopting technologies which are yet to be proven totally safe for biodiversity, environment, human and livestock health and which will encourage monoculture, an option best avoided. The Committee would, therefore, recommend the Government to come up with a fresh road map for ensuring food

security in coming years without jeopardizing the vast bio-diversity of the Country and compromising with the safety of human health and livestock health.

Reply of the Government

MoA is in strong agreement with the view that biodiversity considerations and biosafety concerns will be paramount pre-requisites for utilization of genetic resources for future crop improvement.

As per the present procurement policy, the Central Government extends price support to paddy and wheat through Food Corporation of India (FCI) and State Agencies. All the foodgrains conforming to prescribed specifications offered for sale at specified centres are purchased by the public procurement agencies at the Minimum Support Price (MSP). The farmers have the option to sell their produce to FCI/State Agencies at the MSP or in the open market, as is advantageous to them.

The Central stocks of foodgrains are stored by the FCI and the State Government Agencies in covered godowns and in Cover and Plinth (CAP). The total storage capacity available with the Food Corporation of India (FCI) [owned and hired] as on 1.8.2012 was 372.79 lakh MTs. However, total storage capacity available with FCI and State agencies is 714.14 lakh MTs against the current central pool stocks of 760 lakh MTs in the form of wheat and rice. During procurement season, stock of foodgrains do exceed the available storage capacity for which temporary arrangements are made. However, to increase the covered storage capacity in the long run, the Government formulated the Private Entrepreneurs Guarantee (PEG) Scheme in 2008.

Assessment of additional storage needs under the PEG scheme is based on the overall procurement/consumption and the storage space already available. For the consuming areas, storage capacity is to be created to meet

four month's requirement of PDS and Other Welfare Schemes in a State. For the procurement areas, the highest stock levels in the last three years are considered to decide the storage capacity required.

Under this Scheme, a capacity of 181.08 lakh tonnes is being created in 19 States through private entrepreneurs and Central and State Warehousing Corporations. FCI has already sanctioned a total storage capacity of about 120 lakh tonnes out of which a capacity of about 95.79 lakh tonnes has been sanctioned to the private entrepreneurs. CWC and SWCs have been sanctioned 5.50 lakh tonnes and 19.38 lakh tonnes respectively. A capacity of about 61.09 lakh tonnes is under construction. At present 25.12 lakh MTs have been completed out of which 17.86 lakh MTs has been taken over and the balance is expected to be taken over shortly. It is expected that by March, 2013, further about 48 lakh tonnes would be completed and taken over.

Besides PEG scheme, following steps have been taken by the Government for creating additional storage capacity:-

- A storage capacity of 5.74 lakh tonnes [5.34 lakh tonnes for North East (NE) Region and 40,000 tonnes for other than NE] has been proposed for construction at a cost of Rs. 551.50 crore during 12th Five Year Plan.
- A capacity of 20 lakh tonnes is being created through modern silos in different parts of the country.

Thus it can be seen that the Department is already taking effective measures to improve the storage capacity for foodgrains being supplied under PDS.

Further, there is a well established quality control mechanism for scientific storage of foodgrains followed in FCI godowns for proper storage and to avoid damage during storage. Department of Food & Public Distribution has issued

instructions to all State Governments/UT Administration and Food Corporation of India from time to time to take required measures, for proper enforcement of quality control mechanism of foodgrains during procurement, storage and distribution. Recently the instructions were reiterated on 8th June, 2012 to the Principal Secretaries (Food) of the States where the wheat stocks are stored in CAP to ensure that field functionaries engaged in the preservation of foodgrains strictly follow the code of practices of scientific storage of foodgrain, First-In-First-Out (FIFO) principle and issue the stocks stored in kutchha/unscientific plinths etc on priority basis to prevent any damage.

Some quantities of foodgrains may get damaged during storage due to various reasons such as storage pest attack, leakages in godowns, procurement of poor quality stock, exposure to rains in case of unscientific storage because of lack of storage space, floods, negligence on the part of concerned officials in taking precautionary measures etc. A quantity of 6702 tonnes, 6346 tonnes and 3338 tonnes of foodgrains got damaged/ became non-issuable in FCI during 2009-10, 2010-11, 2011-12 respectively. During the current Financial Year – 2012-13 (as on 01.08.2012), the stock of damaged/non-issuable foodgrains amounts to 1324 tonnes only. In percentage term, accrual of Non-issuable/damaged foodgrains vis-à-vis off take from FCI stocks for the last five years (2007-08 to 2011-12) was 0.10, 0.07, 0.02, 0.014 and 0.006 respectively. It may, therefore, be seen that the percentage of damaged foodgrains has been declining and is extremely low.

So far as the distribution of foodgrains is concerned the Targeted Public Distribution System (TPDS) has been one of the major initiatives of Government of India in its efforts to provide food security to millions of poor in the country. Government of India makes allocation of foodgrains(rice/wheat) to States/Union Territories at highly subsidized Central Issue Prices (CIPs) through Targeted Public Distribution System (TPDS) @ 35 kg per family per month for 6.52 crore Below Poverty Line (BPL) families, including among them 2.43 crore Antyodaya Anna households, the poorest of the poor across the country. Allocation of

foodgrains for Above Poverty Line (APL) families are made based on availability of stocks of foodgrains in the Central Pool and past offtake. Presently, APL allocations range between 15 and 35 kg per family/month in different States/UTs.

Apart from normal TPDS allocations, Government of India also makes additional allocations of foodgrains to the States/UTs from time to time. During the current year 2012-13, the Government of India has so far allocated 573.79 lakh tonnes of foodgrains to the States/UTs under TPDS and including additional allocation of 134.37 lakh tonnes comprising of 17.66 lakh tonnes for additional BPL/AAY families in the poorest/backward districts in 21 States, 50 lakh tonnes to all States/UTs for additional BPL families, 60 lakh tonnes to APL families and 5.43 lakh tonnes for flood/drought relief, festivals, etc.

However, TPDS is operated under the joint responsibility of the Government of India and State Governments/UT Administrations. The responsibility for lifting of the allocated food grains, their further distribution to eligible ration cardholders through fair price shops rests with the State Government/UT Administration.

Government of India has introduced the National Food Security Bill, 2011 (NFSB) in the Lok Sabha on 22nd December, 2011 with the objective to provide for food and nutritional security, in human life cycle approach, by ensuring access to adequate quantity of quality food at affordable prices to the people to live a life with dignity.

Some of the key issues that need attention are:

- Stagnation in yield potential is noticed in food crops over the past ten years. Punjab and Haryana have already reached their plateau without any new infusion of technologies.

- Overcoming various abiotic and biotic stresses in Eastern Region or rainfed areas would require better breeding techniques for new varieties that stabilizes yield gains.
- Focus on practices is knowledge intensive with difficulty in monitoring the expected gains.
- Nutritional security through pulses and millets improvement would require control over pests and also to develop better plant types that improves harvest index and is amenable to mechanization stresses.
- Bio fortification through Nutrient rich rice like golden rice has been developed to overcome iron and beta carotene deficiency
- With increasing demand of food grains for the size of Indian population, sustained production of sufficient food grains would require major technological inputs which molecular marker assisted plant breeding, Genetic engineering including transgenics offer.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

**Contributions made by Bio-technology to the Agriculture Sector
(Recommendation Para No. 8.115)**

The Committee note that Biotechnology has made salutary contributions to the agriculture sector for decades together. Plant breeding, tissue culture, cropping practices, etc. are all practiced worldwide by farmers. Most of these biotechnologies are locally developed with local research support and have significantly contributed to the farmers well being. The Committee further note that in last two decades or so transgenics in agriculture crops is being propagated as the panacea for several ills besetting the agriculture sector. Several Ministries/ Departments/Agencies in their submissions before the Committee have expounded the virtues of this comparatively new technology. The Industry has also been very supportive of transgenics in agricultural crops. According to ICAR transgenic crops by nature are eco-friendly,

sustainable and protective to environment and biodiversity; increase productivity, thereby, contributing to national food, feed and fibre-security, lower production costs, conserve bio-diversity as a land saving technology capable of higher productivity on a per unit land basis; efficiently utilize inputs such as fertilizers and water; increasing stability of production to lessen suffering during famines due to abiotic and biotic stresses, improving economic and social benefits, ensuring safer human health through reduction of chemical inputs in agriculture alongwith safer soil, water and food. The Department of Science and Technology have also recommended recombinant DNA technology as one of the breakthrough technologies like nuclear energy, super computers, etc. and have stated that such breakthrough technologies have revolutionary potential to bring paradigm shifts in the existing systems. Ministry of Environment and Forests, DBT, DHR/ICMR, GEAC have all supported transgenics/genetical engineering in agricultural crops, including the food crops more or less for the same reasons. All of these Ministries/Departments/Agencies have also assured the Committee that the assessment and evaluation protocols and regulatory mechanism in place are adequately robust albeit, they will need to be upgraded as the technology acquires more finesse. The Government have also cited the success of transgenics crops cultivation in countries like USA, Argentina, China, etc. as a justification for introducing transgenics in India. Locally, the substantial increase in the cultivation of Bt. Cotton during the last decade or so has been showcased before the Committee as the measure of success. It is being said that the area under Bt. cotton cultivation has gone up from 24000 ha. in 2001 to 8 million ha. plus now. The Committee have also been informed by the Government that apart from production, productivity has also increased due to cultivation of Bt. cotton. The drop in usage of pesticide due to Bt. cotton cultivation is also being quoted as a plus point of the transgenics technology. The Government have also informed the Committee that Bt. cotton has not affected bio-diversity, is a sustainable crop and has improved the income of the farmers.

Reply of the Government

It is stated by Committee that in last two decades or so transgenics in agriculture crops is being propagated as the panacea for several ills besetting the agriculture sector. Several Ministries/ Departments/Agencies in their submissions before the Committee have expounded the virtues of this comparatively new technology.

However, it may be clarified that if one examines the Annual Reports and other documents made available in public domain of the departments /ministries, none of them seems to have “propagated transgenics as panacea”. In fact investment on transgenics is a small portion of total investment. Although, the potential applications of transgenics technology in agriculture cannot be denied in future, transgenic technology has been the choice only when all the conventional or modern non- recombinant technologies have been exhausted to solve a problem or where eco-friendly, sustainable and protection to environment and biodiversity are needed. Care has also been taken not to employ transgenic technology in crops or varieties where there are trade and traceability implications.

It may also be noted development of transgenic in particular crop addressing a trait is not cheap. From discovery to markets, it estimated that an investment of upto Rs 50 crores covering costs of transgenic crop research, technology development, regulatory tests and commercialisation is required and would take anywhere from 10 to 12 years from laboratory to land .Further, long drawn legal cases, petitions and protests, burning experimental fields by activists, rumours and stories spread by Quack –scientists have already made investment in GM research slow down and unpredictable in terms timely availability of technologies for the benefit of farmers and reap any profits by the developer.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

CHAPTER - III

OBSERVATIONS/RECOMMENDATIONS WHICH THE COMMITTEE DO NOT DESIRE TO PURSUE IN VIEW OF THE GOVERNMENT'S REPLIES

Disclosures made by Supreme Court nominee on GEAC to be looked into (Recommendation Para No. 2.77)

While everything appears to be in order on paper, the disclosures made by Dr. P.M. Bhargava, founder Director of Centre for Cellular and Molecular Biology and the Supreme Court nominee on GEAC have alarmed the Committee no end. His testimony that the requisite number of tests were not done on Bt. Cotton in the Country and even those tests that were performed were done either by the company itself or by an accredited laboratory but on the samples provided by the company. The same thing happened in case of Bt. brinjal also. In both the instances, the promoter company is same and according to Dr. Bhargava it is known for unethical practices the world over including bribery charges in Indonesia, hiding data, falsifying data or presenting wrong data. If the regulatory mechanism including RCGM and GEAC faltered on these counts, it is a serious lapse in the opinion of the Committee and needs to be investigated indepth.

Reply of the Government

The claims made by Dr. P.M. Bhargava needs to be substantiated with evidence. In the absence of such evidences, the allegation made on globally reputed institutions and companies engaged in safety testing do not merit consideration.

Government of India is committed to the safe use of GM crops and accordingly robust evaluation systems are in place. Bt cotton was approved in 2002 after an elaborate safety assessment exercise spanning over 7 years.

India has a robust regulatory framework in place for regulation of GMOs and products thereof. The approval of Bt cotton and Bt brinjal by RCGM and GEAC has been accorded on the basis of elaborate set of guidelines and procedures. It may also be noted that these guidelines are based on state-of-the-art international guidance developed after years of consultations by agencies like FAO, WHO, OECD and Codex Alimentarius (**Annexure-III**).

The RCGM and GEAC together involve more than 60 experts covering multi-disciplines to examine the safety assessment data submitted by the applicant at every step of the regulatory process. Globally, regulatory tests are conducted by notified or accredited testing institutions in both public and private sector. The testing and data submission from these laboratories are according to international best practices and ethical procedures.

The regulatory mechanisms have not faltered and acted in a most transparent manner. In fact all the data, reports, decisions etc. have been made available on these website for information of the public. Views of Dr. P. M. Bhargava are his personal opinion and not subscribed to by majority of scientists in India and in the world.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

**Conflict of Interest in the present Regulatory Mechanism in RCGM
(Recommendation Para No. 3.45)**

Under such circumstances when the stakes are so high, the Committee have strong reasons to agree with the apprehensions expressed by several stakeholders who deposed before the Committee that the basic assessments and data generation by IBSC as also the evaluation of these assessments and

data by the accredited Laboratories and regulatory agencies based on the samples provided by the company cannot be relied upon fully. The case of Bt BN and Bt NHH44 mentioned in the Report is a case in point. Another tier in the regulatory mechanism viz. the RCGM functions under the administrative control of DBT which is the promoter Department for biotechnology particularly modern biotechnology in the Government of India. Quite obviously inspite of their best efforts to do justice with their mandate to assess biosafety, environmental safety, human health safety, food and feed safety, there is a strong possibility of conflict of interest creeping in.

Reply of the Government

It may be clarified that:

“RCGM **does not** function under the Department of Biotechnology (DBT).”
On the other hand “RCGM functions under the GEAC as per rules 1989 of EPA Act 1986. RCGM **is not** under administrative control of DBT. DBT services RCGM in terms of infrastructure and human resource.”

RCGM **does not** report to Secretary, DBT directly or indirectly. No official of DBT has any influence on the functioning of RCGM. **It directly reports to GEAC.**

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Government to bring forth on all Encompassing Umbrella Legislation on Bio-Safety at the earliest **(Recommendation Para No. 3.47)**

The Government time and again justified, before the Committee, the existing regulatory mechanism as based on best global practices and systems which are followed successfully in the pharmaceutical sector also. It is common

knowledge that the regulatory mechanism in the pharmaceutical industry is beset with several problems and shortcomings. In fact the Department Related Standing Committee on Health and Family Welfare in their 59th Report on “The Functioning of the Central Drugs Standard Control Organisation (CDSCO)” presented to the Parliament on 8 May, 2012 have severely criticized CDSCO for several malpractices including working against the interest of patients, collusion with industry and numerous other acts of omission and commission and have recommended to the Government a complete overhaul of the regulatory mechanism for the pharmaceutical industry. Since the Government have drawn a parallel between the regulatory mechanism for GMOs and products thereof with the regulatory mechanism for the pharmaceutical industry, the Committee are of a very strong view that the former also requires to be overhauled, even created *de novo* in the interest of biosafety, environmental safety, human and livestock health safety. Albeit, it is to be ensured that due concern is paid to the interest of the industry. From their examination of the subject the Committee have found that, hitherto, the tendency of the regulatory mechanism in the absence of specialized infrastructure and R&D facilities in the Country is to base their decision making on practices and studies elsewhere, as also on the assessments and data generated by the company concerned. This type of precautionary approach has lot of scope for mistakes, errors, misrepresentation and misinterpretation. It is, therefore, not at all an ideal regulatory mechanism for a Country like India which is the centre of origin, as also one of the richest centres of biodiversity in the world. We should also not forget that we are the second most populous country in the world and have a huge population of livestock, as well. The present state of our health services and various other social sector services also does not inspire confidence that remedial action, post commercialization would be forthcoming, with any degree of alacrity. In such a situation what the Country needs is not a biotechnology regulatory legislation but an all encompassing umbrella legislation on biosafety which is focused on ensuring the biosafety, biodiversity, human and livestock health, environmental protection and which specifically describes the extent to which biotechnology,

including modern biotechnology, fits in the scheme of things without compromising with the safety of any of the elements mentioned above. The Committee, therefore, recommend to the Government with all the power at their command to immediately evolve such a legislation after due consultation with all stakeholders and bring it before the Parliament without any further delay. In this context the Committee would advise Government to duly consult the Norwegian Law which emulates this spirit to a large extent.

Reply of the Government

It is reiterated that the present regulatory system has been working satisfactorily in terms of dealing with the regulation of modern biotechnology products and processes.

However, it may be noted that India is still dealing with first generation GM crops and human and animal health products. In the recent past following complete DNA sequencing of human genome, rice, sorghum and several beneficial and pathogenic micro organisms along with array of tools and techniques of molecular biology, immunology, chemical biology, system biology, synthetic biology, nano biotechnology and stem cell biology have opened up opportunities for development of range of complex products such as crops with complex genetic interventions, biopharmaceuticals, biologicals and gene therapies etc. The global biotech industry is growing at healthy 10-15% and Indian public and private sectors would be registering a growth of US \$ 20 billion in the next decade at the current growth rate.

In view of the future challenges of increased complexities of biotech product developments involving array of converging technologies and responding to public concerns on safety and benefits of these technologies, Govt. of India has been proactive in recognizing need for reforms to have preparedness for future. Accordingly the Biotech Regulatory Authority of India (BRAI) Bill 2012 has

been submitted to the Lok Sabha for introduction. The BRAI Bill is aimed at addressing safety and efficacy issues following international best practices followed in countries with functional regulatory systems.

The issue of whether or not an “umbrella” biosafety law would be useful in India will depend on a variety of factors. No compelling evidence or logic has been offered to support the supposition that such legislation would make regulatory implementation in India more effective. A look at the experience around the world shows mixed results. Many well implemented systems have used existing legislation related to the environment and agriculture in combination with new or existing regulations (e.g. Argentina, United States, Canada) to form the core of their biosafety regulatory system. Others (e.g. Australia, Brazil) have relied on new legislation. In India already there are relevant legislations on environment, biodiversity, food safety and standards, seed registration and certification, drugs and cosmetics. Accordingly, the BRAI Bill takes into account biosafety and efficacy assessment of GM products in agriculture, human and animal healthcare, industry and environment in harmony with the existing acts administered by various departments. Considering the requirements for central coordination on functioning and oversight of various authorities, BRAI Bill provides for constitution of inter-ministerial governing board with members from 15 central ministries. It has also a pragmatic coordinating and feedback system involving all the State Government. In addition the authority will be advised by a National Biotechnology Advisory Committee as a part of the Bill consisting of representatives from civil society, industry, farmers and consumers organisations to provide constant feedback from time to time on the performance and problems related to commercial use of biotechnology products in healthcare and agriculture. Elaborate monitoring systems at authority and state level with financing and technical support and stringent punitive actions and punishments for non compliance are integral to Bill.

The Parliamentary Committee chooses once again to highlight the policies of Norway, a country with a small, wealthy population heavily reliant on fossil fuel exports and with inconsequential agricultural production. This despite the fact that there are plenty of developing and newly industrialized countries that have population demographics and agricultural needs much more closely aligned with those of India, and which have accrued considerable experience with the use of LMOs. These countries include Brazil, China, Mexico and South Africa. The obscure choice of Norway as an appropriate model for India suggests a bias in favour of Norway's regulatory mechanism (a *de facto* ban on the testing and use of LMOs) rather than an understanding its function – particularly since the Norwegian Act has resulted in essentially no decisions on the use of LMOs and is therefore one of those with arguably the least experience in the world (see response to section 3.40).

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Convention on Biological Diversity (CBD)
(Recommendation Para No. 4.29)

The Convention on Biological Diversity (CBD) adopted at Rio Earth Summit was signed by India on 5 June, 1992 and ratified on 18 February, 1994. CBD very unambiguously reaffirms sovereign rights of nations over their natural resources and establishes three clear goals *viz.* conservation of biological diversity, sustainable use of its components and fair and equitable sharing of benefits arising from the use of genetic resources. The access and benefit sharing objective forms the core of CBD. CBD, which are likely to have adverse environmental also directs the members to establish or maintain means to regulate, manage or control risks associated with the use and release of LMOs resulting from biotechnology impacts affecting the conservation and sustainable use of biodiversity as also human health.

Reply of the Government

The report has stated that “CBD, which are likely to have adverse environmental impact also **directs** the members to establish or maintain means to regulate, manage or control risks associated with the use and release of LMOs resulting from biotechnology impacts affecting the conservation and sustainable use of biodiversity as also human health”.

It may be clarified that CBD does not “direct the members to establish or maintain means to regulate, manage or control risks associated with the use and release of LMOs...”. Rather, Article 19.3 of the CBD calls on Parties to “**consider** the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity”. Article 19.3 is an enabling provision, not a directive to Parties. Parties elected to create the CPB in response to this provision, but it is important to note that it did not prejudice the outcome in this regard.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Need for an all Encompassing Bio-safety Authority at the earliest (Recommendation Para No. 4.34)

Apart from these major conventions and treaties there are several more conventions/protocols/treaties/ agreements pertaining to the subject. The Committee note that other than the WTO whose primary focus is facilitation of trade, all other relevant treaties, conventions, protocols and agreement very unambiguously under line the need for ensuring biological diversity and sustainability and eliminating any risk to the human health due to use of LMOs,

GMOs and products thereof. The Committee are however appalled by the existing state of affairs in these matters in the Country. While we have become signatories to these conventions/protocols/agreements/ treaties with alacrity, we have simultaneously not ensured that the necessary wherewithal, scientific expertise, infrastructure and manpower for ensuring compliance is also created. As the succeeding narrative will prove, the Biological Diversity Authority and PPV and FRA could have played a crucial role as an advisor and regulator in several matters pertaining to safety and sustainability of biodiversity but they are just a cosmetic presence. The Committee need not reiterate their observation regarding the state of affairs in the extant regulatory mechanism for the LMOs and products thereof, as it has been already commented upon in one of the previous chapters. However, hugely concerned with the situation on the ground, the Committee cannot but reiterate that the Country requires an all encompassing Bio-safety Authority without any further loss of time.

Reply of the Government

The Parliamentary Committee report states that there are “several more conventions/protocols/treaties/agreements pertaining to the subject.” However it is simply not the case that “all other relevant treaties, conventions, protocols and agreements very unambiguously underline the need for ensuring biological diversity and sustainability and eliminating any risk to human health due to use of LMOs, GMOs and products thereof”. In fact, the only international treaties that address LMOs and their potential impact on biological diversity directly are the CPB and N-KL SP. Importantly both recognize that modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health.

The Parliamentary Committee is correct to point out that ensuring compliance with international treaty obligations should be a priority. However it is important to note that the mechanism being suggested by the Parliamentary

Committee (“an all-encompassing Bio-safety Authority”) is not required under any of the relevant international agreements. Further in India several relevant legislations on biodiversity, PVPFR, environmental protection and food safety are already in place and therefore BRAI Bill proposes an umbrella inter-ministerial governing Board for coordination and oversight of biosafety aspects of GMOs in a comprehensive manner.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

**Challenges Posed by Cultivation of GM Crops on a Commercial Basis
(Recommendation Para No. 5.47)**

The Committee strongly feel that given the reach and spread of outside containment applications of modern biotechnology *viz.* cultivation of GM Crops on commercial scale, containment of harm would be a very challenging task even for some of the most well equipped developed countries and simply impossible in a country like India. The Committee also fully concur with the assessment of the Report that the integration of biotechnology must be within an enabling environment supported by local research and education that empowers local communities. Biotechnology must work with the best production system for the local community for example agro systems of even the poorest societies have the potential through ecological agriculture and Integrated Post Management to meet or significantly exceed yield produced by conventional methods, reduce the demand for land conversion for agriculture, restore ecosystems services (particularly water), reduce the use of and need for synthetic fertilizers derived from fossil fuels, and the use of harsh insecticides and herbicides.

Reply of the Government

Such fear is uncalled for, if the adoption of the new technology is carefully managed. GM crops approved after extensive safety evaluation processes, have

been grown commercially (outside containment) in 29 countries over 160 million hectares without any reports of adverse effects. Food and feed derived products derived from such crops are being used in 55 countries across the world. There are well established scientific processes arrived at, after years of consultations and successfully adopted in India. Government of India is committed to safe use of GM crops and there are enough capabilities in the country to deal with GM crops. The scientific and regulatory capacities are constantly being strengthened in line with the global developments.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Apprehensions Raised in IAASTD Report to be Addressed to Immediately by the Government
(Recommendation Para No. 5.48)

The Report has also drawn attention towards the threat of IP and globalization to public plant breeding institutions in developing countries as privatization fuels transfer of knowledge away from commons. There is a contraction both in crop diversity and numbers of local breed. In many parts of the world, women play this role and thus a risk exists that privatization will lead to woman losing economic resources and social standing as their plant breeding knowledge is appropriated, simultaneously the entire communities run the risk of losing their control over the food security. Based on their Study Visit to Vidharba the Committee are fully in agreement with these apprehensions of IAASTD Report and desire the Government to take immediate steps to remedy the situation in the Country. This Committee find this very true in the context of India also.

Reply of the Government

The Union of India firmly believes that strengthening public sector research institutions in advanced sciences such as molecular biology and biotechnology to foster an enabling environment will ensure that intellectual property issues can be properly managed. . The government has invested significantly in the R&D in public sector research institutions primarily under the aegis of ICAR and DBT for development of technology including GM crops for local needs

In fact public perception on the fear of unknown and consistent attempt by certain sections of society to spread unfounded fears with no scientific or data based evidence severely affect public sector research demoralising dedicated scientific community. Already due to these factors, the Indian R&D in agriculture biotechnology has slowed down. If India continues to lag behind, other countries/multinational companies(MNC) will move forward with research and in due course we may have to import GM technology/seeds by paying higher cost. This may also make India more dependent on newer technologies and affect food security.

Recent initiatives of Indian industry in field of pharmaceutical related intellectual property rights (IPR) show the proactive role that government can play. For example the case of recombinant hepatitis B vaccine, erythropoietin, interferons and other biosimillars, the costs have drastically come down by 40-60% Similar initiative in 12th Plan in DAC's mission on seed and planting material envisage providing financial assistance to public sector seed producing entities either individually or collectively for acquisition of new technology. These seed producing entities can utilize the services of IPR managers for acquiring varietal licences. These initiatives will be the way forward towards ensuring that IPR/technology is accessible to masses within reasonable prices. The PPV&FR Act has adequate provision to recognize farmers' communities' effort towards

germplasm conservation. It not only rewards communities for these efforts but also provides safeguards for benefit sharing. The statement that “privatization will lead to woman losing economic resources and social standing”, is highly generalized. In 2010, researchers at University of Warwick published a peer reviewed research paper titled “ GM crops and Gender issues”. The study reported that employment for cotton picking increased significantly for hired females who benefitted 55% more than male labourers, which translates to about 424 million additional employment opportunities for female earners for the total Bt cotton area in India.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Report of Six Science Academies **(Recommendation Para No. 5.55)**

From the sequence of events narrated above and the views and counter views expressed by various stakeholders, the report by the six science academies is a job hastily done. In view of the high expectations from these very respected bodies, the Country expected a well considered and more professional outcome on this highly sensitive matter rather than a cut and paste effort which invited ridicule and revision and avoidable criticism.

Reply of the Government

As mentioned above in section 5.53, it is reiterated that the report by the six academies is science based and not a cut and paste effort. In fact, the issues raised regarding plagiarism, non citation of references etc. were raised by specific groups with an intention to divert attention and in no way related to safety of Bt Brinjal. All such issues were subsequently resolved. The findings of the committee were sound and cannot be disputed.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Central Government to Apportion Appropriate Responsibilities on the States in the Bio-Safety Law
(Recommendation Para No. 7.18)

The Committee take note of the fact that under the constitutional scheme of things agriculture is a State Subject. Article 246 of Constitution of India explicitly assigns 'agriculture, including agricultural education and research, protection against pest and prevention of plant diseases to the States of the Union. In such a situation, there is no scope for any misinterpretation of role and responsibility of the State Governments with matters concerning or having a bearing on agriculture. In case of field trials of transgenics crops the Committee find that a peculiar situation obtains. For a thing as crucial as field trials till recently the State Governments were not even consulted. The Ministry of Environment and Forests have without any appreciation of the constitutional positions defended their decision on the specious plea that as monitoring during the field trials is the responsibility of SBCCs and DLCs which are entities of State Governments prior approval of State is not necessary. The Committee are not at all convinced by the flawed logic extended by Ministry of Environment and Forests. In view of the diverse opinions about transgenic crops and controversies surrounding their induction a mandatory consultation process with the State Governments culminating into seeking their permission for field trials, in the opinion of the Committee should have been inbuilt in the regulatory mechanism. This was inexplicably not done by Ministry of Environment and Forests leading to several States being compelled to voice their objections to the apparently flawed procedure being followed in a matter, which is in the domain of the State Governments. The Committee note that the Ministry have, thereafter, taken remedial action and from last year onwards the applicant is required to obtain a no objection certificate from the State where the trial is proposed to be conducted. The Committee also recommend that since States have a major role in agriculture sector and most of the responsibility at field level devolves on them,

the Government should apportion appropriate responsibilities on the States in the Biosafety Law recommended by the Committee. This will not only be in consonance with the Constitution and the Government will be saved the embarrassment of a Bihar type incident, but would be a practical and pragmatic approach to deal with various developments in the agriculture sector where at the ground level the Central Government at best has a peripheral role.

Reply of the Government

The information provided to the Committee by MoEF is with respect to the legal position on the requirement of NOC from the State Government under Rules,1989.

The recent practice of seeking approval from States has led to a piquant situation wherein research trials face uncertainty. States while agreeing to cultivation of Bt. Cotton, have been denying trials for other crops. Recently Ministry of Agriculture has written to all states to allow trials and some states are working on the issue.

While it may not be appropriate to assume the role of central government as peripheral, yet the point of the Committee regarding importance of states in decision making is well taken. In a federal structure like India, states are important partners. The SAC – PM report gives important suggestions that will ensure constructive dialogue with the states on related issues. The report suggests the following:

- 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.

- Research and infrastructure of state agriculture universities and colleges be strengthened for addressing the locations- specific needs of the states and regions and generate expertise.
- Priority should be given to strengthen state government departments and laboratories dealing with agriculture inputs, including GM or non GM seeds, extension and education of farmers through major programmes and investments for capacity building tailor made to the needs of the region.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Research and Development Activities on Transgenics to be carried out only in containment and ongoing Filed Trials in all States be Discontinued Forthwith
(Recommendation Para No. 7.21)

Considering the flaws and shortcomings noticed by the Committee in the functioning of the regulatory mechanism meant for the purpose, the lack of preparedness of various agencies who should ideally be involved in various oversight and both, pre and post commercialization surveillance responsibilities in the context of transgenic crops, the still unclear ramifications of transgenic crops on bio-diversity, environment, human and livestock health and sustainability, the Committee desire in consonance with their recommendation in a previous Chapter that for the time being all research and development activities on transgenic crops should be carried out only in containment, the ongoing field trials in all States should be discontinued forthwith.

Reply of the Government

The recommendation to conduct all research and development activities only in the containment is contrary to the recommendation that there is a need for generating data on impacts on biodiversity and human health. 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.

It is also clarified that ban on GM crop field trials will be highly detrimental and not in the national interest. Adoption of this recommendation would bring to a halt the process of testing / assessment of the safety of GM crops. The entire working of the regulatory agencies, the research activities on GM crops and in turn the need of the country to realize the potential benefit of modern biotechnology in terms of food security would come to a virtual halt if field trials of GM crops are stopped in the country. Stopping of GM crop trials in the states will be a blow to Indian science as it would push the country behind in scientific research in comparison to fast growing economies who are developing GM crops like Brazil, China, etc. This will have several cascading implications. The country will fail to attract scientific talent from the younger generations in the absence of opportunity. Over a period of time lack of expertise in a critical area such as food security will set India backward by 30-40 years.

Indian farmers and the Indian economy as a whole will be the biggest loser by stalling the research and development in the area of GM technology because eventually India will be forced to import technology by paying much higher price due to lack of its partnership in the IPR and by losing out on the human resource development required for being in the race of global technological development, that is so essential for maintaining the superiority of the nation.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

CHAPTER - IV

OBSERVATIONS/ RECOMMENDATIONS IN RESPECT OF WHICH REPLIES OF THE GOVERNMENT HAVE NOT BEEN ACCEPTED BY THE COMMITTEE

Regulatory Mechanism for Transgenics and Containment of Trials (Recommendation Para No. 1.20)

The Committee note with great appreciation the fantastic achievements of India's farmers and agriculture scientists leading to an almost five times growth in food grains production in the country during last six decades or so. From a paltry 50 million tonnes in 1950 the Country has produced a record 241 million tonnes in 2010-11. In spite of this spectacular achievement that has ensured the food security of the nation, things continue to be bleak on several fronts. Agriculture sector's contribution to GDP has slid down from 50% in 1950 to a mere 13% now, though the sector continues to provide employment and subsistence to almost 70% of the workforce. The lot of the farmer has worsened with increasing indebtedness, high input costs, far less than remunerative prices for his produce, yield plateau, worsening soil health, continued neglect of the agriculture sector and the farmer by the Government, dependence on rain gods in 60% of cultivated area, even after six and a half decades of Country's independence, to cite a few. All these factors and many more have aggravated the situation to such an extent that today a most severe agrarian crisis in the history is staring at us. The condition of the farming-Community in the absence of pro-farmer/pro-agriculture policies has become so pitiable that it now sounds unbelievable that the slogan Jai Jawan – Jai Kisan was coined in India.

Reply of the Government

India is the second most populous country in the world and with the present rate of increase in population, is soon going to become the most populous country in the world. This increase in population is continuously pushing for enhancing food grain production. With limited land and water resources, climatic changes and available technical knowhow, every effort is being made to increase agricultural production and farmer's income and present level of food production in the country is the testimony of such efforts. It is a fact that, in the process there has been more pressure on land and on exploitation of available resources. However, the interest of farmers and their well being has always been the priority of the govt.

As is evinced from the status of increase in agricultural production, there has also been commensurate increase in the income of the farmers.

Department of Agriculture and Cooperation through its initiatives extending through Tenth and Eleventh Five Year Plan, has implemented several new schemes such as National Food Security Mission(NFSM), Rashtriya Krishi Vikas Yojana(RKVY) Bringing Green Revolution to Eastern India(BGREI), Intensive Millet Programme(INSIMP), National Horticulture Mission. These schemes have made significant efforts to bring new technology in agriculture thereby enhancing production and productivity. This enhancement has directly benefited the farmers thereby increasing their farm income. Moreover several schemes have been conceptualized which are operated in times of calamities such as droughts, floods etc. There are special provisions wherein enhanced seed subsidy is provided during drought situation, providing diesel subsidy and also National Disaster Relief fund wherein farmers' input costs are taken care of during natural calamities. This illustrative list of initiatives shows that government has been continuously formulating and implementing schemes, which aim at well being of farmers and also aims at ameliorating their losses during natural

calamities etc. It may not be correct to say that the country is at the threshold of severe agrarian crisis.

Also keeping in mind the complex socio economic situation of the farmers the government has been implementing several measures to improve financial condition of the farmers. These inter alia include implementation of rehabilitation package covering 31 districts in Andhra Pradesh, Karnataka, Kerala and Maharashtra. implementation of agricultural Debt Waiver and Debt Relief, increasing credit flow to agriculture, providing Kissan Credit Card to all eligible and willing farmers etc. Government has also been providing interest rate subvention for timely payment of crop loans and benefit of pre- harvest interest rate subvention available to small and marginal farmers.

In addition the announcement of Minimum Support Price (MSP) for identified agricultural commodities every year to ensure remunerative price and increase farmers' income. MSP of major agricultural commodities has been stepped up significantly e.g. during 2004-05 to 2012-1. There are also facilities for providing micro finance service through apex institution like National Bank for Agriculture and Rural Development (NABARD), Small Industries Bank of India (SIDBI), commercial banks,. Regional Rural Banks, Cooperative banks etc.

Hence it may not correct to say that there is an absence of pro-farmer, pro-agriculture policies in the government domain.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
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Comments of the Committee

For comments of the Committee please refer to Para No. 1.5 of Chapter of this Report

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

Furthermore, Dr. Bhargava has also 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, which apart from Dr. Bhargava was also brought to the notice of the Committee by Dr. Sagari Ramdas of Anthra and Ms. Kavitha Kuruganti of Kheti Virasat Mission, also raise doubts about the safety of Bt. cotton as feed. Similarly, how the regulatory mechanism has missed the 30 % increase in toxic alkaloid content in Bt. brinjal and approved it for environmental release are all perplexing questions which need honest answers, as all these developments could have devastating effects on environment and human and livestock health.

Reply of the Government

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 appear to be based on allegations made by some activists.

The concerns raised regarding are unfounded and misleading as may be seen below:

- **Resistance to pests it was supposed to kill:** Development of resistance to Bt protein, pesticide etc in agriculture crops is recognized as a natural phenomena requiring various Insect Resist Management Strategies (IRM) to delay the development of resistance. However, 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.

- **Increasing attack of secondary pests:** The main purpose of Bt-cotton is to control bollworms. Bt cotton effectively controlled bollworms, especially the American Bollworm, *Helicoverpa armigera*, 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. Yields are estimated to have increased at least by 30% due to effective protection from bollworm damage.

A recently published high quality analysis based on long-term data collected from India (2006-2008 periods) concludes that Bt cotton cultivation has caused an increase of 24% in cotton yields per acre in form of reduced pest damage and a 50% gain in profits. The study also documents that the gains are stable and have also increased over time resulting in rising of household living standard by 18% that led to the conclusion that “Bt cotton has created large and sustainable benefits, which contribute to positive economic and social development in India” A copy of the study published in a reputed peer reviewed journal i.e. Proceedings of National Academy of Sciences (PNAS) is enclosed at **Annexure-IV**.

- **Death of cattle and livestock in Andhra Pradesh after grazing of Bt cotton feed:** Globally there is adequate peer reviewed scientific literature over two decades as an 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. However, it is only in India that such apprehensions were expressed by certain civil society organisations and individuals regarding cattle/livestock and sheep mortality in Andhra Pradesh due to grazing in Bt cotton fields. The Andhra Pradesh State Department of Agriculture, which investigated the case at the behest of GEAC had the Bt cotton samples

analyzed by four public sector laboratories. The samples were found to contain high levels of nitrates, nitrites, hydrogen cyanide residues and organophosphates, which may have come from the soil, fertilizer or pesticides used in cotton cultivation and were the cause of animal deaths.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.8 of Chapter of this Report

Thorough Probe into the Bt. Brinjal Case **(Recommendation Para No. 2.79)**

The most damaging piece of evidence about the functioning of the extant regulatory mechanism provided by Dr. P.M. Bhargava in his testimony before the Committee is about the confession of the Co-chairman of GEAC (Prof. Arjula Reddy) to him 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 that he (Co-Chairman, GEAC) was under tremendous pressure as he was getting calls from industry, GEAC and from the Minister to approve Bt. brinjal. Nothing can be more disconcerting to the Committee than these goings on as they are not merely slippages due to oversight or human error but indicative of collusion of worst kind. The Committee, therefore, recommend a thorough probe into the Bt. brinjal matter from the beginning upto the imposing of moratorium on its commercialization by the then Minister of Environment and Forests (I/C) on 9 February, 2010 by a team of eminent independent scientists and environmentalists.

Reply of the Government

This 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:-

- iii) “in retrospect, the only conclusion is that he “succumbed”. You are requested to kindly elaborate as to how this conclusion was arrived at.
- iv) “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 :

- iv) “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”
- v) “Even in the case of tests that have been done, many have not been done satisfactorily and adequately”
- vi) “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:

- iv) “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.
- v) 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.
- vi) 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.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.11 of Chapter of this Report

Change in the Role of GEAC **(Recommendation Para No. 2.81)**

These contradictory stances are not restricted to the renaming issue only, but permeate in several other aspects. To say the least, the demarcation of roles and responsibilities between MoEF and GEAC seems 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 feel that this uncertainty is not in the interest of the regulatory mechanism in place for such a sensitive matter. They, therefore, recommend 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.

Reply of the Government

As per Rules 1989, under the EPA, 1986, regulatory powers for environmental release of GMOs rest only with the GEAC. It is 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.

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”.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.14 of Chapter of this Report

Organizational Setup of GEAC **(Recommendation Para No. 2.83)**

While on the aspect of organizational structure, the Committee also feel it their duty to point out to the composition of GEAC. It is chaired by civil servant who also doubles up as Additional Secretary in the MoEF. The Vice-Chairman is also a civil servant, who is concurrently a Joint Secretary in MoEF. The Co-Chairman of GEAC, a nominee of DBT, is a biotechnologist, whose primary vocation is Vice-Chancellorship of a University in Andhra Pradesh. What directional support and policy guidance would be forthcoming from these top functionaries to GEAC is a moot point. The Committee shudder to think 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 disparate set-up for these many years without an eye being raised. They, therefore, recommend that while reviewing the organizational set-up of GEAC the Government should also keep this aspect in mind.

Reply of the Government

The composition of GEAC has been prescribed in Rules, 1989 notified under EPA, 1986.

The GEAC consists of both scientific experts as well as inter- ministerial representatives. Further expert committees or sub- committees are 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.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.17 of Chapter of this Report.

Formulation of a Policy regarding Marker Gene Technology (Recommendation Para No. 2.84)

The Committee note that FAO/WHO expert panel, 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 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 have shown a marked inclination for technologies without antibiotic resistant marker genes. Most of the independent scientists and other witnesses appearing before the Committee have also expressed their concern on use of anti-biotic resistant marker gene in developing GMOs.

Reply of the Government

There is ample scientific evidence that there is no significant, real world hazard associated with the markers that are commonly used. Hundreds of regulatory decisions have considered antibiotic resistance marker genes and they have found the use of antibiotic resistance marker genes is safe for human and animal health. 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 (source-www.ogtr.gov.au/). 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.

In fact several international agencies such as International Food Biotechnology Council, FAO/WHO, USFDA, EFSA, etc. have deliberated on the issue and given statements with regard to safe use of antibiotic resistance markers. For example, in 1996 joint consultation by FAO and WHO stated that there is no recorded evidence for the transfer of genes from plants to microorganisms in the gut and that there are no authenticated reports of such bacterial transformation in the environment of the human gastrointestinal tract.

In 2009 European Food Safety Authority (EFSA) requested the Panel on Genetically Modified Organisms (GMO) 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 (GM) plants. From all the evidence gathered, the two Panels came to the concluded 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 [aph(3')-IIa (nptII) and ant(3'')-Ia (aadA)] from GM plants to bacteria, associated with use of GM plants, are unlikely.”

Regarding the development of marker free transgenic plants, it may be noted that technology for marker free GM crops is available only for few traits and may not be feasible for all GM crops/traits.

In the global context, there is no ban on GM crops containing antibiotic resistance marker (ARM) even in countries like 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 had also deliberated on this issue taking into consideration the scientific reports and international guidance. RCGM 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.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.24 of Chapter of this Report.

**Formulation of a Policy regarding Marker Gene Technology
(Recommendation Para No. 2.85)**

In spite of some of the stakeholders emphasising about the remote possibility of the antibiotic resistant marker gene transferring from GM crop or commodity to cells of body or to bacteria in gut, an overwhelming majority of stakeholders who appeared before the Committee are in favour of use of antibiotic marker resistant gene free technology. GEAC has, 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. Side by side GEAC has also informed the Committee that it had taken note of 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/RCGM ineligible for release. GEAC has further given its mind on this crucial matter by stating that technological interventions and improvements are ongoing process and would be made available for newer products.

Reply of the Government

The 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.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.24 of Chapter of this Report.

**Formulation of a Policy regarding Marker Gene Technology
(Recommendation Para No. 2.86)**

The Committee cannot but express their extreme displeasure at this mindset of a regulatory agency which is mandated with ensuring safety of environment, human health, food and feed of the Country. The above-cited response of GEAC betrays a complete lack of concern towards its role and responsibility. Rather it conveys in unequivocal terms its strong inclination towards the benefit of industry. The Committee, therefore, recommend the Government to not leave such a crucial decision in the hands of GEAC but come up with a clear-cut policy in this regard without any further loss of time.

Reply of the Government

The statement in the GEAC minutes quoted in the report in para2.85 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/RCGM ineligible for release”, is not directed for the products in pipeline of companies alone as many public sector institutions are also having GM crops with antibiotic markers in advanced stages of regulatory pathway. The use 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.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.24 of Chapter of this Report.

Regulatory Mechanism for Transgenics and Containment of Trials **(Recommendation Para No. 3.40)**

The Committee have been informed that Norway has a very comprehensive law for regulation of GMOs and products thereof. The primary focus of the Act No. 38 of 2 April, 1993 relating to the production and use of Genetically Modified Organisms is biosafety, ethics and sustainable development without any adverse effects on the health and the environment. It also has separate provisions for impact assessment; making public methods and plans for monitoring and emergency response and also assessment of foreseeable effects; public consultation; compensation; coercive fines; penal measures; etc.

Reply of the Government

While the Norwegian Act may accurately be called “comprehensive,” it is not a functional legislation for assessing the safety of LMOs. Rather, it is a *de facto* ban on the use of the technology. As such, the government of Norway has arguably the least experience of any developed country with the development and use of agricultural biotechnology. A search of the Biosafety Clearing House (the primary information sharing centre for Parties to the Cartagena Protocol) reveals that Norway has issued 0 (zero) decisions under the AIA clause of the Protocol, posted 0 (zero) risk assessments, and made 0 (zero) decisions under article 11 (imports of LMOs for food and feed). In fact, the only decision Norway has made available at the Biosafety Clearing House is a justification document for a ban on the import of a LMO maize for food and feed which dates back to

2000 (prior to entry into force of the Protocol). Norway currently has no on-going field trials of LMOs for research or product development purposes.

Norway has no interest in the development and use of agricultural biotechnology, and hence has pursued a policy of avoidance. Norway is one of the wealthiest countries in the world, primarily due to oil and gas exports, while agriculture makes up only 2% of GDP (<http://www.nationsencyclopedia.com/economies/Europe/Norway-AGRICULTURE.html>). These policies are supported by Norway's small population of fewer than 5 million people.

The Parliamentary Committee's decision to highlight Norway as a model for Indian regulation of LMOs cannot be justified either by any demonstrated competence on the part of the Norwegian system for regulating LMOs (as Norway has essentially no experience in implementing their regulation), or by the close alignment of Norway's agricultural policies with respect to those of India. In fact, it would be difficult to identify any country in the world that was less aligned with the agricultural needs and interests of the people of India. The fact that the PC has chosen to highlight the policies of a single country with no expertise in LMO risk assessment or regulation, rather than the many other countries with robust and effective biosafety systems that have actually issued decisions, is not acceptable to say the least.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.5 of Chapter of this Report.

Regulatory Mechanism for Transgenics and Containment of Trials
(Recommendation Para No. 3.41)

In Argentina transgenic plants and genetically engineered food products are regulated with the help of a GMOs specific law and pre-existing laws covering seeds and veterinary products. Furthermore, the regulation concerning the environmental release of GMOs which have been developed by the National Advisory Committee on Agricultural Biosafety, are based in the form of non-legislative resolution that are integrated in the overall regulatory system and there is no specific law to make the resolutions legally binding.

Reply of the Government

Argentina does not have a GMO specific law. The regulatory requirements for GMOs are found in guidelines in the form of non-legislative resolutions that are integrated into the overall regulatory system that governs the release of products in the agricultural sector. Although the system is not considered as voluntary, there is no specific law that makes the resolutions legally binding. Under this framework, specific guidelines have been developed to establish conditions under which environmental releases of transgenic materials may be conducted.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.5 of Chapter of this Report.

Regulatory Mechanism for Transgenics and Containment of Trials
(Recommendation Para No. 3.42)

South Africa has in the form of Genetically Modified Organism Act a legal instrument specifically to regulate GMOs. The Act which came in force in 1999 created an executive council, a scientific advisory committee and an inspectorate for implementation of its provisions. Apart from this Act, South Africa has Foodstuff Mechanism and Disinfectants Act, 1972 to regulate the safety of all foods including foods derived from biotechnology.

Reply of the Government

Statement of facts.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.5 of Chapter of this Report.

Conflict of Interest of Agencies involved in Existing Regulating Mechanism
(Recommendation Para No. 3.46)

RDAC, which is an advisory committee incidentally also functions under the administrative control of the Department of Biotechnology. Coming to GEAC, as the Committee have also mentioned in the previous Chapter, it is headed by a civil servant who is also functioning in another capacity in the Ministry of Environment and Forests, the controlling authority of GEAC. The Co-

Chairman of GEAC is a biotechnologist who though purportedly from outside, is nominated by DBT, the promoter Department. The Vice- Chairman is again a civil servant, simultaneously discharging a few more responsibilities in another role in the Ministry of Environment and Forests. By its very composition, the Committee does not have regular existence and meets monthly, only when some decisions are to be taken. It is also a sad reality that modern biotechnology being a nascent discipline in the Country, we have a serious dearth of scientists of eminence in sufficient numbers, therefore, more or less the same set of people sit on both the sides i.e. to develop technologies and products as also to assess, evaluate and approve them.

Reply of the Government

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 advise with respect to issues on GMOs in agriculture and healthcare.

Further, it is already mentioned in para 2.82 that 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.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.30 of Chapter of this Report.

Regulatory Mechanism for Transgenics and Containment of Trials
(Recommendation Para No. 3.48)

In their tearing hurry to open the economy to private prospectors, the Government should not make the same fate befall on the agriculture sector as has happened to the communications, pharma, mineral wealth and several other sectors in which the Government's facilitative benevolence preceded setting up of sufficient checks and balances and regulatory mechanisms, thereby, leading to colossal, unfettered loot and plunder of national wealth in some form or the other, incalculable damage to environment, bio- diversity, flora and fauna and unimaginable suffering to the common man.

Reply of the Government

Adopting pro industry, pro rich and against the nature, policies, in the agriculture sector may adversely affect the sustainability of farming is just a presumption. Indian farmers have adopted all the agricultural technologies which he found beneficial and profitable to him. Therefore, we should not deprive them from the benefits from biotechnology.

We should aspire to make Indian Agriculture Competitive.

We can't simply lament and not adopt technologies only because they are produced by private sector for profit

Further, as mentioned in the response to para 3.47 government departments have made large investments to develop public sector laboratories for development of technologies relevant to Indian needs and several products are in advanced stages of the regulatory pipeline.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.5 of Chapter of this Report.

Regulatory Mechanism for Transgenics and Containment of Trials **(Recommendation Para No. 5.46)**

A significant finding made in the Report is about modern technology creating both costs and benefits, depending upon the manner in which it has been incorporated into societies and eco-systems and whether there is the will to share benefits as well as costs because sometimes benefits are at the expense of reducing biodiversity or access to traditional foods. The Report has also found that neither costs nor benefits are currently perceived to be equally shared, with the poor tending to receive more of the costs than the benefits. Extensive interactions of the Committee during their above mentioned Study Visit to Vidharbha proved that this observation of experts in IAASTD Report has a sound basis. Due to initial increase in production as a consequence of reduction in yield loss, the simple farmers of the area went in a big way for cultivation of Bt. cotton. However, because of very high input costs, yield loss due to development of resistance in the targeted pests, the local agrarian economy has been totally shattered within a few years with great losses, mostly to the small and marginal farmers. There have been 7992 farmers suicides in the region during 2006 to 2011. In several of them, caused due to agrarian reasons, the indebtedness and a multitude of other problems caused by sowing of Bt. cotton have been a contributory factor. Furthermore, due to the craze for cultivating Bt. cotton because of its perceived advantages, the traditional local cotton varieties have been almost wiped out. Seeds of traditional varieties are available even to farmers desperate to return to their old agricultural practices. The Committee during their Study Visit to Vidharbha have seen with their own eyes that while the

seed companies have benefited from the transgenic Bt. cotton, the poor and hapless farmers have received more of the costs than the benefits. The situation is grim today inspite of the massive loan- waiver scheme of the Government in 2009 and several other financial packages for the indebted farmers.

Reply of the Government

Information asymmetry is omnipresent in the system. It is true for all new patents filed, research costs have to be recovered as also the exploitation of segmented market. It has nothing to do with GM crops in particular. Cost- benefit when examined for a widely accepted technology will always be exhibiting beneficial; else the technology could not have been adopted or will not be adopted by the masses. The case of wide adoption of Bt cotton is an example. Numerous studies have concluded that there have been no relation between adoption of Bt cotton cultivation and suicide of the farmers. Implicating the GM technology for all that happens in farming communities on the ground is biased and a strategy designed by trade related lobbies and vested interests to discourage India becoming a technology lead in the world.

The success story of transgenic (Bt cotton) cotton in India is spectacular. Inputs received from states show that farmers' suicide are attributed to a host of reasons which inter alia, include, indebtness, crop failure, drought, socio-economic and personal reasons. Numerous measures that have been taken by Government of India to prevent suicide by farmers, improve financial condition to overcome indebtness include implementation of Rehabilitation Package of 31 districts of Andhra Pradesh, Karnataka, Kerala and Maharashtra, implementation of Agricultural Debt Waiver and Debt Relief Scheme, increasing credit flow to agricultural sector, providing Kissan Credit Cards, providing interest rate subvention for timely payment on crop loans. In addition yearly announcement of Minimum Support Prices (MSP) and providing Microfinance through apex

institutions, are some of the steps taken by the government to help the farmers of the country.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.5 of Chapter of this Report.

Regulatory Mechanism for Transgenics and Containment of Trials **(Recommendation Para No. 5.49)**

The Report also states that since in private sector commercial drivers determine supply, therefore, the public sector engagement in biotechnology should be increasingly emphasised upon for R&D capacities or achieving some goals for which there is no market.

Reply of the Government

Noted. As stated earlier, Government of India has already initiated several projects in public sector research institutions under the aegis of ICAR and DBT. Public Private Partnership schemes are also being implemented to increase R&D capabilities to ensure that products and processes are developed for the benefit of large section of society with access and affordability.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.5 of Chapter of this Report.

Post Marketing Surveillance (Recommendation Para No. 5.50)

The IAASTD Report, has therefore, very rightly concluded about the need for a systematic direction of AKST including a rigorous rethinking of biotechnology and specially modern biotechnology in the decades to come, effective long term environmental and 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 exist to date 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.

Reply of the Government

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.

As clarified in earlier paras the IAASTD report has underestimated the potential of new technologies relative to existing technologies. Hence rigorous rethinking of biotechnology and specially modern biotechnology as suggested to by the committee seems out of place. GOI is committed to continuously learn and

evolve its regulatory procedures based on its home grown experience and scientific data generated worldwide. In addition, GOI 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, it is 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, OECD etc.

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 GE crops, 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.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.39 of Chapter of this Report.

Regulatory Mechanism for Transgenics and Containment of Trials **(Recommendation Para No. 5.52)**

The Committee would like to remind the Government of India that they are a signatory to this path breaking effort and in the opinion of the Committee, the Government would do well if they adopt this Report as the way forward for development of agriculture and allied sectors in India, in a sustainable and environmental friendly manner, and with no unwanted risks to biodiversity, human and livestock health, flora and fauna. The Committee also desire to be apprised of the concrete action taken by the Government on each of the findings contained in IAASTD Report during the four years after the release of the Report.

Reply of the Government

In fact due to controversies surrounding this report, it is not advisable to depend on or to follow it exclusively. Subsequent to this report several international agencies including FAO and World Bank have recommended the use of biotechnology in agriculture as elaborated in section 1.23.

Government of India is guided by its own national policies framed after extensive consultative process such as National Seeds Policy and National Policy for Farmers, which are in conformity with the Indian agricultural conditions addressing the requirements of the farming community while ensuring food security for the nation. As already indicated in the Parliamentary Committee report, several of its recommendations are already part of policy initiatives and hence adopting the report is not required.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.5 of Chapter of this Report.

Regulatory Mechanism for Transgenics and Containment of Trials **(Recommendation Para No. 5.53)**

The Committee also examined the report of the Six Science Academies on Bt. Brinjal. This report had been prepared on the instructions of the then Minister of Environment and Forests (I/C) in order to assess the environmental and bio-safety aspects of Bt. brinjal. The report got mired in controversies at the outset itself as allegations of plagiarism were leveled about some of its content. A revised report had to be, thereafter, brought out. The report has given an

emphatic clearance for commercial release of Bt. brinjal on the basis of 'the overwhelming view (amongst members of academies) that the available evidence has shown, adequately and beyond reasonable doubt that Bt. brinjal is safe for human consumption and that its environmental effects are negligible'. While doing so, inexplicably the six academies relied upon available data which had become suspect in view of other scientific reports prepared on the Subject. Doubts had already been expressed about the environmental risk assessment performed in respect of Bt. brinjal, it was also being pointed out that chronic toxicity tests had not been performed. Moreover, all the recommended tests and protocols had also not been followed. Several stakeholders were of the opinion that Bt. Brinjal being the first GM Food crop in the Country ought to have been put through a far more vigorous assessment and evaluation regime by the regulatory authorities in view of the human health dimensions as also the fact that India is the centre of origin of brinjal. Due to very strong opposition to the commercial release of Bt. brinjal the then Minister of Environment and Forests (I/C) had seven consultations across the Country with stakeholders from all walks of life and after careful evaluation a moratorium on Bt. brinjal was placed. The Committee find that inspite of these developments DARE/ICAR have fully endorsed the report of six science academies. That too when two of their own events for cotton viz. BN Bt and Bt NHH44 which were generated through their own inhouse efforts and assessed in their own network of institutions, have been embroiled in controversies. As referred to in previously in this Report, ICAR is now setting a Committee of outside experts to investigate the entire matter pertaining to BN Bt and Bt NHH44. DBT and DST have also inexplicably come in support of the report of six science academies ignoring several glaring lapses pointed out by various stakeholders in the evaluation and assessment of Bt brinjal. The Department of Health Research without being overtly critical of the report have clearly advised the need for chronic toxicity and other associated tests, independently after exposure for sufficient period. The Department of AYUSH who, inspite of their huge stake in the Subject, had been kept out of loop by GEAC as mentioned previously in this Report, have also brought to the notice

of the Committee the need for several further studies in the matter as brinjal is used in several medicinal preparations under the Indian System of Medicine. They have also emphasized the need for having these studies being undertaken in Public Sector Scientific Institutions to avoid any conflict of interest.

Reply of the Government

MoA and ICAR along with DBT and DST fully endorse the recommendations of Inter-Academy Report on GM Crop especially with reference to Bt brinjal. Bt crops have an exemplary record of safety as evidenced by the extensive body of literature of studies undertaken by academic and government research organizations, and by the accumulated experience gained globally in the many countries where these are grown and consumed since these crops were first cultivated over 15 years ago.

The issues raised regarding plagiarism, non citation of references etc. were raised by specific groups with an intention to divert attention and in no way related to safety of Bt Brinjal. All such issues were subsequently resolved. The findings of the committee were sound and cannot be disputed

The post moratorium review of Bt Brinjal so far by the experts has also confirmed the findings of Academies' report.

The observations of AYUSH with respect to safety assessment process have been very general e.g. it has been indicated that Bt brinjal could lead to cross pollination with wild relatives. It has been established through extensive literature search as well as crossability experiments conducted by Indian Institute of Vegetable Research, Varanasi that such concerns are not valid. Regarding other concerns, it is clarified that the ICMR guidelines based on Codex Alimentarius take into account unintended effects through suggested test protocols.

The controversy regarding BN BT does not in any way impact the findings contained in the Academies report as those are not safety issues. The BN Bt issue is under examination with ICAR.

Regarding the involvement of AYUSH in GEAC, it is clarified that the composition of GEAC is as per statutory requirements of Rules, 1989. Ministry of Health & Family Welfare, (of which AYUSH is a part) is represented in GEAC.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.5 of Chapter of this Report.

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

The Committee would also like to say a word about the examination of the various reports on the merits and demerits of GM crops by GEAC in consultation with eminent experts and scientists. GEAC had approved the commercial release of Bt. brinjal on the basis of its own assessments as the apex regulatory body for the purpose in the Country. The same agency is now sitting on the judgment of its own decision and also of the various reports on the merits and demerits of GM crops in general and Bt. brinjal in particular. In the opinion of the Committee, it is a clear case of conflict of interest. They, therefore, recommend that evaluation of the various reports on this matter should be done by some other agency such as CSIR, since they not only have sufficient expertise in this regard but also have minimum conflict of interest in the matter amongst the various public sector

scientific institutions. The Committee also feel that the examination of various reports has to be expedited and results conveyed to the them at the earliest so that a final view in the matter is facilitated without any further delay.

Reply of the Government

In this regard, it may be noted 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.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.45 of Chapter of this Report.

Evaluation of Environmental Risks **(Recommendation Para No. 5.57)**

The Committee note 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. This report had been cited before the Committee by several stakeholders who are against transgenics in crops. The report has criticized GEAC for setting too narrow a 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.

Reply of the Government

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 quote 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.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.48 of Chapter of this Report.

Evaluation of Environmental Risks **(Recommendation Para No. 5.58)**

The Committee also note the views of various ministries and departments on this report. Most of them have expressed their disagreement with the observations made in the report regarding the shortcomings in the parameters set out by GEAC for the Experts Committee-II to conduct environmental risk assessment of Bt. brinjal. Some of them have even gone to the extent of justifying their views on the report on the ground that 'if simple, reproducible, cost effective and interpretable scientific processes and procedures are able to assess and predict possible risks it is time consuming and expensive to use

concepts and tools which are not validated and have no rational for the purpose'. It has also been put forth before the Committee that 'it is true that regulation should flow from an ideal standpoint and may have to consider application of every known scientific concept, tool and technique for assuring that new genetic modifications in crops are safe as enshrined in the said report. However, decision support systems should also be careful to take into account that the suggested tools and concepts are pragmatic and is sure to lead to interpretable and unambiguous conclusions.'

Reply of the Government

Indian regulatory authorities regularly review available scientific information as well as approaches followed internationally to ensure that the decision making framework are in accordance with global best practices incorporating key findings of scientific research from above databases.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.48 of Chapter of this Report.

Expeditious Evaluation of Reports **(Recommendation Para No. 5.59)**

In the opinion of the Committee the above justifications betrays hint of a cavalier attitude towards this highly sensitive issue. 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. Moreso, the contents of the report are still under examination as post moratorium follow-up. In the considered opinion of the Committee since the matter pertains

to as a vital issue as human health safety any amount of time and money spent on any number of studies and analysis to evaluate the product is perfectly justified. And taking refuge behind global best practices and internationally laid down norms would not at all suffice. The Government also ought not forget the admission of one of the witness before the Committee that his having put one gene into a rice plant is affecting 600 other genes as well. The Committee, therefore, recommend that the Government should come out of this stereotyped mindset and for the reason enumerated previously in this Chapter get all these reports evaluated and examined by any agency other than GEAC like CSIR, etc., strictly in national interest on the basis of sheer scientific merits.

Reply of the Government

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.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.51 of Chapter of this Report.

Regulatory Mechanism for Transgenics and Containment of Trials **(Recommendation Para No. 6.144)**

In view of the Committee, Department of Agriculture and Cooperation has not discharged its mandated responsibility in a professional manner, in so far as, the introduction of transgenic agricultural crops in India as a policy matter is

concerned. At that point of time it was a technology that was being applied in hardly a few countries whose agricultural practices, farmers profile, populations dependence on agriculture and allied sectors was totally different from the situation obtaining in India. Department of Agriculture and Cooperation failed to appreciate the fact that India has 70% population surviving on agriculture and allied activities against 2% or so farming community in USA, Canada, etc. It also failed to appreciate the huge difference in size of land holdings in India where 70% of farmers are small and marginal ones with average land holding of about 1.25 acre against hundreds of hectares of land owned by individual farmers in USA. The huge differences in farmers' incomes, levels of mechanization, availability of irrigation facilities, etc. were also not properly analysed. The ineffectiveness of PPV&FRA Authority and National Biodiversity Authority which are virtually non-existence even now was also ignored.

Reply of the Government

DAC is fully aware of its responsibilities and does not promote any technology, which adversely affects the farmers and environment. Guided by NPF, DAC takes up technology or related initiatives that have potential to improve the well being of farmers as well as enhance agricultural production in the country. The fact that farmers have enthusiastically adopted Bt. Cotton cultivation is a testimony to this fact.

Making agriculture a sustainable and economically viable activity for farmers has been Ministry of Agriculture's concern. Fact that a large population depends on agriculture makes it important that we adopt modern biotechnology, which is both, inclusive and safe.

As regards the Committees observation on the PPV & FRA and NBA, the following information is provided for clarification.

Considering the national requirements and the obligations under international agreements, Government of India enacted the Protection of Plant Varieties and Farmers' Rights (PPV & FR) Act in 2001. It provides an effective legal system of protection of plant varieties and rights of farmers, communities, plant breeders and researchers. The Act is the first of its kind in granting intellectual property rights not only to plant breeders but also to the farmers by protecting new, extant and farmers' varieties. For implementing the various provisions of the Act, the Protection of Plant Varieties and Farmers' Rights Authority was established in November 2005.

The establishment of Authority and notification of PPV & FR Rules 2003, PPV&FR Regulations 2006 & 2009, Tribunal Rules 2010, PPV&FR (Recognition and Reward from the Gene Fund) Rules 2012, Amendments to the PPV&FR Rules 2003 and various other gazette notifications has enabled the Authority to implement the various provisions envisioned under the Act. They have made significant achievements such as:-

Registration of plant varieties was started by the Authority with twelve crop species in 2007, which in due course has been extended to 57 crop species. 4070 applications have been received for registration of different varieties under various categories and 502 certificates of registration have been issued.

The Authority maintains its website in English and Hindi (<http://www.plantauthority.gov.in>). Provision for online filing of application for registration and Authority portal has also been initiated

Regarding NBA, it is submitted, India was one of the first few countries to have enacted a legislation in 2002, the Biological Diversity Act, to give effect to the provisions of the CBD. India has also recently ratified the Nagoya Protocol on ABS.

The National Biodiversity Authority (NBA), 2003 was set up to implement the Biological Diversity Act 2002 (BD Act) and Biological Diversity Rules, 2004. The BD Act provides a legal mechanism for establishing sovereign rights over the Indian biodiversity and its conservation, protection against misappropriation, regulation of access and sustainable use of biodiversity and associated knowledge. The Act is implemented engaging decentralized regulation of activities through Biodiversity Management Committees (BMCs), State Biodiversity Boards (SBBs) and the NBA, each with well-defined functions. Accordingly, it is being operated at national, state and local levels, as a three-tier system. Besides NBA, 26 SBBs have been established and 32,796 BMCs have been formed as on December, 2011.

Hence, it is clarified that both the authorities i.e. PPV&FRA and NBA have made commendable progress considering the challenges that emerge in a country as large and diverse as India. The comments of the Standing Parliamentary Committee on Agriculture about PPV&FRA and NBA appear not to be based on the above facts.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.5 of Chapter of this Report.

Regulatory Mechanism for Transgenics and Containment of Trials **(Recommendation Para No. 6.145)**

Another aspect on which Department of Agriculture and Cooperation failed miserably was the cost of seed and other inputs that the introduction of transgenics in agricultural crops would entail. The cost benefit analysis was clearly in favour of industry and not the farmers. Resultantly, Bt. cotton seed

was sold at a whopping Rs. 2200 per kg. when local seed cost hardly a fraction of it. The difference was so outrageously high that a judicial intervention was required to force the company in question to lower the price of seed. Even now at Rs. 1500 per kg. or so the cost of seed in the opinion of the Committee is still very high considering that for a majority of farmers in India for whom even a single rupee matters in these several distressful years of agrarian crisis this amount is a tall order. The decline in yield after initial two three years of increase due to reduction in yield loss caused by pests caused additional distress to the farmers. Furthermore, the exorbitantly high input costs, as one of the witnesses, who has been closely monitoring Vidharbha region for years together, apprised the Committee that from an average Rs. 8000 to Rs. 12000 per acre investment in cultivating traditional varieties of cotton the farmer had to invest a massive Rs. 48000 to Rs. 54000 per acre for Bt. cotton cultivation. Thus the input cost escalated almost five times the yield did not increase in commensurate measures and even fell after the initial years. Bt. cotton has also not been a sustainable agriculture technology. The Committee have been informed by farmers that it uses massive quantities of water and other outputs. Though farmers in Gujarat, where availability of water is better than Vidharbha, were benefitted to some extent, in Vidharbha, however, Bt. cotton has only contributed towards agrarian crisis. The better productivity of Bt. cotton also has not stood the test of time as in the latest estimates productivity figures have gone considerably down. In fact, Secretary of Department of Agriculture and Cooperation admitted before the Committee that several traditional varieties of cotton grown in Brazil had three times more yield than Bt. cotton yield in India and Brazil was not encouraging cultivation of Bt. cotton now. A team of Government was going to Brazil to study these developments for being gainfully utilized in India.

Reply of the Government

Bt Cotton seed supply was dominated by one company at the time of its release in 2002. Only three Bt. Cotton hybrids developed by M/s Mahyco. were then available. However, the situation has changed considerably since then. The number of biotech events has increased from one event in 2002 to five events. Currently cotton hybrids are being produced by approximately 40 companies in the private sector, most of which are Indian entities.

Any new technology when introduced comes at a higher price as there is motive for recovering the cost for developing the technology. As the new technology gains popularity due to its success, more and more people take up the same and cost comes down due to economy of scale in operation. The case of Bt Cotton technology is no different. Moreover, cost of any advanced technology is always higher than the existing local technology. Hybrid and High yielding varieties seed cost more than the local variety. Adoption of Bt cotton in India is reflection of farmers' free will in view of its advantages, there was no proactive effort on the part of the Government to push the same.

As regards prices of Bt cotton seeds is concerned, seeds were initially sold between Rs. 1650 to Rs. 1850 per packet of 450 gm including trait value, which was around Rs. 1250. Later the cost of Bt. Cotton was reduced to Rs. 1250 per packet by the Company including Rs. 900 as trait value for 450 gm of Bt Cotton Seed per packet. Consequent upon the intervention of MRTPC; legislative intervention by some States and the existing competition in the sector, Bt cotton seed is being sold at much lower rates. Prices of Bt cotton seeds during the period 2004 to 2012 have not been increased rather decreased. Table below gives prices in Rs. per packet of Bollgard I and Bollgard II Bt. cotton seeds in 2004-05 & 2011-12.

Year	BG-1			BG-II		
	North PUN, HAR & RAJ *	Central MH,MP & GUJ**	South A.P., KAR & TN***	North PUN, HAR & RAJ	Central MH,MP & GUJ	South A.P.,KAR & TN
2004-05	-	1600 1525(GUJ)	1600	NA	NA	NA
2011-12	825	830-	830	1000	930	930

NA- Not applicable

*Punjab, Haryana & Rajasthan

**Maharashtra, Madhya Pradesh & Gujarat

***Andhra Pradesh, Karnataka & Tamil Nadu

It is also submitted that input costs have increased in similar proportion for other crops like cereals and pulses as well, if Minimum Support Price (MSP) increase over the years, is any indication. Further through declaration of MSP, Government do take necessary steps to cover the cost of production of the farmers for the particular crop, including cotton.

Prior to the introduction of Bt cotton, about 9400 metric tonnes (mt) of insecticides were used for bollworm control in India. In 2011, only 222 mt were used for bollworm control. The reduction is from 1.08 Kg/ha in 2001 to only 18g/ha in 2011. Had the Bt not been there, India would have pumped 12,960 tons of pesticides for bollworm control. The saving is therefore, 12,738 tons of pesticides getting released annually into the environment (**Annexure-IV**).

It is true that Bt cotton adoption rate in Brazil is hardly 20% and they cultivate cotton varieties only. The yield level of cotton production in Brazil is 2.5-3 times more than Indian yield level with even 90% Bt cotton adoption. Brazil follows the High Density Planting System (HDPS) and maintains nearly 1.0 lakh plants/acre as compared to 8000 plants/acre of India. Their farming system is fully mechanized followed by use of high dose of inputs. An Indian delegation visited Brazil during middle of April, 2012 to study cotton cultivation in Brazil and identify practices which can be adopted in India for enhancing productivity of cotton. On the basis of the recommendation of the delegation CICR, Nagpur has

initiated trials on HDPS with cotton varieties at different locations. Possibilities of introduction of HDPS concept will be decided on the basis of the results of these trials.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.5 of Chapter of this Report.

Decision Making Process in Commercial Release of Bt. Cotton **(Recommendation Para No. 6.146)**

Another very important question that needs to be answered by DAC is about the approval for commercialization of Bt. cotton in India. Bt. cotton is a cash crop which in no way would have contributed to the food security of the Country. The lacs and lacs of hectares of land that have got diverted to Bt. cotton cultivation because of misconception about its potential have obviously reduced the area of cultivation of several food crops during all these years thus jeopardizing the Country's food security to that extent. That the Department of Agriculture and Cooperation did not discharge its responsibility in terms of NPF 2007 even when commercialization of Bt. brinjal was approved is apparent from the fact that brinjal though a staple food in many States of the Country has never been in short supply inspite of losses caused by pests, etc.. Its cultivation is restricted to very small patches of farmers' fields and in the cost benefit terms brinjal was not going to make any noticeable difference in the fortunes of the vast majority of cultivators in the Country. DAC also failed to appreciate that both in case of cotton and brinjal the Country has countless number of traditional varieties. Most of them have been wiped out in their natural form in case of Bt. cotton, and had the monatorium not been placed on the commercialisation of Bt. brinjal, the same fate would have been fallen on

the traditional brinjal varieties. The Committee feel that this is a very serious matter and, therefore, recommend that an indepth probe may be carried out to track the decision making involved in commercial release of Bt. cotton right from the initial stage. It has to be found out how Bt. cotton became priority when the avowed goal for introduction of transgenics in agricultural crops was with a view to ensure and maintain food security.

Reply of the Government

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.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.54 of Chapter of this Report.

Regulatory Mechanism for Transgenics and Containment of Trials **(Recommendation Para No. 6.147)**

The Committee also examined the role of Department of Food and Public Distribution in this regard. This Department procure colossal amounts of food grains for the central pool, stores them and then distributes the foodgrains through the Public Distribution System at affordable prices. The Department also represent the Government of India at various international fora on food

related matters. The Committee during their interaction with the representatives of the Department of Food and Public Distribution ironically found that there was a total lack of appreciation of their own role with regard to procurement, handling, storage and distribution of food derived from transgenic food crops as and when the eventuality arose. The stock reply to some of the major queries of the Committee was that the Department do not handle foodgrains produced from GM/transgenic crops. Subsequently, however, they admitted to Genetically Modified Crops posing challenges in the fields of food labeling, segregation and identification, preservation and procurement and storage points, testing facilities of the Genetically Modified Crops; provision of separate storage infrastructure and handling practices; and regulation of policies regarding such crops. The Department also admitted that they would devise standard operating procedures and other ways and means to address the issue of foodgrains derived from GM crops plants once FSSAI and other concerned agencies issue their guidelines in the matter. The Committee gathered a clear impression that the Department was not at all geared up to face the challenges that will be posed by transgenic food crops in the eventuality of labeling, segregation of GM and Non-GM food crops, movement of foodgrains between GM and Non-GM States, etc. becoming a reality in near future.

Reply of the Government

As already deposed in the oral evidence before the Committee, the mandate of the Department of Food & Public Distribution is procurement of specified quality of Foodgrains for central pool at fixed MSP through FCI and State Government agencies for distribution through Public Distribution System. The Department only deals with wheat, rice, coarse grains and sugar. The quality specifications are fixed by FSSAI under FSS Act, 2006.

It is clarified that import of all GMOs including GM foods is governed by Rules 1989 under EPA and the importers have to take permission from

GEAC. The GEAC has also been notified as competent authority as per the obligations under the Cartagena Protocol on Biosafety. Therefore the decision to import any GM foods by Department of Food and Public Distribution or any other agency would entail seeking required permissions from GEAC and following prescribed conditions if any. Further, it may be noted that approval of GM crops is based on comparative approach and confirming that a GM crop or food derived from it is as safe as its non GM counterpart. In case any special needs evolve, the country has adequate scientific manpower, experience and law in place to take necessary measures.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.5 of Chapter of this Report.

Field Trials of Transgenic Crops in various States **(Recommendation Para No. 7.19)**

Coming to the position obtaining in various States in regard to transgenics crops and field trials Andhra Pradesh, Chattishgarh, Karnataka, Bihar, West Bengal, Orissa, Uttarakhand, and Madhya Pradesh have expressed their reservations about Bt. brinjal. Kerala and Uttarakhand have in fact decided to prohibit environmental release of all GM seeds to keep the State totally GM free. Bihar, Kerala, Madhya Pradesh and Rajasthan have also disallowed field trials in the State. 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.

Reply of the Government

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.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.68 of Chapter of this Report.

Field Trials of Transgenic Crops in various States **(Recommendation Para No. 7.20)**

The Committee also note that Maharashtra, Tamil Nadu, Karnataka, Andhra Pradesh, West Bengal, Punjab and Haryana have allowed field trials.

Reply of the Government

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.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.68 of Chapter of this Report.

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

Section 22, the above mentioned special provision in the FSS Act stipulates that no person shall manufacture, sell or import any novel food, genetically modified articles of food, irradiated food, organic food, foods for

special dietary uses, functional foods, nutraceuticals, health supplements, proprietary foods and such other articles of food which the Central Government may notify in this behalf. Surprisingly, however, the GM foods were not included when Section 22 was notified by the Government. The Ministry of Health and Family Welfare instead asked GEAC to continue regulating GM foods under Rule 11 of Rules 1989 by keeping the notification of 23 August, 2007 in abeyance for six months or until the Ministry of Health and Family Welfare notified regulation of GM processed food by FSSAI whichever was earlier. The Committee were able to track five extensions of six months and a sixth one of one year upto September, 2011 but still the FSSAI regulation for GM processed food is nowhere in sight though so many years have gone by. Resultantly, 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. To compound this inaction further, now the Government seems to entrust this responsibility to the proposed BRAI. The Committee wonder when actually the regulation of GM food and products thereof will commence when BRAI itself is nowhere in sight. In the opinion of the Committee this dilly dallying and delay in bringing 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 would like to be apprised of the results of the investigation and the action taken in pursuance thereof.

Reply of the Government

Same as response to recommendation at serial no. 7.59

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.71 of Chapter of this Report.

Post Marketing Surveillance (Recommendation Para No. 7.61)

The Committee would also like to be apprised about what all action has been 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.

Reply of the Government

As indicated in response to Para 5.50, the post marketing surveillance of GM foods or any food in terms of safety aspects is not scientifically feasible. The relevant portion is reiterated here for ready reference.

Regarding the issue of long term environmental and health monitoring programmes, it is 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, OECD etc.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.39 of Chapter of this Report.

Allegation of Bio-Piracy **(Recommendation Para No. 7.75)**

With a view to control unauthorized access to our precious biological resources or knowledge associated therewith, Section 3 of Biodiversity Act,2002 stipulates that certain categories of persons shall not obtain any biological resources occurring in India or knowledge associated thereto for research or for commercial utilization or for bio-survey and bio-utilisation without prior approval of National Biodiversity Authority. These categories include a person who is not a citizen of Indian; a citizen of India, who is a non-resident and a body corporate, association or organization not incorporated or registered in India; or incorporated or registered in India under any law for the time being in force, which has any non-Indian participation in its share capital or management. In this connection a report appeared in media about one particular case of 2010 pertaining to alleged misappropriation of local brinjal varieties by M/s Mahyco

and others. Allegations about continued in action of the Authority in respect of this case were also reported in the media. The Committee 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 is being undertaken considering the elements and extent of violation of the provisions of Biological Diversity Act. Between August and October, 2011 further information was sought from the agencies involved in the development of this material. NBA 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 is still to be cleared.

Reply of the Government

NBA is in the process of resolving the issue as per the provisions of the Biological Diversity Act, 2002.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.75 of Chapter of this Report.

Allegation of Bio-Piracy
(Recommendation Para No. 7.76)

The Committee are not at all convinced by the dilatory response of NBA on this sensitive issue. The matter is very simple as to whether the Company in question has 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. Taking so long in coming to a conclusion on this simple issue shows the NBA in a very poor light. It would also be worth mentioning here that during this period Chairman, GEAC was simultaneously also holding the charge of Chairman, NBA from 11 November, 2010 to 11 August, 2011. The Committee not only desire a thorough inquiry in the matter of continued paralysis in decision making on a case of this dimension but also recommend that the NBA should decide upon this case without any further delay.

Reply of the Government

NBA is in the process of resolving the issue as per the provisions of the Biological Diversity Act, 2002.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.75 of Chapter of this Report.

Regulatory Mechanism for Transgenics and Containment of Trials
(Recommendation Para No. 8.116 and Para No. 8.117)

About the safety concerns, which are aplenty, transgenics being a comparatively new technology, the Government have told the Committee that no approval is granted to the transgenic crops unless these has been a thorough analysis of its effects on the environment, bio-diversity, bio-safety, human health and health of livestock and animals. The Government have also informed the Committee that safety and efficacy is evaluated by science based experimentation and analysis on a case by case basis and, therefore, cannot be generalized as these are product specific. Simultaneously, some of the Departments/Ministries/Agencies of the Government viz. DSIR/CSIR, Department of AYUSH, Department of Commerce, Department of Consumer Affairs, Department of Food and Public Distribution, National Biodiversity Authority and Food Safety Standards Authority of India have expressed their serious concerns on various aspects relating to transgenics in agriculture crops. These pertain to effect on bio-diversity, safety and efficacy of the technology, sustainability, chronic toxicity, cost benefits analysis, human and livestock health, environment impact assessment, safety of GM food and food products, exports of food grains, etc.

The Committee also have had the benefit of well considered views of several other stakeholders from outside the Government. These views based on science, field experience, first hand observation, evaluation and assessment totally go against the views of the Government and build a strong case against transgenic in agriculture crops more particularly in food crops.

Reply of the Government

It is stated in the report “that some Departments/Ministries/Agencies of the Government viz. DSIR/CSIR, Department of AYUSH, Department of

Commerce, Department of Consumer Affairs, Department of Food and Public Distribution, National Biodiversity Authority and Food Safety Standards Authority of India have expressed their serious concerns on various aspects relating to transgenics in agriculture crops. These pertain to effect on bio-diversity, safety and efficacy of the technology, sustainability, chronic toxicity, cost benefits analysis, human and livestock health, environment impact assessment, safety of GM food and food products, exports of food grains, etc.”

The five elements of transgenic crop development - (i) Policy ,(ii) R&D (iii) regulatory framework(act, rules and regulations) ,(iv) scientific risk assessment process of product and (v) commercial use need to be clearly understood. GM technology development and deployment policy is inter-ministerial/departmental and directs choice of technology over others, investment focus and integration with existing practices and overall policies in agriculture, food and environment including biodiversity, trade and traceability issues and measures. A good Policy directs focussed public and private sector investments. Regulatory framework addresses process and systems to enforce regulations, monitoring and compliance. Commercial use depends on public understanding and acceptance, rules and regulations of central/ state governments on seed pricing, certification and registration. Quite often in many media reports, activists slogans and adhoc reports all these issues are mixed, jumbled up and generalised to give an impression that everything is wrong without any evidence .

It may be clarified that safety assessment of GM crops/foods under a given regulatory framework is based on the principle that these crops can be compared with traditional crops/foods that have established history of safe use. The objective is to establish “as safe as” with the traditional crops and not absolute safety. Regarding identification of uncertainties, it is to be noted that this approach takes into account both intended and unintended effects. Further, the inherent precision of genetic engineering techniques for introducing specific

genetic changes enables a direct and focussed assessment of safety. Further, globally, scientific risk assessment is based on Standard Operational Practices (SOPs) and testing protocols. Consensus documents of international agencies i.e. Food and Agricultural Organisation (FAO), Rome; World Health Organisation (WHO), Geneva; FAO-Codex (Food Code), Organisation of Economic Co-operation and Development (OECD), Paris; Secretariat to Convention on Biological Diversity (CBD), Canada etc. developed over years off discussion and peer reviewed research literature and regulatory guidelines/decisions of regulatory bodies of countries which are active in regulation of GM crops are referred for assessments case- by case. Indian biosafety testing guidance documents or SOPs for comprehensive food and environmental safety assessment of transgenics have been prepared and updated after consultation within the country and peer reviewed scientific publications and harmonising with international best practices.

The concerns of AYUSH- whether medicinal value of crops subjected to GM technology are altered or cross pollinations contaminate relatives of target crop used in traditional medicine has no scientific evidence. The current testing methods include a detailed compositional analysis of GM and non-GM version which would indicate such changes if any. Since the assessment is case- by case any additional analysis can be included to ensure the same. If any unintended drastic changes occur, such cases are rejected by the regulatory system.. However, Department of AYUSH has representative in Review Committee on Genetic Manipulation (RCGM) and has an observer from Department of AYUSH in GEAC. Therefore more meaningful inputs can be given by the Department of AYUSH for clarifications for such concerns in future.

CSIR in their response to this report stated that it will be willing to assist the current regulatory system in assessment of dossiers of GM crops submitted to GEAC. It may be noted that DSIR provides R&D recognition certificate to all private and non profit R&D laboratories including those engaged transgenic R&D

and regulatory testing in health care and agriculture. CSIR has some capacity in GM research, regulation and biodiversity utilisation and product development. DBT and DST supplement the resources of CSIR system (which is largely focussed in industrial products and technologies) through extramural grants for R&D and product development. It has reasonable representation in all technology development programs of other departments proving expertise or implementing projects. CSIR labs have successfully commercialised recombinant human health products cleared by RCGM for example recombinant streptokinase etc and also represent through its members in GEAC and RCGM. Providing or assisting inputs in such statutory forums to address the concerns case by case or expressing concerns with adequate scientific evidence are appropriate.

The Department of Commerce in response to the statement made in the report clarified that it endorses that the view of the Government that transgenics being a comparatively new technology, no approval can be granted to the transgenic crops unless there has been a thorough analysis of its effects on the environment, bio-diversity, bio-safety, human health and health of livestock and animals and the safety and efficacy is evaluated by science based experimentation and analysis on a case by case basis.

National Biodiversity Authority and Food Safety Standards Authority of India have to provide evidence either from existing scientific literature or provide experimental evidence for substantiating their concerns. The concern about safeguarding biodiversity is acceptable. But stretching the idea of center of origin and center of biodiversity presumes that the transgenics will contaminate the biodiversity in all cases and under all circumstances. It is important to realize that even in cases such as rice where vast areas are cultivated to improved varieties for more than five decades now, there has been no obvious loss of native varieties or variability in nature to the point of their getting contaminated or being lost due to genetic contamination from the pollen from advanced varieties. It would be appropriate to associate agencies like NBA to carry out trials on this

aspect during field testing protocols to provide evidence before concluding that a possibility of gene flow would mean that the diversity will be lost. This presumption has no validity because it equates GMOs with genetic pollution as if they are inherently polluting and will contaminate biodiversity. Taking a cautious approach in biodiversity conservation is different from treating GM plants as harmful for biodiversity. The National Biodiversity Authority has not given any evidence to the Parliamentary Committee to prove this presumption.

Other stakeholders whose considered views have been heard by the committee include activists' or their nominees or Written submissions of selected international experts namely Dr. David Andow. Even in the countries where the author reside, there is no evidence of this report considered by regulatory authorities. It is difficult to comprehend how a few deliberately selected publications have been considered leading to misinformation to the committee instead of considering huge amount of scientific peer reviewed literature, decisions by regulatory authorities and consensus publications of international bodies. For example, A careful analysis of Dr. David Andow paper, which is cited by name and excerpts occur twice in the report, reveals certain misconception. For example, in the sections on gene flow the author ignores the fact, that hundreds of traditional varieties exist in the Indian agricultural traditional system without any remarkable hybridization over extremely long timespans, on the contrary, they co-exist without difficulties over centuries. In the erroneous view of the 'Genomic Misconception' the exclusive focus on coexistence with GM crops is unreflected and automatic, without scientific justification. The Committee has largely relied upon the IASSTD report (IAASTD Report, 2007) which is well known for its deep bias against biotechnology. This has been commented extensively: (Ammann, 2008; DeGregori, 2008; Keith, 2008; Murphy, 2008; Stokstad, 2008; van Montagu, 2008).

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.5 of Chapter of this Report.

Effects of Transgenic Crops on Environment, Humans and Livestock (Recommendation Para No. 8.118)

The Committee have critically analysed the evidence placed before them both for and against the transgenic agriculture crops. And pure science, within its restrictive realm, has not been the only benchmark of this analysis. Some of the most compelling concerns factored in by the Committee include India being one of the richest centres of bio-diversity, agriculture providing sustenance to almost 70% of 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; food security and safety; manpower intensive nature of agriculture in India; the severe agrarian crisis afflicting the Country for years now; 60 per cent of cultivated area still being rainfed; the irretrievability of transgenic crops once released in the environment; effects on environment, human health and livestock and animal health, to quote a few.

Reply of the Government

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.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.78 of Chapter of this Report.

Regulatory Mechanism for Transgenics and Containment of Trials **(Recommendation Para No. 8.119)**

The experience of the Country with Bt. cotton shows that with the advent of the transgenic variants and the initial hype surrounding it, the traditional cotton varieties have just been wiped out. The Committee could very well sense the desperation of farmers of Vidharbha with whom they interacted during their Study Visit in March 2012, due to non-availability of traditional varieties of cotton. In spite of their best efforts, they are now not able to shift from transgenic cotton cultivation to cultivation of traditional and more farmer friendly varieties due to total non-availability of seeds. The Committee witnessed with their own eyes these serious disadvantages caused by the practice of monoculture. The National Bio-diversity Authority has further proved with concrete instances that transgenics affect bio-diversity in a big way. Several other stakeholders including eminent scientists, farmer's organization, etc. have also informed the Committee about the adverse and lasting impact of transgenic crops on bio-diversity. The Government's assertions that our bio-diversity will be safely stored in gene banks may be a museologist's delight but do not comfort the Committee a bit, as bio-diversity can only evolve further in nature and not in gene banks. It has also to be borne in mind that India has a substantial stake in Nagoya Protocol on Access and Benefit sharing which will be affected adversely with any tinkering with our rich bio-diversity.

Reply of the Government

Traditional cotton varieties have not been wiped out. It is farmers' preference alone that Bt. Cotton accounts for more than 95% acreage. Experiences vary from region to region and farmer to farmer, although technology performance is neutral to size of the farm under a given package of practices. For example a case from Andhra Pradesh reported recently is quoted here :

"I can't grow cotton crop if not for Bt cotton, We harvest 12 to 15 quintals of cotton per acre from Bt cotton field significantly higher than 7-8 quintals harvested in the past with non-Bt cotton hybrids " said M. Mohammad Habibuddin, a small cotton farmer who led a group of 40 small cotton farmers who met with delegates of 16 countries visiting his 1 acre of Bt cotton field in the outskirts of his village Hussainpur of Shankarpalli Mandal, Ranga Reddy District of Andhra Pradesh, India on 3 October 2012. The COP-MOP6 delegates of CBD conference, many of whom visited a cotton field for the first time, interacted with small farmers who have been planting for seven consecutive years. The 34 delegates included senior government officials from Brazil, Canada, Switzerland, Japan, Korea, China, Philippines, Indonesia, Iran, Kuwait, Egypt, Kenya, Nigeria, Zimbabwe, Burkina Faso, Uganda, and India.

The Central Institute of Cotton Research, Nagpur has been conducting a series of demonstration trials in farmers fields in 8 districts of Vidharbha region, such as Chandrapur, Nagpur, Amaravathi, Wardha, Yawatmal, Akola, Washin and Buldana. The demonstrations are conducted with traditional varieties of hirsutum cotton such as Suraj, PKV 081, NH 615 and desi cotton varieties HD 123, AKA 7. In addition separate trials of arboreum desi cotton race Cernuum is also being conducted, on an acre each, so that farmers can have a real time relook into the traditional varieties to make their own judgement. The trials are currently on, during Kharif 2012.

The native biodiversity of cotton in India is represented only in the *Desi* cotton species which have evolutionary origins in India and are known to have been cultivated in the country for the last 5000 years.

Since the *Desi* cotton species *Gossypium arboreum* and *G. herbaceum* have native origins, there is high level biodiversity of the *Desi* species in India. However, there is no possibility, whatsoever, of any of the native India *Desi* cotton species, *G. arboreum* and *G. herbaceum* species getting genetically contaminated with *Bt* cotton, so as to threaten the extant biodiversity.

Even if there is any hybridization between Bt cotton and desi cotton, they will not be fertile because of cytogenetic instability and genome differences. American cotton was introduced in India 1790 and still, the desi cotton retains its properties, and there is loss to diversity by gene contamination.

Considering the need to address the crisis In Vidharbha region, essentially of the problem of availability of water, DAC has taken a new initiative to boost irrigation in the region through the scheme Vidarbha Intensive Irrigation Development Programme (VIIDP). VIIDP programme has been started as a sub-scheme of RKVY from the XIIth Plan period. The programme aims at developing irrigation infrastructure in all the 11 districts of Vidarbha and was conceived in the backdrop of low productivity of most crops and especially cotton on account of agriculture in the area being rainfed. The broad objective of the programme is to bring enhanced cotton area under cotton cultivation and increase the protective cultivation area under cotton in order to increase production and productivity and thereby increase the returns to the farmer. For 2012-13 the allocation under the programme is of Rs.300 crore. With creation of irrigation facility the agrarian crisis will surely mitigate.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.5 of Chapter of this Report.

Regulatory Mechanism for Transgenics and Containment of Trials **(Recommendation Para No. 8.120)**

Coming to the aspect of food security, the Committee are more than convinced that there are better options available for increasing food production and productivity than transgenics technology about whose safety, sustainability

and a host of issues of concern, the last word is still long long away. Most importantly, India today is not in the situation of desperation that was obtaining before the first Green Revolution. Hence any short cuts or desperate measures are not required to be experimented with. Integrated Pest Management, organic farming, bio-fertilisers, molecular breeding, increasing irrigation potential, minimizing post harvest crop losses, efficient and leak proof distribution system, etc. in the opinion of the Committee, are far more simpler, easy to do, sustainable, bio-diversity friendly options which also do not have any ill effects on human health and livestock and animal health.

Reply of the Government

It is stated in the report that “Committee are more than convinced that there are better options available for increasing food production and productivity than transgenics technology about whose safety, sustainability and a host of issues of concern, the last word is still long long away”

It may be clarified that, It is not debatable issue that all available technologies whether conventional or modern should be employed in addressing issues of food security. At the same time all technologies have their own limitations and advantages. No single technology so far has been free from any risk although only GM crops are the only group of technologies which undergo exhaustive food and environmental safety assessment Therefore, it may be clarified that adoption of GM technology for agricultural purpose has not been a short cut way or a desperate measure. Lots of investments, time and efforts are being made to develop this technology as clarified in 8.114. It is also essential that India maintains its place as a leading scientific country in the hall of nations by playing lead role in the development of this All these measures along with path breaking scientific tools need to be undertaken simultaneously.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.5 of Chapter of this Report.

Reforms in Current Regulatory System **(Recommendation Para No. 8.121)**

While summing-up, the Committee would also like to comment further on the regulatory mechanism although it has already been dealt with in a separate Chapter in this Report. 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, as stated previously in this Report. 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 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, inspite of DBT's protestations to the contrary, have 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, reflects a pro-DBT/pro-industry tilt which is best avoided. Apart from this major shortcoming, the Committee's examination has

revealed that the extant system is 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.

Reply of the Government

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 on 9th October 2012 on Agriculture biotechnology are 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.”

It may be noted that Institutional Biosafety Committee (referred as Internal Bio-Safety Committee) is not responsible for assessment and evaluation of transgenic products being developed that a particularly company. The responsibility of IBSC are clearly defined and its role is basically to ensure that organization is conducting guidelines.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.81 of Chapter of this Report.

Absence of Liability Clause **(Recommendation Para No. 8.122)**

The Government have been for some years now toying with the idea of a Biotechnology Regulatory Authority. The Committee feel that regulating biotechnology is too small a focus in the vast canvas of biodiversity, environment, human and livestock health, etc. and a multitude of other such related issues. They have, therefore, already recommended in a previous Chapter setting up of an all encompassing Bio-safety Authority through an act of Parliament, which is extensively discussed and debated amongst all stakeholders, before acquiring shape of the law. Unless and until such an authority is in place, any further movement in regard to transgenics in agriculture crops will obviously be fraught with unknown consequences. While there is a lot of apprehension about the safety of the technology, what is more worrying is

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, reeling is they already are under severe agrarian crisis for years together now.

Reply of the Government

As explained earlier, after wide ranging stakeholders discussions and elaborate inter-ministerial consultation the Biotechnology Regulatory Authority of India (BRAI) Bill has been prepared and submitted to Parliament for introduction. SAC-PM is 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 parliament committee would be opened up for wider debate and discussions for shaping the draft legislation into a model regulatory framework.” All concerned departments/ministries agree with these views as the bill also takes into consideration the collaborative and coordinated mechanisms across different existing legislations and authorities. The BRAI bill provides 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.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.84 of Chapter of this Report.

Food Safety and Standards Authority of India (FSSAI)
(Recommendation Para No. 8.123)

In such a situation the various players in the system of governance, who have some role or the other in the regulation, management, handling, oversight, distribution, consumer affairs, human health, livestock health, etc. have to shoulder the responsibility of ensuring that any potential harm or damages to the system are eliminated/controlled. However, as has been very clearly brought out in a previous Chapter most of the Ministries, Departments and other agencies of the Government who have to shoulder major responsibility, when the transgenic agricultural crops come into the system, are not at all ready to optimally perform their designated roles. In fact some of the Ministries/Departments have been revved into action only after the Committee took this subject for examination and interacted with them. FSSAI, which has to play the most important role in the scheme of things alongwith NBA is still grappling with teething troubles and is not in a position to deliver atleast for coming years. NBA and PPV & FRA, as has been brought out previously in the Report, are virtually non-existent. In such a scenario how the Government intends to deal with the effects of cultivation of transgenic crops outside containment defies logic.

Reply of the Government

As has been elaborated in earlier chapters, the Ministries/Departments do have systems in place. 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. As responded to earlier PPV&FRA and NBA have made significant achievements even though the legislations have been a new area. The PPV&FRA has done commendable work to bring about awareness on farmers' and communities' rights towards conserving biodiversity. As also elaborated earlier, NBA too has contributed towards the mandate under which it was created.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.62 of Chapter of this Report.

Post Marketing Surveillance **(Recommendation Para No. 8.124)**

On another plane, 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 are yet to take a final call on labelling. There is 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.

Reply of the Government

So far globally, Bt cotton has been in cultivation for the last 16 years with no report of any negative impact on health and environment issue. 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.)

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.39 of Chapter of this Report.

Ethical Dimensions of Transgenics **(Recommendation Para No. 8.125)**

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

Reply of the Government

It may be 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 taking care all biosafety measures as per 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 farmers choice that determine the adoption .

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.87 of Chapter of this Report.

Cultivation of Bt. Cotton Compounding the Miseries of the Small and Marginal Farmers **(Recommendation Para No. 8.126)**

During their extensive interactions with farmers in the course of their Study Visits, the Committee have found there have been no significant socio-economic benefits to the farmers because of introduction of Bt. cotton. On the contrary, being a capital intensive agriculture practice, investments of the farmers have increased manifold thus, exposing them to far greater risks due to massive indebtedness, which a vast majority of them can ill afford. Resultantly, after the euphoria of a few initial years, Bt. Cotton cultivation has only added to the miseries of the small and marginal farmers who constitute more than 70% of the tillers in India.

Reply of the Government

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.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.90 of Chapter of this Report.

Regulatory Mechanism for Transgenics **(Recommendation Para No. 8.127)**

The Rashtrapati in his maiden address in the Central Hall of Parliament on 25 July, 2012 observed 'trickle down theory do not address the legitimate aspirations of the poor. We must lift those at the bottom so that poverty is erased from the dictionary of India'. In case of transgenics in agriculture crops in India, the experience of last decade has conclusively shown that while it has extensively benefitted the industry, as far as the lot of poor farmers is concerned, even the trickle down is not visible. The Committee, therefore, unanimously recommend that till all the concerns voiced in this Report are fully addressed and decisive action is taken by the Government with utmost promptitude, to put in place all regulatory, monitoring, oversight, surveillance and other structures, further research and development on transgenics in agricultural crops should only be done in strict containment and field trials under any garb should be discontinued forthwith.

Reply of the Government

As stated earlier, 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.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.93 of Chapter of this Report.

CHAPTER - V

OBSERVATIONS/ RECOMMENDATIONS IN RESPECT OF WHICH FINAL REPLIES OF GOVERNMENT ARE STILL AWAITED

Setting up of Experts Committee by Indian Council of Research (ICAR) (Recommendation Para No. 2.89)

The Committee are extremely perturbed with these developments as they pertain to a research venture in public sector domain and with public good in mind. Though not being a scientific entity, they are still not convinced by the inexplicable time lags and information gaps in the explanations furnished by various agencies of Government involved with the matter. They, therefore, exhort ICAR to go ahead with the setting up of the proposed experts Committee without any further loss of time and convey their findings to the Committee within three months of presentation of this Report to Parliament. Any further delays in the matter will only add to the environment of suspicion prevalent about the issue nowadays.

Reply of the Government

Findings of the expert committee shall be made available to the Committee.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Expert Committee to Examine cases of Bt. Cotton Feed causing Physiological changes in Sheep
(Recommendation Para No. 2.90)

While on this aspect the Committee would also refer to the findings of the report on animal feeding trial on biosafety studies with biotechnologically transformed Bt cotton crop seed meal conducted at Central Sheep and Wool Research Institute, Avikanagar, Rajasthan in 2008. Some of the findings are Bt cotton seed feeding increased RBC and decreased WBC in blood, the weight of kidney, spleen, pancreas, heart, lung, penis, kidney fat, cole fat, GI tract, ingest and empty GI tract were not different among Bt cotton seed and non Bt cotton seed fed lambs. However, Bt cotton seed feeding increased liver weight, testicle weight and testicle fat g/kg empty live weight. The Committee as laymen, cannot fathom the import of these findings, but since there are deviations in important biological attributes in the target group, when fed with Bt cotton seed, they would definitely like a professional evaluation of these developments, their possible causes and consequences by an expert committee comprising of eminent scientists from ICMR, pathologists, veterinarians and nutrition experts.

Reply of the Government

The study referred to by the Standing Parliamentary Committee has been undertaken in 2008 whereas Bt cotton was accorded approval in 2002 after a detailed review of all the studies required for regulatory approval. Prima facie it appears that the study has not been undertaken as per the define set of DBT protocols. A preliminary review of report also shows several discrepancies; such as

- While the Hb Values are around 11 G/dl, the Packed cell volumes or PCV also known as Hematocrit are also around 11 and 12 %. This is impossible. The PCV values should be normally 3 times the Hb in any animal with normal

complement of Hb per Red blood cell. According to Merck Vet Manual the PCV values are normally 22 to 38 %. There seems to be an error here.

- The RBC values are within the range. Here again if RBC values are high , how come hematocrit or PCV is so low. Since PCV is after all the %age of red cells vis a vis the plasma in blood.
- All values even if they are lower or higher between the groups should be compared with the normal range of values and only if they are outside the range do they attain any significance even if the differences are statistically significant.

As desired by the committee, RCGM and GEAC would examine the study report to provide considered views.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

RCGM and GEAC to furnish their considered views on the Feed Study Report
(Recommendation Para No. 2.91)

Furthermore, and again as laymen they would like to point out that the data in the said report pertaining to kidney weight, spleen weight, heart weight, lung weight, kidney fat, cole fat, pancreas weight and penis weight also shows variations in Bt cotton seed fed lambs and non Bt cotton seed fed lambs. They would, therefore, recommend a relook by the expert committee constituted for the purpose, into all these findings and apprise the Committee about their evaluation and interpretation of the data at the soonest. Lastly, the Committee desire RCGM and GEAC to furnish their considered views on this feed study report and how it fared in their consideration while deciding the bio-safety and health safety aspects of the product in question.

Reply of the Government

- The safety of foods derived from Bt crops, including cotton has been exhaustively considered by regulatory authorities in dozens of countries. Bt crops are approved in 13 countries plus EU for cultivation and many more for food and feed
- Bt crops have an exemplary record of safety as evidenced by the extensive body of literature of studies undertaken by academic and government research organizations, and by the accumulated experience gained globally in the many countries where these are grown and consumed since these crops were first cultivated over 15 years ago.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Conversion of Biodiversity **(Recommendation Para No. 5.51)**

The Committee's interactions with the various ministries/ departments/ agencies of the Government who were examined for and in connection with the subject have revealed 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 health and livestock health is unfortunately yet to be initiated in right measures.

Reply of the Government

India has been at the forefront in identifying suitable technologies and developing sustainable and environmental friendly practices in agriculture. The National Agriculture Research System (NARS) with its extensive network of research institutions along with State Agriculture Universities (SAUs) has been continuously working towards the above agenda. Besides spanning across various stakeholder departments several initiatives such as Task force, constitution of expert committees, framing of policy guidelines is a continuous process and these update as well as guide the agenda that is to be taken up. Union of India is more comfortable to take cognizance of home grown recommendations for making agriculture more competitive as well as sustainable rather than drawing conclusions only from IASTTD, which has only provided sweeping generalised statements

In fact, the Independent Evaluation Group, an independent 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 NGOs over national and local NGOs and therefore local knowledge representation was found to be inadequate.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Comments of the Committee

For comments of the Committee please refer to Para No. 1.42 of Chapter of this Report.

Department of Consumer Affairs expressing unawareness and unpreparedness in handling of transgenic food crops and related aspects. (Recommendation Para No. 6.148)

The examination of Department of Consumer Affairs which are the guardian of consumer rights in the Country also revealed the same status of unawareness and unpreparedness in so far as handling of transgenic food crops and related aspects are concerned. The Committee found it indeed surprising that the Department which administer the Consumer Protection Act, 1986 and which are intimately involved in the issues concerning consumer rights, consumer interest, informed consumer choice, etc. have not taken any proactive steps inspite of the controversies surrounding transgenic crops. While justifying their inaction before the Committee they took refuge behind the Clause in the Consumer Protection Act which puts the onus for filing a complaint in an appropriate form on the consumer. The Department were also blissfully unaware of the reports that commodities derived from transgenic food crops were coming into the Country, unchecked and uncontrolled and tried to wash their hands in the matter by stating that there is no stipulation regarding mandatory mention of any transgenic food in the existing rules. On a persistent query of the Committee they volunteered only to the extent of amending, if necessary, the packaged commodities rules to make it mandatory for the manufacturer to indicate whether the product is a GM product. The Committee also found that the Bureau of Indian Standards which is a body under the Department has set up a technical Committee by the name of Biotechnology for Food and Agriculture Sectional Committee for standardization in the field of food and agriculture products derived from modern biotechnology. Nine Indian standards have been formulated by the said Committee, however, these standards which are mostly test methods and guidelines are voluntary in nature for the producers to adopt. As has been mentioned elsewhere in this Report copious amounts of cotton seed oil has been produced in the Country from Bt. cotton seeds during last decade since Bt. cotton cultivation started in India. The Committee would like to have the considered views of the Department on this issue from the point of view of

Consumer Protection Act, consumer rights, informed consumer choice, etc. without any delay.

Reply of the Government

The issue of labelling of foods is under the purview of FSS Act, 2006 which is working on the issue. Meanwhile the Department of Consumer Affairs has issued a notification on labelling of GM food. The details of implementing the same have to be elaborated.

Regarding the consumption of cotton seed oil, it is clarified that safety studies on Bt cotton included assessment of cotton seed oil. Further, it is clarified that labeling of oil derived from GM crops is exempted (except if oil has special properties such as high oleic soy oil) even in countries with mandatory labeling regulation in place because highly processed oils do not contain proteins expressed in GM crops.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Implications of Transgenic Food Crops on Indian System of Medicines (Recommendation Para No. 6.149)

As is common knowledge, several food crops have substantial medicinal value and they are extensively used in the Indian System of Medicines viz. Ayurveda, Unani, Siddha. Agricultural food crops are also used in Naturopathy and Homeopathy. The Committee, therefore, examined the Department of AYUSH which are mandated with the formulation of policy issues for development and propagation of India System of Medicines. It came as a huge surprise to the Committee when the principal witness admitted during the his oral evidence before the Committee on 10 February, 2011 that the Department became aware of the various implications of transgenic food crops on the Indian System of Medicines only after they received the questionnaire of the Committee for eliciting written information from the Department. The Committee

also note that the Department of AYUSH had on 1 June, 2010 through a communication to the Secretary, Ministry of Environment and Forests conveyed their concerns that Bt. brinjal may have implications on AYUSH sector. They had also asked them not to permit open trial or commercialization of Bt. brinjal or any other medicinal plant until detailed analysis of their impact on India System of Medicines is done as plant materials are highly sensitive to phytochemical/agroclimatic/ environmental factor. The Department of AYUSH had in view of all these developments requested Ministry of Environment and Forests to co-opt Chief Executive Office of National Medicines Plant Board, Adviser, Ayurveda, Director General, Central Council for Research in Unani Medicines in GEAC. Interestingly, the Ministry of Environment and Forests through their letter dated 7 February, 2011 informed the Department of AYUSH that so far 'no transgenic medicinal plant have been developed and none are under field trials. The research being conducted is of a preliminary nature, where the research institutions are developed a transformations protocol for integration of all the new genes as the whole process will take several years the request for inclusion of AYUSH/Unani and National Medicinal Plants Board to GEAC will be considered at the appropriate stage.'

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Reply of the Government

It is clarified that the concerns expressed on Bt brinjal by Department of AYUSH are under consideration by GEAC as part of review process of Bt brinjal.

Regarding nomination of representative from AYUSH to GEAC, the Department of AYUSH had requested three members (Ayurveda, Unani & Siddha) be co- opted by the GEAC. GEAC being a statutory body experts are invited as special invitees on a case-by-case basis based on the agenda items.

Further, a nominee of Department of AYUSH has been included in the reconstituted “Review Committee on Genetic Manipulation” in the Department of Biotechnology.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

FSSAI to Notify Labeling and Related Aspects of All Items covered under Section 23 of FSS Act.
(Recommendation Para No. 7.62)

A similar dithering by the Government is observed by the Committee on the issue of labeling of GM foods and products thereof. Section 23 of FSS Act requires FSSAI to notify labeling and related aspects of all items covered under the Act. However, it has not been able to do so inspite of being in existence for years now. The Committee understand that FSSAI is presently working upon the procedure of labeling for GM foods and products thereof within its system and would be forwarding its recommendation to the Ministry of Health & Family Welfare.

Reply of the Government

FSSAI is in the process of developing the regulation for labelling for GM foods and as indicated in earlier paras, the committee will be kept informed of the developments.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

Government to Immediately Issue Regulation for Labelling of all Genetically Modified Products
(Recommendation Para No. 7.63)

In this context the Committee have considered the various opinions proffered to them by various ministries/departments of the Government, scientists and experts, both within the system and outside, NGOs and civil society, general public regarding labeling of genetically modified crops, food and products, thereof. In spite of the various reasons cited by ICAR and some other ministries/departments the Committee are in agreement with the majority opinion that the consumer has the supreme right to make an informed choice. They, therefore, recommend that the Government should immediately issue regulation for making labelling of genetically modified products including food crops, food and food products so as to ensure that the consumer is able to make an informed choice in the important matter of what she/he wants to consume. When China, which is more populous a country and which also produces transgenic products can make labeling of such products mandatory the Committee find no hitch in labeling being made mandatory in India.

Reply of the Government

As indicated above, the discussions on labelling of GM foods are under consideration of FSSAI and the committee shall be informed about the developments. Regarding the example of China it may be noted that although China introduced mandatory labelling, no authentic data is available regarding the extent of implementation of the same.

[Ministry of Agriculture (Department of Agriculture & Co-operation),
F. No. 4-5/2011-SDV dated the 30th November, 2012]

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

BASUDEB ACHARIA
Chairman,
Committee on Agriculture

ANNEXURE-I

**INDICATIVE LIST OF THE SCIENTIFIC SUBJECTS FOR WHICH EXPERTISE
IS REQUIRED FOR SAFETY ASSESSMENT OF GM CROPS**

Core Characterization	Plant Biotechnology and impact on environment	Impact on human health
Molecular biologist	Plant physiologist	Immunologist
Genetics	Plant pathologist	Pharmacologist
Microbiologist	Entomologist	Clinical scientist
Biochemist	Agronomist	Toxicologist
Toxicologist	Plant breeder	Food technology and nutrition
Bioinformatics	Environmental biologist	

COMPOSITION OF IBSC AND RCGM**1. Institutional Biosafety Committee (IBSC)**

As per Rules, 1989, each IBSC of an organization shall have the following members:

Head of the organisation or his designate (a suitable senior officer) as the Chairperson

Three or more scientists engaged in rDNA work or molecular biology with atleast one outside expert in the relevant discipline.

A member with medical qualifications - Biosafety Officer (in case of work with pathogenic agents/large scale use).

A nominee of DBT.

The Head of the organisation or his designate (suitable senior officer) shall chair the IBSC. The Chairperson should represent the organization and preferably have knowledge and experience in scientific research pertaining to rDNA technology and GMOs/LMOs.

Each IBSC has a nominee from DBT who oversees the activities to ensure that safety aspects are being fully adhered by the organisation. The DBT nominee serves as the link between DBT and the respective IBSC.

2. Review Committee on Genetic Manipulation (RCGM)

RCGM has scientists from public sector research institutions as members in individual capacity and representatives from the three research bodies viz. Indian Council of Agricultural Research (ICAR), Indian Council of Medical Research (ICMR) and Council of Scientific and Industrial Research (CSIR). List of members of the present RCGM, their affiliations and areas of expertise are as follows:

No.	Expert	Current Affiliation	Scientific Expertise
1	Dr. B. Sesikeran	National Institute of Nutrition (NIN)	Nutritional pathology, toxicology, oncology, nutrition and apoptosis
2	Dr. A. K. Kondapi	School of Life Sciences University of Hyderabad	Biochemistry, drug delivery stem, basic biology
3	Dr. A. C. Mishra	National Institute of Virology	Epidemiology, virology, taxonomy,

No.	Expert	Current Affiliation	Scientific Expertise
			ecology and vector bionomics
4	Dr. S. V. Chiplunkar	Advanced Centre for Treatment Research and Education in Cancer	Immunology
5	Dr. Madhu Dixit	Central Drug Research Institute	Pharmacology
6	Dr. S. K. Subbarao	National Institute of Malaria Research	Genetics, cytogenetics, epidemiology & Malariology
7	Dr. R. S. Gokhale	Institute of Genomics and Integrative Biology	Medical biotechnology
8	Dr. P. Kondaiiah (Served for One Term during 2003-2006)	Indian Institute of Science	Molecular characterization
9	Dr. K. V. Prabhu	Indian Agricultural Research Institute	Plant breeding and genetics
10	Dr. P. K. Gupta	Ch. Charan Singh University,	Plant breeding and genetics
11	Dr. S. J. Rahman	Acharya N.G. Ranga Agricultural University	Entomologist
12	Dr. T. Mohapatra	Central Rice Research Institute	Genetics, genomics and plant breeding
13	Dr. Kantipudi N. Babu	Indian Institute of Spices Research,	Plant pathology and plant biotechnology, genetic resources and crop improvement
14	Dr. O. P. Yadav	Directorate of Maize Research	Plant breeding and genetics
15	Dr. S. Solomon	Indian Institute of Sugarcane Research	Sugarcane Breeding and Insect Pest Management
16	Dr. K. S. Varaprasad	Directorate of Oilseeds Research	Insect Pest Management and Biodiversity/ Varietal Conservation
17	Director	National Bureau of Plant Genetic Resources	Germplasm Conservation, plant biotechnology
18	Dr. J. S. Sandhu	Indian Council of	Quality Control,

No.	Expert	Current Affiliation	Scientific Expertise
	(Nominee ICAR)	Agricultural Research	Regulation and production of crop seeds
19	Prof. Ram Rajasekharan, (Nominee, CSIR)	Central Food Technological Research Institute	Food technology and nutrition
20	Dr. Vijay Kumar, (Nominee, ICMR)	Indian Council of Medical Research	Pre-clinical and Clinical studies, Toxicology
21	Dr. Ranjini Warriar, (Nominee MoE&F / GEAC)	Ministry of Environment & Forests	Biodiversity and Environment Risk Assessment
22	Sh. Satyapal Shani, [Nominee DCG (I)]	Drugs Controller's Office (Ministry of Health)	Pre-clinical and Clinical Trials, Animal Testing, Toxicology
23	Dr. Ramesh Babu Devalla (Nominee AYUSH)	Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH)	Medicinal plants Biology and use in Ayurveda, Siddha and Unani medicine
24	Dr. B.K. Shukla, (Nominee DST)	Department of Science & Technology	Basic Biology
25	Dr. K.K.Tripathi, (Scientist-G, DBT)	Department of Biotechnology,	Vaccines & Toxicology
26	Dr. K.S. Charak, (Scientist-G, DBT)	Department of Biotechnology,	Botany and plant physiology
27	Dr. Bindu Dey, (Scientist-G, DBT)	Department of Biotechnology,	Medical Biotechnology, Clinical Trials
28	Ms. Rajalakshmi Muralidharan, (Scientist-E, DBT)	Department of Biotechnology,	Regulatory Affairs

ANNEXURE-III

Key international consultations addressing the safety assessment of GM foods (1990-2007)

Year	Organization	Title and link (where available)
1990	FAO ¹ /WHO ²	Strategies for assessing the safety of foods produced by biotechnology, a joint FAO/WHO consultation, Geneva, Switzerland, 5-10 November 1990 (http://www.who.int/foodsafety/publications/biotech/1990/en/index.html)
1990	IFBC ³	Biotechnologies and food: Assuring the safety of foods produced by genetic modification. Regulatory Toxicology and Pharmacology, 12: S1-S196.
1993	WHO	Health aspects of marker genes in genetically modified plants. Report of a WHO Workshop, Copenhagen, Denmark, 21-24 September 1993.
1994	WHO	Application of the principles of substantial equivalence to the safety evaluation of foods or food components from plants derived by modern biotechnology. Report of a WHO Workshop, Copenhagen, Denmark, 31 October-4 November 1994.
1996	FAO/WHO	Biotechnology and food safety. Report of a Joint FAO/WHO Consultation, Rome, Italy, 30 September-4 October 1996. FAO Food and Nutrition Paper No. 61
1996	ILSI ⁴	ILSI Allergy and Immunology Institute (All) guidance for assessing the allergenic potential of foods derived from biotechnology.
1997	OECD ⁵	Safety Assessment of New Foods: Results of an OECD Survey of Serum Banks for Allergenicity Testing, And Use of Databases (http://www.olis.oecd.org/olis/1997doc.nsf/LinkTo/sg-icgb(97)1-final)
1998	OECD	Report of the OECD Workshop on the Toxicological and Nutritional Testing of Novel Foods (http://www.olis.oecd.org/olis/1998doc.nsf/LinkTo/sg-icgb(98)1-final)
2000	FAO/WHO	Safety aspects of genetically modified foods of plant origin, a joint FAO/WHO consultation on foods derived from biotechnology, Geneva, Switzerland (http://www.who.int/foodsafety/publications/biotech/ec_june2000/en/index.html)
2000	CAC ⁶	First session of the Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology. (http://www.who.int/foodsafety/publications/biotech/ctf_march2000/en/index.html)
2001	FAO/WHO	Allergenicity of genetically modified foods, a joint FAO/WHO consultation on foods derived from biotechnology, Rome, Italy, 22-25 January 2001
2001	CAC	Second session of the Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology. (http://www.who.int/foodsafety/publications/biotech/ctf_march2001/en/index.html)
2002	OECD	Report of the OECD Workshop on the Nutritional Assessment of Novel Foods and Feeds (http://www.olis.oecd.org/olis/2002doc.nsf/LinkTo/env-jm-mono(2002)6)
2002	CAC	Third session of the Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology. (http://www.who.int/foodsafety/publications/biotech/ctf_march2002/en/index.html)
2003	CAC	Fourth session of the Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology. (http://www.who.int/foodsafety/publications/biotech/july2003/en/index.html)
2003	OECD	Report on the Questionnaire on Biomarkers, Research on the Safety of Novel Foods and Feasibility of Post-Market Monitoring (http://www.olis.oecd.org/olis/2003doc.nsf/LinkTo/env-jm-mono(2003)9)
2005	CAC	Fifth session of the Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology. (http://www.who.int/foodsafety/publications/biotech/sept05/en/index.html)
2006	CAC	Sixth session of the Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology. (http://www.who.int/foodsafety/publications/biotech/dec06/en/index.html)
2007	CAC	Seventh session of the Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology. (http://www.who.int/foodsafety/publications/biotech/sept07/en/index.html)

¹Food and Agriculture Organization of the United Nations

²World Health Organization

³International Food Biotechnology Council

⁴International Life Sciences Institute

⁵Organization for Economic Cooperation and Development

⁶Codex Alimentarius Commission

ANNEXURE IV

Economic impacts and impact dynamics of Bt (*Bacillus thuringiensis*) cotton in India

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Edited by Calestous Juma, Harvard University, Cambridge, MA, and approved May 15, 2012 (received for review March 2, 2012)

Despite widespread adoption of genetically modified crops in many countries, heated controversies about their advantages and disadvantages continue. Especially for developing countries, there are concerns that genetically modified crops fail to benefit smallholder farmers and contribute to social and economic hardship. Many economic studies contradict this view, but most of them look at short-term impacts only, so that uncertainty about longer-term effects prevails. We address this shortcoming by analyzing economic impacts and impact dynamics of Bt cotton in India. Building on unique panel data collected between 2002 and 2008, and controlling for nonrandom selection bias in technology adoption, we show that Bt has caused a 24% increase in cotton yield per acre through reduced pest damage and a 50% gain in cotton profit among smallholders. These benefits are stable; there are even indications that they have increased over time. We further show that Bt cotton adoption has raised consumption expenditures, a common measure of household living standard, by 18% during the 2006–2008 period. We conclude that Bt cotton has created large and sustainable benefits, which contribute to positive economic and social development in India.

farm survey | small farms | agricultural biotechnology

Despite widespread adoption of genetically modified (GM) crops in many countries (1), controversies about their advantages and disadvantages continue. In the public debate, negative attitudes often seem to dominate. Civil society groups tend to emphasize potential risks of GM crops and question reports about positive agronomic and economic effects (2–5). Especially with a view to developing countries, there are widespread concerns that GM crops fail to benefit smallholder farmers and contribute to social and economic hardship (4, 5). Much of this debate focuses on Bt cotton (5–9), as this is currently the most widely used GM crop technology among smallholders. Using comprehensive data from India, we show that these concerns about negative social and economic impacts are not backed by representative empirical evidence.

Bt cotton contains genes from *Bacillus thuringiensis* that make the plant resistant to the cotton bollworm complex. This inbuilt insect resistance can lead to savings in chemical pest control and higher effective yields in farmers' fields (9). Several studies have shown that Bt cotton adoption is associated with significant benefits to farmers in various countries (10–14). In addition to productivity gains (15–19), Bt adoption entails reduced incidence of acute pesticide poisoning among smallholders (20). However, the available literature on Bt cotton impacts has four important shortcomings, which may also explain why controversies continue. First, with very few exceptions (21), most of the evidence is based on data from field trials or from the first few growing seasons after the commercial release of Bt varieties in a country. This evidence is unsatisfying because it does not allow analysis of longer-term developments. For example, resistance build-up in pest populations or growing importance of secondary pests may potentially lower Bt benefits over time (22–24). Second, most impact studies do not properly control for nonrandom selection bias (17), which may occur when more successful farmers adopt the new technology earlier or more widely (25). As these

successful farmers may have higher crop yields and profits anyway, this can result in inflated benefit estimates. Third, most available studies focus on agronomic impacts of Bt, such as yield and pesticide use effects, but economic effects, such as profit changes, are not analyzed at all or only based on simplistic comparisons. Fourth, and related to the previous point, many existing studies concentrate on impacts at the plot level, without considering possible broader welfare effects for farm households.

We address these shortcomings by using comprehensive panel data collected in India in four waves between 2002 and 2008. Estimation of panel data models allows us to account for selection bias and also analyze impact dynamics. In particular, we estimate fixed-effects specifications of yield, profit, and consumption expenditure models to derive net impacts of Bt adoption on cotton yield per acre, profit per acre, and household living standard. To our knowledge, this economic impact assessment of any GM crop technology that builds on more than 2 y of panel data is unique.

Results

In India, cotton is primarily grown by smallholder farmers with farm sizes of less than 15 acres and cotton holdings of 3–4 acres on average. The first Bt cotton hybrids were commercially released in India in 2002. By 2011, 7 million farmers had adopted Bt on 26 million acres, around 90% of the total Indian cotton area (1). We carried out a survey of Indian cotton farmers in four waves between 2002 and 2008. This survey covered a total of 533 farm households in four principal cotton-producing states (see *Materials and Methods*). The sample is representative of Bt and conventional cotton farmers in central and southern India. Given that we purposively oversampled Bt adopters in the first wave, sample adoption rates differ from actual adoption rates. The share of Bt-adopting farmers in our sample was 38% in 2002. After a small decline in 2003, it increased to 46% in 2004. (In the 2004, 2006, and 2008 survey waves, we also asked farmers for their adoption of Bt hybrids in 2003, 2005, and 2007, respectively. However, further details about the cultivation experience were only asked for the respective survey years.) The adoption share jumped to 93% in 2005 and reached 99% in 2008. A similar trend is also observed for individual adoption intensities, defined as the Bt acreage relative to the total cotton acreage on a farm. Alongside a range of household characteristics, data on all cotton plots of surveyed households were recorded, leading to a total of 1,655 plot observations.

Table 1 compares selected variables between Bt and conventional cotton plots and farms (for a more detailed overview, see

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Table 1. Descriptive statistics for 1,655 plots and 533 associated households (averages for 2002–2004 and 2006–2008)

Plot or household information	2002–2004		2006–2008	
	Conventional	Bt	Conventional	Bt
Plot level information				
Seed cost (1,000 Rs/acre)	0.51 (0.26)	1.60*** (0.43)	0.47 (0.21)	0.91*** (0.32)
Pesticide cost (1,000 Rs/acre)	2.27*** (1.80)	1.43 (1.57)	1.07 (1.21)	1.07 (1.38)
Yield (kg/acre)	520.64 (315.54)	705.40*** (360.41)	588.85 (318.66)	829.03*** (341.08)
Profit (1,000 Rs/acre)	3.60 (5.80)	6.14*** (6.89)	5.31 (6.80)	10.32*** (7.73)
No. of plots	601	298	64	692
Household level information				
Land owned (acres)	13.25 (15.45)	15.07* (18.42)	11.48 (12.28)	11.61 (12.68)
Expenditures (1,000 Rs/y)	85.87 (71.01)	122.76*** (79.00)	87.90 (64.14)	90.43 (88.82)
No. of households	363	222	61	432

*, ***, imply that the mean value is significantly higher than that of conventional/Bt in the same time period at the 10% and 1% level, respectively. Mean values are shown with SDs in parentheses. Household expenditures were deflated using the consumer price index. Rs, Indian Rupees. Additional variables are shown in Table S1.

Table S1). We differentiate between early (2002–2004) and late (2006–2008) adoption periods. Most previous studies on Bt cotton impacts in India concentrated on the early period; evidence for the later period is thin. Bt seed costs per acre were more than three times higher than conventional seed costs during the early period. During 2006–2008, the cost difference was lower because of government interventions in seed pricing and increasing competition in the market for Bt technology (19, 26). Pesticide costs were significantly higher on conventional plots than on Bt plots during 2002–2004, and there was no difference during 2006–2008. Widespread adoption of Bt has led to area-wide suppression of bollworm populations, so that conventional cotton farmers also substantially reduced their pesticide applications (27). Similar positive spillover effects were observed for Bt cotton in China and Bt maize in the United States (28, 29).

In terms of yield per acre, Bt strongly outperformed conventional cotton in both time periods (Table 1). This finding is not because of higher yield potentials of Bt hybrids, but because of more effective pest control and thus lower crop losses. Higher yields are also the main reason for much higher profits on Bt cotton plots. These observed differences provide interesting insights into Bt effects, but they cannot be interpreted as net impacts of the technology, because confounding factors and possible nonrandom selection bias have to be controlled for. This process requires regression analysis.

Impact on Cotton Yield. Results of panel fixed-effects specifications of a cotton yield function are shown in Table 2 (full model

results with all control variables are shown in Table S2). The positive and significant coefficient of Bt in column 1 indicates that Bt has a positive net impact on cotton yield per acre. Controlling for all other factors, Bt increases cotton yield by 126 kg per acre, which is equivalent to a 24% gain over mean yields on conventional cotton plots. The Bt dummy variable captures Bt adoption in any year, whereas the additional Bt 2006–2008 dummy takes a value of one only when Bt was used in the 2006 or 2008 survey waves. In the first column, the Bt 2006–2008 coefficient is insignificant, indicating that the Bt yield effect was stable over time and did not increase or decrease in the later compared with the earlier period.

The dummies for the three survey waves in column 1 of Table 2 are all positive and significant, indicating that overall yield levels were higher in 2004, 2006, and 2008, compared with the reference year 2002. Omitting these year dummies in column 2 leads to a large positive and significant Bt 2006–2008 coefficient. These results suggest that the Bt yield gain was in a magnitude of 297 kg per acre (sum of Bt and Bt 2006–2008 coefficients) in the later period and thus more than doubled compared with 2002–2004. As Bt adoption strongly increased over time, there is a close correlation between Bt 2006–2008 and the year dummies. Hence, some of the Bt effects are captured by the year dummies in column 1. Not including year dummies, as in column 2, may overestimate the Bt yield gains, because Bt 2006–2008 may then also capture time effects that are unrelated to the technology. However, systematic changes in temperature or rainfall did not occur during the period of analysis (30, 31), and there were also

Table 2. Net impact of Bt on cotton yield and profit per acre

Explanatory variables	Yield (kg/acre)		Profit (Rs/acre)	
	1	2	3	4
Bt (dummy)	125.90*** (20.41)	116.91*** (20.68)	1,877.21** (889.16)	2,151.51** (893.33)
Bt 2006–2008 (dummy)	3.59 (43.46)	180.06*** (20.54)	–260.45 (1,144.58)	1,736.39** (803.31)
2004	125.39*** (17.68)		2,066.07*** (466.18)	
2006	297.03*** (40.53)		5,006.86*** (1,017.09)	
2008	208.61*** (43.68)		2,332.61** (1,149.50)	
R ²	0.39	0.34	0.38	0.36
Hausman test	90.47***	70.00***	42.39***	24.60**

***, Coefficient is statistically significant at the 5% and 1% level, respectively. Coefficient estimates are shown with SEs in parentheses. Estimates are based on panel regressions with household fixed effects to control for nonrandom selection bias. The reference year is 2002. Not all explanatory variables included in the models (e.g., input quantities, prices, and other controls) are shown for brevity (full model results with all control variables are shown in Tables S2 and S3). The Hausman test results show that fixed-effects are preferred over random-effects specifications. Rs, Indian Rupees.

no other breakthrough technologies in Indian cotton production (20, 32). Nor did we find evidence of attrition bias. (Because we have an unbalanced panel, there is the possibility of attrition bias, which could emerge when farmers who obtained lower than average yields with Bt cotton in 2002–2004 dropped out of the sample in the later 2006–2008 period. This drop could potentially hide a decrease in Bt impact over time. Analyses with different subsamples that we carried out do not support this hypothesis. We re-estimated the model in column 1 of Table 2 excluding the dropout farmers. With this smaller sample, the Bt coefficient is 130.94, which is very similar to the original coefficient of 125.90, and the Bt 2006–2008 coefficient remains insignificant. Hence, we conclude that there is no attrition bias.) Therefore, Bt was probably the main factor contributing to the observed time effects.

Impact on Cotton Profit. Bt technology can influence cotton profit mainly through three channels, namely changes in yield, changes in pesticide cost, and changes in seed cost (33). To assess net profit changes per acre, we estimated fixed-effects specifications of a profit function (Table 2; full model results with all control variables are shown in Table S3). The coefficients in column 3 indicate that Bt increases profit by 1,877 Rs per acre (38 US\$), equivalent to a 50% profit gain over conventional cotton. In this specification, the Bt impact per acre does not change significantly over time. However, total cotton profits per farm rose, because farmers increased their Bt adoption intensity. Combining the estimate of 1,877 Rs with the data on adoption intensity, Bt added 5,307 Rs (107 US\$) to annual farm-level cotton profits during 2002–2004 and 10,524 Rs (213 US\$) during 2006–2008. Nationwide, for the 26 million acres currently under Bt, this implies an annual net gain of almost 50 billion Rs (1 billion US\$) in cotton profits.

Similar to the yield analysis above, the year dummies in column 3 of Table 2 are all significant. When omitting these year dummies, the Bt 2006–2008 coefficient turns positive and significant (column 4), indicating that the Bt profit gains may actually have increased substantially in the later period to 3,888 Rs (79 US\$) per acre (sum of Bt and Bt 2006–2008 coefficients). This result may partly be explained by lower Bt seed prices during 2006–2008. However, as seeds only account for a relatively small share of total production costs, the more important reason for larger profits per acre are higher yield gains and thus higher sales revenues.

Impact on Household Living Standard. Cotton is often the major crop for cotton-producing households in India, so that profit gains through Bt technology are also likely to increase household living standard. A common way of measuring living standard in the development literature is to look at household consumption expenditures, because expenditure is usually a more reliable indicator than income (34). We use a fixed-effects specification of a consumption expenditure model. As the level of analysis is the household, instead of using dummy variables to capture Bt adoption, we use the households' Bt area in any year and the Bt area in 2006–2008 as variables of particular interest. The results suggest that Bt had no significant effect on consumption expenditures in the early adoption period, but it increased household living standard significantly in the later period (Table 3; full model results with all control variables are shown in Table S4). This finding is plausible. Although Bt-adopting households also increased cotton profit during 2002–2004, they did not immediately change their consumption behavior but waited until they realized that the profit gains are sustainable.

In 2006–2008, each acre of Bt increased household consumption by 2,826 Rs (57 US\$) per year (Table 3). Based on this finding, we can also calculate the total living standard effect per household by multiplying with the mean Bt area of adopting

Table 3. Net impact of Bt on household living standard

Explanatory variables	Consumption expenditure (Rs/y)
Bt area (acres)	197.65 (1,227.07)
Bt area 2006–2008 (acres)	2,825.65** (1,196.64)
2004	19,433.01*** (4,543.11)
2006	1,257.58 (5,653.66)
2008	9,250.43 (5,937.91)
R ²	0.17
Hausman test	35.50***

***, **, Coefficient is statistically significant at the 5% and 1% level, respectively. Coefficient estimates are shown with SEs in parentheses. Household expenditures were deflated using the consumer price index. Estimates are based on panel regressions with household fixed effects to control for nonrandom selection bias. The reference year is 2002. Control variables include cotton area, so that the coefficients of Bt area and Bt area 2006–2008 can be interpreted as the net effect of Bt technology (full model results with all control variables are shown in Table S4). The Hausman test result shows that fixed-effects are preferred over a random-effects specification. Rs, Indian Rupees.

farms. During 2006–2008, Bt-adopting households increased their annual consumption expenditures by 15,841 Rs (321 US\$) on average. Compared with nonadopters, this finding implies a net increase of 18%, which underlines that Bt cotton has significantly raised living standards of smallholder farm households.

Discussion

The results show that Bt cotton adoption has caused sizeable socioeconomic benefits for smallholder farm households in India. The technology has increased cotton yields and profits by 24% and 50%, respectively. These effects are similar in magnitude to the ones shown in earlier studies for India based on cross-section data (15–19, 33). The panel data used here confirm that impacts per acre of Bt cotton have been stable over time. Because of rapidly rising Bt adoption rates in India, the aggregate benefits increased tremendously. Countrywide, this technology is now used on 90% of the cotton area. On average, household living standard increased by 18% among Bt adopters. Most of these adopting households are relatively poor. Hence, Bt cotton contributes to positive economic and social development.

The stable Bt effects per acre are a conservative interpretation. Robustness checks indicate that the per acre benefits probably increased over time. This finding could be explained by the growing number of available Bt hybrids and the release of new Bt events after 2005. In 2002, only three Bt hybrids, which were developed by the Indian seed company Mahyco and contained Monsanto's Bollgard I technology (event MON 531), were approved by the national regulatory authorities. In 2004 and 2005, three other Indian seed companies, which had sublicensed the Bollgard I technology, received approval for the commercialization of several additional Bt hybrids. In 2006, the number of approved Bt hybrids increased sharply. In addition, new Bt events were deregulated by the national authorities, including Monsanto's Bollgard II technology, but also technologies developed by public research institutes. By 2011, the number of commercialized Bt varieties and hybrids containing different events had increased to over 880 (1). More Bt events and greater varietal diversity imply effectiveness against a broader spectrum of insect pest species and better adaptation to different agroecological conditions.

Our findings of large and sustainable economic and social benefits of Bt cotton do not imply that impacts may not decrease in the long run. As of now, Bt resistance development and secondary pest outbreaks do not seem to be major problems in India, but this should be further monitored. Sustainable innovation in agriculture always implies that technologies are

further improved or replaced by new technologies after some time. Nonetheless, our results clearly refute the assertion that Bt technology would harm smallholder farmers because of low and eroding economic benefits. As Bt cotton is the only GM crop technology that is already widely used by smallholder farmers, these findings may add to the wider public biotechnology debate.

Materials and Methods

Survey. A panel survey of Indian cotton farmers was carried out in four waves between 2002 and 2008. A multistage random sampling procedure was used. The survey covered four states of central and southern India, namely Maharashtra, Karnataka, Andhra Pradesh, and Tamil Nadu. These four states encompass a wide range of different cotton-growing situations. A total of 10 different districts and 63 villages were surveyed. The first wave was implemented in early 2003, covering the 2002 cotton growing season. Because this was the first season where Bt cotton was officially commercialized, the number of adopters was still very low. Therefore, Bt cotton adopters were purposely oversampled by randomly selecting from complete lists of technology users at the village level (33). Follow-up waves were implemented in 2-y intervals, in early 2005 (referring to the 2004 cotton season), early 2007 (referring to the 2006 season), and early 2009 (referring to the 2008 season). The survey is representative of Bt cotton adopters and nonadopters in central and southern India, where over 60% of the total Indian cotton area is located.

To some extent, sample attrition occurred over time, as is normal in panel surveys extending over several years. Some farmers had migrated to other areas, which happened particularly in one district of Karnataka. Other farmers had stopped cotton cultivation during the period, mostly because of focusing on new cash crops, such as sugarcane. Farmers who dropped out during the period were replaced by other randomly selected farmers in the same locations. The sample size was also slightly increased over time. In total, the sample includes observations from 533 different farm households, of which 198 were included in all four survey waves. All observations were used for the regression analysis, resulting in an unbalanced panel. An unbalanced panel allows more efficient estimation than any balanced subset of it (35).

During face-to-face interviews in all four waves, farmers were asked to provide a wide array of agronomic and economic information, including input-output details on their cotton plots. Farmers who grew Bt and conventional cotton simultaneously provided details for both alternatives, so that the number of plot observations is somewhat larger than the number of farmers surveyed. The total number of cotton plot observations is 1,655 over the four waves. At the household level, data were collected about household structure, asset ownership, and living standard. Living standard is measured by household consumption expenditures (including the value of subsistence consumption), which were captured through a 30-d recall for food and other consumables, and a 12-mo recall for more durable items.

Regression Models. We want to estimate unbiased treatment effects of Bt adoption on cotton yield per acre, profit per acre, and household living

standard. For this purpose, we develop and estimate three types of models where Bt is included as an explanatory variable: a cotton yield function, a cotton profit function, and a household consumption expenditure model. These models can generally be represented as:

$$y_{it} = \mathbf{x}_{it}\beta + v_{it}, \quad [1]$$

where

$$v_{it} = c_i + \mu_{it}, \quad [2]$$

where y is the respective outcome variable (yield per acre, profit per acre, consumption expenditure per household), subscript i is the plot or household observation, and subscript t is time (survey wave). This fixed-effects specification allows for individual heterogeneity c_i to be correlated with the vector of explanatory variables \mathbf{x}_{it} . We use fixed effects because we suspect that more progressive and efficient farmers are more likely to adopt Bt technology. The existence of such selection bias and thus the superiority of a fixed-effects over a random-effects specification is tested with a Hausman test.

Year dummies are included in the regression models to control for time fixed effects, using the first survey wave in 2002 as the reference year. For the yield and profit functions, which are estimated using plot observations, we use a Bt adoption dummy as treatment variable, which is one for a Bt plot in any particular year and zero otherwise. In addition, we include a Bt 2006–2008 dummy, which is one if Bt was used in 2006 or 2008. The Bt dummy indicates whether or not the technology has a positive net effect on cotton yield and profit, and the Bt 2006–2008 dummy reveals whether there are impact dynamics: if the Bt coefficient is positive and significant and the Bt 2006–2008 coefficient is statistically insignificant, then the technology causes benefits that do not change over time. On the other hand, a negative Bt 2006–2008 coefficient would indicate shrinking benefits, whereas a positive coefficient would reveal increasing benefits over time.

The consumption expenditure model is estimated at the household level. Some farm households have both Bt and conventional cotton. Moreover, the acreage cultivated with Bt varies. Therefore, instead of Bt dummies, we use two continuous Bt variables. The first such dummy is Bt area, which measures the number of acres cultivated with Bt on the farm, independent of the time period. The second is Bt area 2006–2008, which measures the number of Bt acres only during that later period. We control for total cotton area on the farm. Thus, the Bt estimation coefficients can be interpreted as the effects on household consumption expenditures per acre of Bt cotton. The test for impact dynamics is as explained for the yield and profit function models.

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Supporting Information

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Table S1. Descriptive statistics for 1,655 plots and 533 associated households (averages for 2002–2004 and 2006–2008)

Plot or household information	2002–2004		2006–2008	
	Conventional	Bt	Conventional	Bt
Plot level information				
Seed cost (1,000 Rs/acre)	0.51 (0.26)	1.60*** (0.43)	0.47 (0.21)	0.91*** (0.32)
Seed rate (g/acre)	659.82*** (552.39)	490.72 (114.23)	646.64*** (474.33)	570.75 (160.93)
Irrigation (share of plots)	0.46 (0.50)	0.58*** (0.49)	0.48 (0.50)	0.59* (0.49)
Fertilizer (t/acre)	0.23 (0.15)	0.26*** (0.16)	0.20 (0.10)	0.25*** (0.15)
Pesticide (1,000 Rs/acre)	2.27*** (1.80)	1.43 (1.57)	1.07 (1.21)	1.07 (1.38)
Labor (d/acre)	70.72 (32.30)	83.23*** (40.81)	63.12 (35.74)	69.75 (44.67)
Yield (kg/acre)	520.64 (315.54)	705.40*** (360.41)	588.85 (318.66)	829.03*** (341.08)
Cotton price (Rs/kg)	19.67 (3.06)	19.52 (2.69)	20.07 (4.87)	23.31*** (4.05)
Revenue (1,000 Rs/acre)	10.22 (6.36)	13.79*** (7.32)	12.41 (7.48)	19.35*** (8.42)
Total cost (1,000 Rs/acre)	6.62 (3.07)	7.65*** (2.94)	7.10 (3.34)	9.03*** (5.12)
Profit (1,000 Rs/acre)	3.60 (5.80)	6.14*** (6.89)	5.31 (6.80)	10.32*** (7.73)
No. of plots	601	298	64	692
Household level information				
Age of farmer (y)	44.24 (12.49)	44.43 (12.47)	48.14** (12.52)	45.18 (12.67)
Education of farmer (y)	7.29 (4.97)	8.04** (4.81)	4.73 (5.08)	7.32*** (5.15)
Land owned (acres)	13.25 (15.45)	15.07* (18.42)	11.48 (12.28)	11.61 (12.68)
Cotton area (acres)	6.99 (37.12)	6.20 (6.73)	4.42 (4.51)	5.79** (4.60)
Household size (head)	6.46 (3.46)	6.75 (3.80)	6.59 (3.38)	6.28 (4.07)
Expenditures (1,000 Rs/y)	85.87 (71.01)	122.76*** (79.00)	87.90 (64.14)	90.43 (88.82)
No. of households	363	222	61	432

* ** *** imply that the mean value is significantly higher than that of conventional/Bt in the same time period at the 10%, 5%, and 1% level, respectively. Mean values are shown with SDs in parentheses. Household expenditures were deflated using the consumer price index. Rs, Indian Rupees.

Table S2. Estimated coefficients of quadratic production (yield) function

Explanatory variables	Pooled-data model 1	Fixed-effects models	
		2	3
Inputs			
Bt (dummy)	156.46*** (21.85)	125.90*** (20.41)	116.91*** (20.68)
Bt 2006–2008 (dummy)	31.62 (44.79)	3.59 (43.46)	180.06*** (20.54)
Seed rate (g/acre)	0.54** (0.02)	–0.004 (0.03)	–0.01 (0.03)
Sow date (d)	0.23 (0.40)	–0.85** (0.42)	–0.86** (0.44)
Harvest date (d)	1.16*** (0.27)	1.03*** (0.29)	–0.08 (0.25)
Irrigation (yes/no)	139.75*** (15.80)	97.26*** (19.35)	83.00*** (0.00)
Fertilizer (t/acre)	70.61 (135.43)	1.29 (144.01)	–29.08 (149.13)
Square of fertilizer	844.08** (351.59)	558.55 (358.62)	646.46* (371.64)
Pesticide (1,000 Rs/acre)	20.62 (13.17)	1.72 (14.24)	–8.91 (13.58)
Square of pesticide	–1.85 (2.91)	–1.86 (2.94)	–1.52 (3.03)
Labor (d/acre)	4.44*** (0.55)	5.11*** (0.69)	4.83*** (0.72)
Square of labor	–0.01*** (0.003)	–0.02*** (0.01)	–0.01** (0.01)
Fertilizer-pesticide interaction	–72.08*** (27.31)	–35.28 (27.95)	–38.85 (28.97)
Fertilizer-labor interaction	–1.77 (1.22)	–2.91** (1.35)	–3.23** (1.39)
Pesticide-labor interaction	0.14 (0.13)	0.17 (0.14)	0.29** (0.14)
Household characteristics			
Age of farmer (y)	–2.34*** (0.65)		
Education of farmer (y)	–0.29 (1.55)		
Cotton experience of farmer (y)	0.62 (0.91)		
Karnataka	–9.89 (20.64)		
Andhra Pradesh	19.43 (20.87)		
Tamil Nadu	–193.54*** (40.79)		
2004	103.94*** (19.91)	125.39*** (17.68)	
2006	235.41*** (41.42)	297.03*** (40.53)	
2008	128.01*** (44.64)	208.61*** (43.68)	
Constant	–130.12 (82.19)	–104.19 (83.07)	287.23*** (69.10)
No. of observations	1648	1648	1648
R ²	0.38	0.39	0.34
Hausman test		90.47***	70.00***

*. **. ***, Coefficient is statistically significant at the 10%, 5%, and 1% level, respectively. The model in column 1 is based on comparisons of plots both within and between households. Columns 2 and 3 are based on comparisons of plots within households (household fixed effects). The dependent variable in all three models is cotton yield in kilogram per acre. Coefficient estimates are shown with SEs in parentheses. The reference year is 2002. The Hausman test results show that fixed-effects are preferred over random-effects specifications. Rs, Indian Rupees.

Table S3. Estimated coefficients of quadratic profit function

Explanatory variables	Pooled-data model 1	Fixed-effects models	
		2	3
Inputs			
Bt (dummy)	1,595.67* (847.63)	1,877.21** (889.16)	2,151.51** (893.33)
Bt 2006–2008 (dummy)	1,485.88 (1,087.64)	–260.45 (1,144.58)	1,736.39** (803.31)
Seed rate (g/acre)	0.72 (0.47)	0.09 (0.63)	–0.07 (0.63)
Sow date (d)	–4.56 (8.47)	–18.37* (9.59)	–19.92** (9.72)
Harvest date (d)	14.26** (5.73)	13.72** (6.73)	–2.36 (6.15)
Irrigation (yes/no)	2,922.27*** (318.20)	2,087.24*** (439.54)	2,027.25*** (442.23)
Seed price (Rs/450 g)	0.71 (0.70)	0.16 (0.76)	–0.35 (0.76)
Cotton price (Rs/kg)	812.81*** (64.91)	814.17*** (71.21)	615.53*** (53.88)
Fertilizer price (Rs/kg)	–286.88*** (90.49)	–361.04*** (98.40)	–340.12*** (99.74)
Square of fertilizer price	6.37*** (1.98)	8.39*** (2.21)	7.58*** (2.24)
Pesticide price (Rs/L)	0.60 (0.43)	0.05 (0.48)	0.53 (0.47)
Square of pesticide price	0.0001 (0.0001)	0.0002* (0.0001)	0.0001 (0.0001)
Wage rate (Rs/h)	138.38 (136.08)	–74.12 (152.33)	230.42 (145.12)
Square of wage rate	–10.50* (6.00)	–3.27 (9.37)	–23.84*** (8.84)
Fertilizer-pesticide price interaction	–0.10*** (0.02)	–0.09*** (0.02)	–0.09*** (0.02)
Fertilizer-labor price interaction	18.45 (13.78)	3.20 (15.66)	7.45 (15.83)
Pesticide-labor price interaction	–0.01 (0.03)	0.02 (0.04)	–0.00004 (0.04)
Household characteristics			
Age of farmer (y)	–45.37*** (13.71)		
Education of farmer (y)	5.43 (32.59)		
Cotton experience of farmer (y)	2.12 (19.25)		
Karnataka	997.04** (428.77)		
Andhra Pradesh	–757.56* (412.86)		
Tamil Nadu	–2,331.92*** (825.00)		
2004	1,454.26*** (464.90)	2,066.07*** (466.18)	
2006	2,093.82** (933.78)	5,006.86*** (1,017.09)	
2008	–1,389.82 (1,064.79)	2,332.61** (1,149.50)	
Constant	–15,530.24*** (2,276.21)	–14,554.41*** (2,268.62)	–6,492.66*** (1,676.44)
No. of observations	1648	1648	1648
R ²	0.35	0.38	0.36
Hausman test		42.39***	24.60**

*. **. ***, Coefficient is statistically significant at the 10%, 5%, and 1% level, respectively. The model in column 1 is based on comparisons of plots both within and between households. Columns 2 and 3 are based on comparisons of plots within households (household fixed effects). The dependent variable in all three models is cotton profit in Indian Rupees (Rs) per acre. Coefficient estimates are shown with SEs in parentheses. The reference year is 2002. The Hausman test results show that fixed-effects are preferred over random-effects specifications.

Table S4. Estimated coefficients of household consumption expenditure function

Explanatory variables	Pooled-data model	Fixed-effects model
	1	2
Bt area (acres)	2,636.22*** (925.83)	197.65 (1,227.07)
Bt area 2006–2008 (acres)	428.85 (973.06)	2,825.65** (1,196.64)
Cotton area (acres)	104.81 (69.19)	41.55 (74.10)
Cultivated area (acres)	1,374.32*** (147.68)	1,123.82*** (229.72)
Household size (AE)	13,735.91*** (807.15)	9,255.51*** (1,259.57)
Age of farmer (y)	564.98*** (134.82)	
Education of farmer (y)	1,832.08*** (344.70)	
Karnataka	–2,048.50 (4,211.89)	
Andhra Pradesh	35,430.50*** (4,283.91)	
Tamil Nadu	39,745.87*** (7,346.99)	
2004	14,234.28*** (4,556.09)	19,433.01*** (4,543.11)
2006	–406.97 (5,179.06)	1,257.58 (5,653.66)
2008	3,957.18 (5,237.25)	9,250.43 (5,937.91)
Constant	–58,234.18*** (8,787.57)	15,250.02** (6,663.66)
No. of observations	1,431	1,431
R ²	0.43	0.17
Hausman test		35.50***

*** **, Coefficient is statistically significant at the 5% and 1% level, respectively. The model in column 1 is based on comparisons within and between households. Column 2 is based on comparisons within households (household fixed effects). The dependent variable in both models is annual household consumption expenditures in Indian Rupees. Household expenditures were deflated using the consumer price index. Coefficient estimates are shown with SEs in parentheses. The reference year is 2002. AE, adult equivalents.

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**

2. At the outset the Chairman welcomed the members to the Sitting of the Committee and read out the valedictory Speech. The Committee, then, took up the draft Reports for consideration and adoption:-

(i) The Committee first took up for consideration the draft Action Taken Report on the Action Taken by the Government on Observations/Recommendations contained in the Thirty-Seventh Report on "Cultivation of Genetically Modified Food Crops – Prospects and Effects" decided that the following 23 recommendation para nos. given below should be reiterated::

1.20, 3.40, 3.41, 3.42, 3.48, 5.46, 5.49, 5.52, 5.53, 5.57, 5.58, 5.59, 6.144, 6.147, 8.116, 8.117, 8.118, 8.119, 8.120, 8.121, 8.124, 8.126 and 8.127. The Committee also decided to include the following comment in the Report in appropriate para:

'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.'

Subject to above amendments, the Committee adopted the report.

*(ii)	xxxx	xxxx	xxxx	xxxx
*(iii)	xxxx	xxxx	xxxx	xxxx

3. The Committee authorized the Chairman to finalise the aforesaid report on the basis of factual verification and present the same to the Hon'ble Speaker, as the Parliament is not in session.

*4.	xxxx	xxxx	xxxx	xxxx.
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The Committee then adjourned.

*Matter not related to this Report.

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 (2011-12) 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 %