FIFTY-NINTH REPORT

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)]

Presented to the Hon'ble Speaker on 15.03.2014
Presented to Lok Sabha on 2014
Laid on the Table of Rajya Sabha on 2014

LOK SABHA SECRETARIAT
NEW DELHI

March, 2014/*Phalguna,* 1935 *(Saka)*

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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,* 2014
12 *Phalguna,* 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 Pradesh 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 Minster 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 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. 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 setup 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 resistant 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 rigourous 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 tonnes 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 Cooperation 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 soyabean, 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 Cooperation 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-Governmental 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 judgement 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 some fate would have be fallen 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 2010-11 accounted for record food production of 244.78 million tonnes, 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 tonnes 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 and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH Ayurveda, Yoga and 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 custom airports, 132 land custom 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 framework. 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 framework. 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 transgenic 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 be 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 "provides 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 was 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 bio-safety and bio-efficacy assessment of all recombinant products. Decision on commercial use of biotechnology produced crops should be taken by the Agriculture Ministries/Department of Central and State Governments as per existing policies and regulations on crops. For medical products Central Drugs Standard Control Organization (CDSCO) of Ministry of Health and Family Welfare, Government of India would approve commercialization as of now.

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

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

(iv) GEAC and RCGM should have full time Chairpersons. The Chairman of GEAC, may be of Special Secretary Status for 3 year period and RCGM one level lower. Chairman of RCGM be the Co-chair in GEAC and not the expert nominee of Department of Biotechnology. For greater synergy at least three members should be common between RCGM and GEAC.

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

The Department further stated that the Institutional Bio-safety 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 effect 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 policies.

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 bio-diversity health, environment, etc. The Committee further pointed out that with the various crop insurance schemes also not being of much help to a majority of farmers any prospective losses to the farmers due to cultivation of transgenic agricultural crops would have crippling effects on their fortunes, as they are already under severe agrarian crisis for years together now. The Government's reply has not given any response on this very crucial point. The Committee urge the Government to take appropriate action in this regard under intimation to the Committee.

Ethical Dimensions of Transgenics

Recommendation (Para No. 8.125)

1.85 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 framework 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 Rs. 7058/- in 2000 increased to Rs. 16125/- in 2010 under rainfed conditions and from Rs. 15370/- in 2000 to Rs. 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, socio-economics, 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 discourge 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 foodgrains 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 bio-technologies *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 Bio-technology 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 micro-organisms 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 Bio-technology (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 bio-safety 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. The 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 bio-technology 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

Bio-safety 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, bio-chemistry, toxicology, etc. (**Annexure-I**). In the current, regulatory framework the safety assessment is carried out by statutory committees at three levels; institutional Bio-safety 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 polices 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 labelled 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 potentional 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), F. No. 4-5/2011-SDV, dated the 30th November, 2012]

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 biologies. 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 Family 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 Bio-safety 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 Bio-safety 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-I 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 commercialisation 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) Act, 1986 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-I 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 IAASTD 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, indebtness, 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), F. No. 4-5/2011-SDV, dated the 30th November, 2012]

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), F. No. 4-5/2011-SDV, dated the 30th November, 2012]

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, Deptt. 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-I 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 algonwith 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 in 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 create by the multiplicity of laws. The Committee note 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, accredition 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-I 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. Imparts 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-I 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-I 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 alongwith 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 foodgrains and vegetables. The rise in foodgrains and fruits and vegetable production has continued inspite 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. Inspite 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 foodgrains, 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 tones of extra foodgrains. 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 alongwith 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 and 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 kutcha/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.

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