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**COMMITTEE ON AGRICULTURE
(2011-2012)**

FIFTEENTH LOK SABHA

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

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

THIRTY SEVENTH REPORT



**LOK SABHA SECRETARIAT
NEW DELHI**

August, 2012/Shravana 1934 (Saka)

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PROSPECTS AND EFFECTS**

Presented to Lok Sabha on 09 August, 2012
Laid on the Table of Rajya Sabha on 09 August, 2012



**LOK SABHA SECRETARIAT
NEW DELHI**

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INTRODUCTION

I, the Chairman, Committee on Agriculture, having been authorized by the Committee to submit the Report on their behalf, present this Thirty-seventh Report on 'Cultivation of Genetically Modified Food Crops – Prospects and Effects'.

Taking cognizance of the serious differences of opinion amongst the various stakeholders and the controversies surrounding the cultivation of transgenic food crops, the Committee on Agriculture (2009-10) (Composition at Annexure – I) had selected this subject for detailed examination and Report to the Parliament. In view of the vastness of the Subject, the multiplicity of issues and stakeholders and the intricacies involved, the examination of the Subject could not be completed during the term of the Committee on Agriculture (2009-10). The Committee on Agriculture (2010-11) (Composition at Annexure – II), therefore, re-selected to subject to continue further, the examination. Since the examination remained inconclusive during the term of Committee on Agriculture (2010-11), the present Committee again selected the Subject to complete the unfinished task. In all 27 Sittings of the Committee lasting 60 hours and 52 minutes were held for and in connection with the examination of this Subject of considerable sensitivity and importance.

In order to elicit public opinion, a press communication was issued on 13 March, 2010 seeking views and suggestions on the Subject from the various stakeholders. 467 memoranda, most of them signed by several stakeholders were received. In all, the Committee received documents running into 14826 pages. The Committee also extensively interacted with various stakeholders including State Governments, farmers organizations, NGOs, farmers and their families, etc. during their Study Visits to the various parts of the Country during this period. The Committee on the suggestion of some stakeholders also viewed 'Poison on the Platter' a documentary on the Subject on 10 November, 2010. 50 individuals and organizations tendered Oral Evidence before the Committee. The list of individuals and organizations whose representatives tendered oral evidence before the Committee is given in Annexure - III. Verbatim record of proceedings of the Oral Evidence running into 863 pages has been kept.

The Committee wish to express their sincere thanks and gratitude to the officers of the Department of Agriculture and Cooperation and other Ministries/Departments, Organisations and individuals for furnishing the information the Committee desired in connection with the examination of the Subject and for appearing before the Committee to tender evidence.

The Report was considered and adopted by the Committee at their Sitting held on 3 August, 2012.

The Observations/Recommendations of the Committee have been printed in bold at the end of each Chapter of the Report.

New Delhi
07 August, 2012
16 Shravan, 1934 (Saka)

BASUDEB ACHARIA
Chairman,
Committee on Agriculture

COMPOSITION OF THE COMMITTEE ON AGRICULTURE (2011-12)

Shri Basudeb Acharia - Chairman

MEMBERS

Lok Sabha

2. *Shri Narayansingh Amlabe*
3. *Shri K.C. Singh 'Baba'*
4. *Shri Thangso Baite*
5. *Smt. Shruti Choudhary*
6. *Smt. Ashwamedh Devi*
7. *Shri Biren Singh Engti*
8. *Shri Anant Kumar Hegde*
9. *Shri Deepender Singh Hooda*
10. *Shri Sk. Nurul Islam*
11. *Shri Naranbhai Kachhadia*
12. *Shri Premdas*
13. *Shri Surendra Singh Nagar*
14. *Shri Devji M. Patel*
15. *Shri Vitthalbhai Hansrajbhai Radadiya*
16. *Shri Nripendra Nath Roy*
17. *Shri Jagdish Thakor*
18. *Shri Laxman Tudu*
19. *Shri D. Venugopal*
20. *Shri Hukmadeo Narayan Yadav*
21. *Shri Ramakant Yadav*

Rajya Sabha

22. *Shri Shashi Bhusan Behera*
- *23. *Shri Narendra Budania*
- *24. *Shri Satyavrat Chaturvedi*
25. *Shri A. Elavarasan*
- *26. *Shri Vinay Katiyar*
27. *Shri Mohd. Ali Khan*
28. *Shri Upendra Kushwaha*
29. *Shri Bharatsinh Prabhatsinh Parmar*
30. *Shri Rajpal Singh Saini*
31. *Shri S. Thangavelu*

* Nominated to the Committee on 04.05.2012.

COMPOSITION OF THE COMMITTEE ON AGRICULTURE (2009-10)

Shri Basudeb Acharia - **Chairman**

Lok Sabha

2. Shri Narayan Singh Amlabe
3. Shri K.C. Singh 'Baba'
4. Shri Thangso Baite
5. Shri Jayant Chaudhary
6. Smt. Shruti Choudhry
7. Smt. Ashwamedh Devi
8. Shri Biren Singh Engti
9. Smt. Paramjit Kaur Gulshan
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11. Shri Sk. Nurul Islam
12. Shri Naranbhai Kachhadia
13. Shri Surendra Singh Nagar
14. Shri Prabodh Panda
15. Shri Premdas
16. Shri Vitthalbhai Hansrajbhai Radadiya
17. Shri Nripendra Nath Roy
18. Shri Bhoopendra Singh
19. Shri Uday Singh
20. Shri Jagdish Thakor
21. Shri Hukmdeo Narayan Yadav

Rajya Sabha

- @22. Vacant
23. Shri Satyavrat Chaturvedi
24. Shri A. Elvarasan
- #25. Vacant
26. Shri Vinay Katiyar
27. Shri Mohd. Ali Khan
28. Shri M. Rajasekara Murthy
29. Shri Bharatsinh Prabhatsinh Parmar
30. Prof. M.S. Swaminathan
- *31. Smt. B. Jayashree

@ Vice Shri Narendra Budania who ceased to be a member of the Committee on his retirement from Rajya Sabha on 4 July, 2010.

Vice Shri Sharad Anantrao Joshi who ceased to be a member of the Committee on his retirement from Rajya Sabha on 4 July, 2010.

* Nominated to the Committee w.e.f. 2 July, 2010 vice Shri Khekiho Zhimomi who retired from Rajya Sabha on 2 April, 2010.

COMPOSITION OF THE COMMITTEE ON AGRICULTURE (2010-11)

Shri Basudeb Acharia – Chairman

MEMBERS

Lok Sabha

2. *Shri Narayansingh Amlabe*
3. *Shri K.C. Singh 'Baba'*
4. *Shri Thangso Baite*
5. *Shri Jayant Chaudhary*
6. *Smt. Shruti Choudhry*
7. *Smt. Ashwamedh Devi*
8. *Shri Biren Singh Engti*
9. *Smt. Paramjit Kaur Gulshan*
10. *Shri Anant Kumar Hegde*
11. *Shri Sk. Nurul Islam*
12. *Shri Naranbhai Kachhadia*
13. *Shri Surendra Singh Nagar*
14. *Shri Prabodh Panda*
15. *Shri Premdas*
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17. *Shri Nripendra Nath Roy*
18. *Shri Bhoopendra Singh*
19. *Shri Uday Singh*
20. *Shri Jagdish Thakor*
21. *Shri Hukmdeo Narayan Yadav*

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23. *Shri Narendra Budania*
24. *Shri Satyavrat Chaturvedi*
25. *Shri A. Elavarasan*
26. *Shri Vinay Katiyar*
27. *Shri Mohd. Ali Khan*
28. *Shri Upendra Kushwaha*
29. *Shri Bharatsinh Prabhatsinh Parmar*
30. *Shri Rajpal Singh Saini*
31. *Shri S. Thangavelu*

List of Organisations/Individuals who tendered

Oral Evidence before the Committee

1. Ministry of Agriculture (Department of Agriculture and Cooperation)
2. Prof. Deepak Pental - Vice – Chancellor, Delhi University, New Delhi
3. Dr. S. Nagarajan – Chairperson, Protection of Plant Varieties & Farmers’ Right Authority, New Delhi.
4. Prof. V.S. Chauhan – Director, International Centre for Genetic Engineering and Biotechnology, New Delhi
5. Dr. C.R. Bhatia – Former Secretary, Department of Biotechnology
6. Prof. A.K. Tyagi - Director, National Institute of Plant Genome Research, New Delhi
7. Dr. Rakesh Tuli – Director, National Agri-Food Biotechnology Institute, Mohali, Punjab
8. Shri Devinder Sharma - Forum for Biotechnology & Food Security, Noida
9. Dr. Ajay Parida – Executive Director, MS Swaminathan Research Foundation, Chennai
10. Dr. R.S. Paroda – Former DG, ICAR and Chairman, Trust for Advancement of Agricultural Sciences, New Delhi
11. Shri Sekhar Natarajan – Chairman, Monsanto India Limited, Mumbai
12. Shri S. Ramchandra Pillai – President, All India Kisan Sabha, Ashoka Road, New Delhi
13. Sh. K. Nageswara Rao – Vice President, All India Kishan Sabha (Ajoy Bhavan), Windsor Place
14. Sh. Samit Aich - Executive Director, Greenpeace India Limited, Bengaluru
15. Prof. N.K. Ganguly - Former DG, ICAR, Distinguished Biotech Scientist, THSTI.
16. Ms. Sunita Narain - Director, Centre for Science and Environment, New Delhi
17. Dr. Vandana Shiva – Director, Director, Research Foundation for Science, Technology and Ecology, New Delhi
18. Dr. Sagari R. Ramdas – Director, Anthra, Secundrabad, Andhra Pradesh
19. Ms. Kavitha Kuruganti – Trustee, Kheti Virasat Mission, JAITU, Faridkot, Punjab
20. Prof. G. Padmanabhan – Scientist Emeritus, Department of Biochemistry, Indian Institute of Science, Bengaluru
21. Sh. Prashant Bhushan - Advocate, Supreme Court of India, New Delhi
22. Ms. Aruna Rodrigues - Sunray Harvesters, Mhow, Madhya Pradesh
23. Sh. M. Prabhakar Rao - Chairman & Managing Director, Nuziveedu Seeds Pvt. Ltd., Hyderabad
24. Dr. Sujatha Byravan – Former Director, Council for Responsible Genetics, USA and Senior Fellow, Centre for Development of Finance, Institute for Financial Management and Research, Chennai
25. Dr. G.V. Ramanjaneyulu - Director, Centre for Sustainable Agriculture, Hyderabad
26. Dr. G.P.I. Singh - Director, Adesh Institute of Medical Sciences and Research, Bathinda

27. Dr. S. Bhaskar Reddy – Head – Agriculture, FICCI, New Delhi
28. Prof. R.N. Basu - Former Vice-Chancellor, Calcutta University
29. Prof. T.K. Bose - Former Director, Bidhan Chandra Krishi Vishwa Vidyalaya
30. Dr. Pushpa M. Bhargava, Anveshna
31. Dr. V.M. Katoch, Secretary, Department of Health Research & DG, Indian Council of Medical Research
32. Sh. Aniruddha Ramchandra Murkute - President, Bhartiya Kisan Sangh, New Delhi
33. Ministry of Health and Family Welfare (Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy)
34. Indian National Science Academy, New Delhi
35. Indian National Academy of Engineering, New Delhi
36. Indian Academy of Sciences, Bengaluru
37. National Academy of Agricultural Sciences, New Delhi
38. National Academy of Medical Sciences, New Delhi
39. Ministry of Commerce and Industry (Department of Commerce)
40. Ministry of Science and Technology (Department of Biotechnology)
41. Ministry of Science and Technology (Department for Scientific and Industrial Research and Council of Scientific and Industrial Research)
42. Ministry of Science and Technology (Department of Science of Technology)
43. Ministry of Environment and Forests
44. Food Safety and Standards Authority of India
45. Ministry of Agriculture (Department Agricultural Research and Education/ICAR)
46. Genetic Engineering Appraisal Committee
47. National Biodiversity Authority of India, Chennai
48. Ministry of Consumer Affairs, Food and Public Distribution (Department of Consumer Affairs)
49. Ministry of Consumer Affairs, Food and Public Distribution (Department of Food and Public Distribution)
50. Shri P. Sainath – Rural Affairs Editor, The Hindu

ABBREVIATIONS

GM	Genetically Modified
Bt.	Bacillus Thuringiensis
GEAC	Genetic Engineering Appraisal Committee
CBD	Convention on Biological Diversity
CPB	Cartagena Protocol on Biosafety
IAASTD	International Assessment of Agricultural Knowledge, Science and Technology for Development
GMO	Genetically Modified Organism
DBT	Department of Biotechnology
AYUSH	Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy
MT	Metric Tonne
NBA	National Biodiversity Authority of India
FSSAI	Food Safety and Standards Authority of India
DAC	Department of Agriculture and Cooperation
DARE	Department of Agricultural Research and Education
MoEF	Ministry of Environment and Forests
ICMR	Indian Council for Medical Research
ICAR	Indian Council for Agricultural Research
CSIR	Council for Scientific and Industrial Research
RCGM	Review Committee on Genetic Manipulation
FAO	Food and Agriculture Organisation
DLC	District Level Committee
SBCC	State Biotechnology Coordination Committee
IBSC	Institutional Biosafety Committee
SOP	Standard Operating Procedures
OECD	Organization for Economic Co-operation and Development
IPCC	International Plant Protection Convention
MEC	Monitoring–cum Evaluation Committee
CCMB	Centre for Cellular and Molecular Biology
DSIR	Department of Scientific and Industrial Research

CHAPTER - 1

GENESIS

(i) Introduction

1.1 India has made rapid strides in agriculture and allied sectors after independence. From a net importer of food grains the Country has not only achieved food security through domestic production, even export of several commodities is being regularly undertaken. Statistically speaking we have gone up from a production of about 50 MT of food grains in 1950 to 241 MT in 2010-11. In spite of such spectacular achievements the road to ensuring and maintaining food security in the years to come is full of challenges. A more worrying and daunting problem to be attended to with equal seriousness would be the deceleration in the availability of food grains.

1.2 The Ministry of Science and Technology (Department of Science and Technology) in their written submission to the Committee while explaining this dilemma stated that ever since domestication of crop plants ten millennia ago, man has endeavoured to improve productivity of crop plants. Advances in mineral nutrition, irrigation and plant breeding have led to series of revolutions, resulting in increased manifold crop productivity and ensuring food security to ever-increasing population, worldwide. India's population is expected to reach 1.5 billion by 2025, making food security most important social issue and food production will have to be increased considerably, to meet needs of growing population. Dwindling water and land resources will further aggravate enormity of challenge, since additional food will have to be produced on existing agricultural land or marginal soils. In addition, crop losses due to insects, pests, diseases and declining soil fertility, will worsen due to climatic conditions, which favour insect pests and disease vectors. This challenge calls for harnessing powerful tools of molecular biology and biotechnology in agriculture. Scientific and technological advances in these fields have progressed, at remarkable pace, during last decade and most compelling case of intervention of biotechnology is its capability to contribute to:

- (i) increasing crop productivity thus contributing to global food, feed and fibre security,

- (ii) lowering production costs,
- (iii) conserving biodiversity, as a land-saving technology capable of higher productivity,
- (iv) more efficient use of external inputs – for more sustainable agriculture and environment,
- (v) increasing stability of production – to lessen suffering during droughts due to abiotic and biotic stresses and
- (vi) improvement of economic and social benefits and alleviation of poverty.

(ii) Biotechnology in Agriculture and GM Food Crops

1.3 In the International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD) Report Biotechnology is defined as ‘any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for a specific use.’ In this inclusive sense biotechnology can include anything from fermentation technologies to gene splicing. It includes traditional and local knowledge and the contributions to cropping practices, selection and breeding of plants and animals made by individuals and societies for millennia. It would also include the application of tissue culture and genomic techniques and marker assisted breeding or selection to augment natural breeding.

1.4 According to IAASTD Report modern bio-technology is a term adopted by international convention to refer to biotechnological techniques for the manipulation of genetic material and the fusion of cells beyond normal breeding barriers. The most obvious example is genetic engineering to create genetically modified/genetically engineered organism (GMOs/GEOs) through ‘transgenic technology’ involving the insertion or deletion of genes.

1.5 Revolution in plant biotechnology and genomics has opened new perspectives and opportunities for plant breeders, who now apply molecular markers to assess and enhance diversity in germplasm collections, to introduce valuable traits from new sources and to identify genes that control key traits. Functional genomics provides another powerful tool for identification of such genes. The ability to introduce beneficial genes under

control of specific promoters through transgenic approaches is another stepping stone in path towards targeted crop improvement. Development and commercialization of transgenic crops, expressing wide range of agronomic traits during mid-nineties, has virtually revolutionized faced of global agriculture.

1.6 In past forty years, advances in plant breeding, water and nutrient management and control of pests and diseases has led to substantial increase in crop productivity in India. Food production will have to be doubled by 2025 to meet the needs of growing population. Furthermore, crop loss due to insect, pests and diseases has to be controlled in eco-friendly and sustainable manner. Challenges of malnutrition, enhanced production and crop diversification can only be met by better resource management and by breeding more productive, more nutritious and at the same time, less resource input demanding crops.

1.7 Amplifying further on this aspect the Report of the six Science Academies on Bt. Brinjal, which was taken on record by the Committee states that in the last century, the major increase in global food production was mainly due to the improvement in yield through the green revolution. This involved identification of gene(s) controlling agronomic traits and their introgression into local varieties of staple crops like rice and wheat. At the beginning of the 21st century, such efforts could help produce food enough to feed 6 billion people. The number of people is likely to increase to 9 billion by 2050. This will necessitate a mega-jump in productivity, with dwindling land reserves, scarce water and nitrogen and daunting challenges of climate change. Malnutrition of a billion people also needs to be addressed urgently for a healthy world. The present growth of agricultural productivity, at the rate of about 2% per year, is much lower in comparison to the 3% growth required for food security. The food grain production in India has increased four times over the last five decades. But, in India also, the yield of major food grain crops is reaching a plateau although its population continues to rise and is expected to reach 1.5 billion people in 2050. Also, 27% of world's undernourished people live in India. This will require an increase of more than 50% in agricultural production and calls for judicious use of agricultural biotechnology.

(iii) Advances made in Plant bio-technology

1.8 According to the Department of Science and Technology, plant biotechnology has made significant strides in past twenty years, encompassing developments in plant molecular biology and genetic engineering. Variety of traits has been introduced in plant species which include:

- Herbicide resistance
- Pest resistance
- Viral resistance
- Slow-ripening
- Fungal and bacterial resistance
- Quality improvement (protein and oil)
- Value addition (Vitamins, micro-and macro-elements)

1.9 First commercial GM food crop variety 'FlavrSavr' tomato, released in 1994, was engineered for slow-ripening character. List of GM food crop species that have been commercialized in past fifteen years is given below:

- Herbicide resistance:- Corn, Soybean, rice, corn, and Sugar beet
- Insect Pest resistance:- Corn, rice tomato and potato
- Viral resistance:- Papaya, Squash and potato
- Slow-ripening and softening- Tomato and melon
- Improved oil quality -Canola and soybean
- Male sterility - Canola and corn

1.10 GM food crops along with other GM non-food crops were grown by farmers in 134 million hectares, in 2009 in 25 countries.

(iv) Global Scenario of GM Crops

1.11 The Department of Science and Technology also informed the Committee that due to consistent and substantial economic, environmental and welfare benefits of GM crops, 14 million farmers, including small and resource-poor, planted 134 million hectare of GM crops in 2009, across 25 countries during fourteenth year of commercialization of GM crops with share of developing countries at 46%. Out of 25 countries growing transgenic crops, countries growing transgenic crops in more than one million hectare, include USA, Brazil, Argentina, India, Canada, China,

Paraguay and South Africa. India grows transgenic Bt. Cotton in 8.4 million hectares. Six EU countries also planted 94,750 hectares of Bt. Maize in 2009. Major transgenic crops include soybean, maize, cotton, and canola; and major engineered traits include insect resistance, herbicide tolerance and virus resistance. Thus GM crops can contribute to major challenges facing global society such as food security, sustainability, alleviation of poverty and hunger, and help mitigate some challenges associated with climate change.

(v) Prospects and Effects of GM Food Crops

1.12 About the prospects and effects of transgenic food crops the Department of Science and Technology were of the view that conventional technologies of agriculture are inadequate to meet formidable challenges of feeding burgeoning population with limited land and water resources. In addition, adverse effects of global climate change impose new limitations on crop production. Some limitations of conventional breeding are:

- (a) Lack of germplasm resources for some of the major pests and pathogens of crops,
- (b) New plant types evolved for higher productivity are more vulnerable to pests and diseases,
- (c) Problems in sourcing genes from wild relatives,
- (d) Lack of nutritional qualities in major cereals crops,
- (e) Methodology of plant breeding is based on phenotypic selection and,
- (f) Plant-environment interactions affect selection process. Advances in modern biology, especially biotechnology, offer many advantages over traditional techniques of plant breeding in major food crops. In addition to enhanced levels of crop production, human society can realize benefits of food, feed and fibre security, low production costs, conservation of biodiversity, more efficient use of external inputs for sustainable agriculture and environment, improvement of economic and social benefits and poverty alleviation.

1.13 Shri S. Ramchandra Pillai, President of All India Kisan Sabha (Ashoka Road) which is one of the largest farmers' organization in India while being technology in the agriculture sector a precautionary approach during his Oral Evidence on 19 October, 2010 said:

"I am President of the All India Kisan Sabha. I am for making use of the achievements of science and technology in agriculture as in the case of other areas. Science and Technology has made great progress in the area of bio-technology and genetic engineering. There are possibilities for increasing productivity and production in agriculture by making use of genetically modified crops. But there are many risks involved in the use of genetically modified crops. The risks are much more in the case of food grains or food crops rather than in the case of non-food crops. So, all appropriate measures should be taken to avoid all ill effects of the genetically modified crops. Very rigorous bio-diversity tests should be conducted to ensure that the genetically modified crops should not cause any ill effects on human life, other plant and animal life and also on the overall environment. These tests should be conducted by an independent and competent authority.

1.14 Strongly advocating public sector intervention he further stated :

"The experience of the performance of the private sector in this area is totally disappointing. The multinational companies charge exorbitant rates for the genetically modified crops. This is the experience in the case of Bt. Cotton that because of the patent regime they hold their monopoly power over the genetic resources; because of the high rates for the genetically modified seeds, the common peasants do not get benefits from the use of genetically modified crops. Profit motive is the chief driving force of the activities of the private sector in this area. So, because of their drive for more profits, they may fail even to give appropriate importance to the safety measures. They may also not give adequate importance to harness the pro-poor features of the use of bio-technology to find solution to the problems of food security, malnutrition, poverty, unemployment and backwardness, etc.

Taking all these factors into consideration, I argue that the State should give appropriate attention and importance to the development of genetically modified crops. The Indian institutions have not made adequate advances in using this technology for meeting the national needs. There are possibilities and need for developing salinity resistant, drought resistant and flood resistant variety of crops. Efforts also should be made to produce food grains with enhanced level of micro nutrients.”

1.15 He further added:

“What I would argue is that it should be verified. This is a new area of development. Certainly we should make use of this new area of development for increasing productivity and production in agriculture. When we use a new technology and a new achievement of science, yes, there may be risks. We cannot take a position that all risks should be absolutely avoided. It may not be possible. But this is a new area of development, and when we use this new area of development, we should ensure the ill-effects of this new technology should not make any difficulties to other plant life, animal life and human life. So, it should be tested. I am only arguing for appropriate tests in this regard..... There are reports in Maharashtra; there are reports in Andhra Pradesh that the production rate is not commensurate to the claims that they are making. There are also reports that new pests are coming in and pests are affecting the BT cotton. The producers of the BT cotton seeds themselves admitted it and they are now talking about new generation of seeds.”

1.16 When the Committee took-up these issues with the Chairman of Monsanto India Ltd. during his Oral Evidence on the same day (19 October, 2010) he informed them:

“Firstly, your question was on the need of the farmers to depend on us for a seed or a technology or a product. In India, Bt cotton technology is the most competitive in the world. There are six technologies approved by the Government for Bt cotton in India as

against one in Brazil, two in Australia, two in US, one in South Africa and two in China. Also, our seeds are licensed to 33 Indian seed companies. Around 80 Indian seed companies are marketing and selling Bollgard cotton to Indian farmers. The beauty of GM crops is such that even as a technology provider and the owner of the technology, my market share in Bt cotton is only six per cent. So, I am irrelevant player as far as Bt cotton is concerned. Also, the largest player in India is Nuziveedu seeds which is 20 per cent market share. There are a lot of Indian companies selling Rasi seeds, Mahyco, Namdhari, Vibha, Ankur, Krishi dhan, and others.”

1.17 Clarifying on the issue of Bt. Cotton seed pricing he stated:

“The next important question that you had asked was about technology cost. Every company that introduces a technology is always very careful about pricing. It is because you cannot get the prices wrong as farmers have a choice. If you get the pricing wrong, people are not going to buy it. When we did the initial studies for Bt. cotton before 2006, we found that farmers used to spend Rs. 3,700 for seed and bollworm control which Bt. cotton does. We priced it at less than half for him as the cost, giving him more than sixty per cent. Even after the change in the price as mandated by the Government, the price was Rs. 750. One of the important things which need to be understood is that for every acre, the Bt. cotton farmer saves around Rs. 3,000 on account of seeds and insecticides, plus he saves on the yield, due to increased yield. So, on an average Rs. 10,000 is the gain. In fact, the farmers of Bt. cotton earn Rs. 20,000 crore of additional income from Bt. cotton. That is why it caught up so very fast and has become so popular. Also, in the first four years even when we had the higher price – in those years of early adoption – the farmers never felt the product was costly enough. That is why the demand went up from 72,000 packets to 33 lakh packets.

1.18 Queried as why then there was need for judicial intervention to bring down Bt. Cotton seed prices, he admitted:

“The royalty at that point of time was Rs. 700 per packet to MMB. I think when competition comes in, as the volume goes up, the

prices have to come down because that is the only way in which economics will work. It is unfortunate that the intervention has been made. I think it is also an important lesson learnt by the companies like us who have been operating for sixty years in India. We have to work with the State Governments to get the pricing right. We have been selling seeds in all markets in all parts of the country. Even now we are working with the Governments in almost seven States. We acknowledge the fact that we should have taken that into account as we had started off. But the pricing was right because for Rs. 10,000 benefit, we used to charge around Rs. 700 for the technology.”

1.19 GM crops are released in environment only after stringent evaluation of food/biosafety protocols/issues. To have a holistic and comprehensive view on the pros and cons of application of bio-technology on agricultural sector the Committee took on record IAASTD Report as it is an authentic research document prepared after painstaking effort of four years by 400 scientists from all over the world. India is a signatory to this Report which has been extensively quoted in a subsequent Chapter of the present Report of the Committee. Amongst various recommendations germane to all spheres of agriculture and allied activities and sectors, the following recommendations on bio-technology caught the attention of the Committee in all context of their present examination:

- Conventional biotechnologies, such as breeding techniques, tissue culture, cultivation practices and fermentation are readily accepted and used. Between 1950 and 1980, prior to the development GMOs, modern varieties of wheat may have increased yields up to 33% even in the absence of fertilizer. Even modern biotechnologies used in containment have been widely adopted. For example, the industrial enzyme market reached US\$1.5 billion in 2000. Biotechnologies in general have made profound contributions that continue to be relevant to both big and small farmers and are fundamental to capturing any advances derived from modern biotechnologies and related nanotechnologies. For example, plant breeding is

fundamental to developing locally adapted plants whether or not they are GMOs. These biotechnologies continue to be widely practiced by farmers because they were developed at the local level of understanding and are supported by local research.

- Much more controversial is the application of modern biotechnology outside containment, such as the use of GM crops. The controversy over modern biotechnology outside of containment includes technical, social, legal, cultural and economic arguments. The three most discussed issues on biotechnology in the IAASTD concerned:
 - Lingering doubts about the adequacy of efficacy and safety testing, or regulatory frameworks for testing GMOs ;
 - Suitability of GMOs for addressing the needs of most farmers while not harming others, at least within some existing IPR and liability frameworks;
 - Ability of modern biotechnology to make significant contributions to the resilience of small and subsistence agricultural systems.
- The pool of evidence of the sustainability and productivity of GMOs in different settings is relatively anecdotal, and the findings from different contexts are variable, allowing proponents and critics to hold entrenched positions about their present and potential value. Some regions report increases in some crops and positive financial returns have been reported for GM cotton in studies including South Africa, Argentina, China, India and Mexico. In contrast, the US and Argentina may have slight yield declines in soybeans, and also for maize in the US. Studies on GMOs have also shown the potential for decreased insecticide use, while others show increasing herbicide use. It is unclear whether detected benefits will extend to most agroecosystems or be sustained in the long term as resistances develop to herbicides and insecticides.
- Biotechnology in general, and modern biotechnology in particular, creates both costs and benefits, depending on how it is incorporated into societies and ecosystems and whether there is the will to

fairly share benefits as well as costs. For example, the use of modern plant varieties has raised grain yields in most parts of the world, but sometimes at the expense of reducing biodiversity or access to traditional foods. Neither costs nor benefits are currently perceived to be equally shared, with the poor tending to receive more of the costs than the benefits.

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

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.

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..

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, moreso, 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.

CHAPTER - II

PRESENT REGULATORY MECHANISM

(i) Rules and Regulations

2.1 The Genetically Engineering Appraisal Committee previously known as Genetic Engineering Approval Committee (GEAC) is the apex regulatory body for genetically engineered organisms and their products in India. GEAC when asked about the regulatory framework in place in the Country to regulate the activities involving and relating to the use of genetically engineered organisms, their products, etc. informed the Committee that Genetically Modified Organisms (GMOs) and products thereof including GM crops are regulated products in India 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 through their Notification No. 621 in Official Gazette of Government of India on December 5, 1989 under the provisions of the 'Environment (Protection) Act', 1986 with a view 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.

2.2 These rules and regulations commonly referred as 'Rules 1989' cover areas of research, as well as large scale applications of GMOs and their products. These rules and regulations are implemented by MoEF, DBT and State Governments.

2.3 About the procedure GEAC informed the Committee that the development and commercialization of a genetically engineered crop can be broadly categorized into four stages namely laboratory and greenhouse experiment, open field trials for generation of biosafety data, commercialization and market approval with large scale production. In view of various concerns related to the safety of GE crops extensive evaluation and regulatory approval process takes place before any GE plant is introduced for commercial cultivation. This includes generation and documentation of relevant biosafety information/data and its elaborate analysis to ensure food, feed and environmental safety.

(ii) Constituents

2.4 The Rules 1989 also define the competent authorities and composition of such authorities for handling of various aspects of the Rules. Presently there are six competent authorities. The mandate of the six Committees notified under Rules 1989 is as follows:

- **Recombinant DNA Advisory Committee (RDAC):** The functions of RDAC are of an advisory nature and involve review of developments in biotechnology at national and international levels and recommend suitable and appropriate safety regulations for India in recombinant research, use and applications from time to time.
- **Review Committee on Genetic Manipulation (RCGM):** Established under the DBT, its functions are to monitor the safety related aspects in respect of on-going research projects and activities (including small scale field trials) and bring out manuals and guidelines specifying procedure for regulatory process with respect to activities involving genetically engineered organisms in research, use and applications including industry with a view to ensure environmental safety.
- **Genetic Engineering Appraisal Committee (GEAC):** Established under MoEF, GEAC is the apex body to accord approval of activities involving large scale use of hazardous microorganisms and recombinants in research and industrial production from the environmental angle. GEAC is also responsible for granting approvals relating to release of genetically engineered organisms and products into the environment including experimental field trials (Biosafety Research Level trial-I and II known as BRL-I and BRL-II).
- **State Biotechnology Coordination Committees (SBCC's):** SBC has a major role in monitoring. It also has powers to inspect, investigate and take punitive action in case of violations of statutory provisions.
- **District Level Committees (DLCs):** DLC has a major role in monitoring the safety regulations in installations engaged in the

use of genetically modified organisms/hazardous microorganisms and its applications in the environment.

- **Institutional Biosafety Committee (IBSC):** IBSC is established under the institution engaged in GMO research to oversee such research and to interface with the RCGM in regulating it.

(iii) Bio-safety Guidelines

2.5 Rules 1989 is supported by the following bio-safety guidelines which are regularly updated keeping in tune with the international practices and developments in biotechnology:

- Recombinant DNA Safety Guidelines, 1990
- Revised Guidelines for Research in Transgenic Plants and Guidelines for Toxicity and Allergenicity Evaluation, 1998
- Guidelines and SOPs for the conduct of Confined Field Trials of Transgenic Plants, 2008
- Guidelines for the Safety Assessment of GM Foods, 2008
- Protocol for Safety Assessment of Genetically Engineered Plants /crops, 2008.

2.6 In 1990, the DBT formulated the 'Recombinant DNA Safety Guidelines'. These guidelines cover genetically engineered organisms, genetic transformation of green plants and animals, rDNA technology in vaccine development, and large scale production and deliberate/accidental release of organisms, plants, animals, and products derived by rDNA technology. The guidelines also deal with import and shipment of genetically modified plants for research purposes. DBT revised these guidelines to accommodate the safe handling of GMOs in research applications and technology transfer in 1994. 'Revised Guidelines for Research in Transgenic Plants and Guidelines for Toxicity and Allergenicity Evaluation, 1998' included considerations to be followed for conducting limited field experiments of GE crops i.e. strip trials, multi location research trials and large scale trials on the lines of varietal testing in plant breeding. These also include the guidelines for toxicity and allergenicity of transgenic seeds, plants and plant parts.

2.7 GEAC further informed the Committee that with the successful adoption of Bt cotton in the country, the research and development efforts received a momentum and applications for field trials of several different crops with new genes/events were submitted to regulatory agencies. DBT and MoEF initiated an exercise to provide detailed guidance on the conduct of confined field trials so as to strengthen the management and monitoring mechanism. A series of documents have been prepared which include 'Guidelines and SOPs for the conduct of Confined Field Trials of Transgenic Plant, 2008'. The objective of the guidelines is to ensure that confined field trials are conducted under appropriately controlled conditions and in workable and efficient manner. A new application format has been designed to seek detailed information at the beginning of the process itself. A glossary of terms has been prepared to ensure the uniform usage of various terms. Four crop specific biology documents for Cotton, Maize, Okra and Rice have also been prepared. To address health safety issues 'Guidelines for the Safety Assessment of GM Foods, 2008' formulated by Indian Council for Medical Research (ICMR) and 'Protocol for Safety Assessment of Genetically Engineered Plants / crops, 2008' formulated by DBT have also been adopted by the RCGM/GEAC.

2.8 These guidelines cover areas of recombinant DNA research on plants including the development of transgenic plants and their growth in soil for molecular and field evaluation. Genetic engineering experiments on plants have been grouped under three categories based on risk factor. The guidelines include complete design of a contained green house for conducting research with transgenic plants. Besides, it provides the basis for generating food safety information on transgenic plants and plant parts

2.9 Recognizing that regulation is a dynamic process, these guidelines and protocols are being regularly reviewed / updated through a consultative approach and following the international norms prescribed by the Organization for Economic Co-operation and Development (OECD), CODEX Alimentarius Commission and International Plant Protection Convention (IPPC).

2.10 When asked about the Laws, Rules and Guidelines pertaining to and having a bearing on the Subject; the adequacy or otherwise of the extant

Laws, Rules and Guidelines and suggestions of GEAC for any additional provisions safeguards and measures it was submitted that the following Laws, Rules and Guidelines pertained to the subject matter:

- The Environment (Protection) Act, 1986
- The 'Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro Organisms/ Genetically Engineered Organisms or Cells, 1989
- Recombinant DNA Safety Guidelines, 1990 & 1994
- Revised Guidelines for Research in Transgenic Plants and Guidelines for Toxicity and Allergenicity Evaluation, 1998
- Guidelines and SOPs for the conduct of Confined Field Trials of Transgenic Plant, 2008
- Guidelines for the Safety Assessment of GM Foods, 2008
- Protocol for Safety Assessment of Genetically Engineered Plants / crops, 2008.

2.11 No comments were offered on the remaining two queries of the Committee.

(iv) Procedure

2.12 The Government of India is following a policy of case by case approval of GM crops. Any company involved in the development of GM crops has to undertake extensive biosafety assessment which includes environmental safety assessment as well as food and feed safety even if it has been approved for commercial cultivation in other countries. The environmental safety assessment includes studies on pollen escape out-crossing, aggressiveness and weediness, effect of the gene on non-target organisms, presence of the protein in soil and its effect on soil micro-flora, confirmation of the absence of Terminator Gene and baseline susceptibility studies. The food and feed safety assessment studies include allergenicity and toxicological studies dietary exposure and substantial equivalence using test protocols such as: protein thermal stability, pepsin digestibility, molecular characterization, compositional assessment, acute oral toxicity (mice or rat), 90-day sub-chronic rat feeding, and livestock feeding (case by case basis).

2.13 For the development of GM crops at the laboratory stage, confined multi-location trials for generation of biosafety data known as Biosafety Research Trials – I and Biosafety Research Trials-II (BRL-I and BRL-II) require prior approval of the RCGM and the GEAC set up under the Rules, 1989. The compliance of the regulatory procedures during GM crop field trials is monitored by the Monitoring–cum Evaluation Committee (MEC). The agronomic performance of the GM crops is also evaluated under the Indian Council of Agriculture & Research testing system. The GEAC takes into consideration the findings of the biosafety and agronomic studies as well as recommendations of the RCGM, ICAR and MEC before according approval for environmental release. Only those transgenic crops which are found to be safe for human consumption as well as the environment are approved for commercial release.

2.14 The regulatory and control mechanism prescribed by the GEAC during field trials of GM crops to minimize contamination due to gene flow include:

- (i) Maintaining a crop specific isolation distance from the periphery of the experimental site to other sexually compatible rice fields as prescribed under the Indian Minimum Seed Certification Standards.
- (ii) Biological barrier by planting border rows all around the experimental plot. The width of the border row would vary on a case to case basis.
- (iii) Maintaining a physical barrier around the experimental plot to keep away unauthorized persons.
- (iv) Submission of a validated event specific test protocol of 0.01% before undertaking the trials.
- (v) Designating a lead scientist who would be responsible for conducting the trial.
- (vi) Field trials (BRL-1) for new events are not permitted in the farmers' field. BRL-1 should be undertaken by the Companies/Institutions either in their own premises, research farms, long-leased land (minimum of three years) or at the SAU/ICAR institutions.

- (vii) Event selection for new events should be undertaken by the Company in their own premises/ research farms.
- (viii) Post harvest restrictions include (a) burning of the border rows and left over plants and plant parts from the entire experimental plot; (b) the trials sites should not be used for planting the same plant species and (c) the site should be monitored for volunteers and rendered non-viable before flowering.

2.15 Field trials form an integral part of research and development and serve multiple purposes as under:

- (i) For the plant breeder, they provide the first opportunity to evaluate the agronomic potential of novel-plant trait combinations in open environment which is not possible in contained conditions of greenhouse.
- (ii) It is necessary to measure the level of protein expression from any newly introduced genes in the plant tissues to assess its efficacy in the open environment and impact on the target and non target organisms consuming the genetically modified plant.
- (iii) It allows the production of sufficient quantities of plant material for use in livestock feeding studies/trials and to conduct compositional analyses, which are necessary for human food safety assessment.
- (iv) Such trials are also necessary to collect the agronomic and ecological data required to complete the environment safety assessment of genetically modified plant.

2.16 To ascertain the efficacy of the extant system in general and role of GEAC as the apex regulator in particular, the Committee sought the views of Dr. P.M. Bhargava, founder Director of Centre for Cellular and Molecular Biology, Hyderabad and currently the Supreme Court nominee on GEAC. The witness informed the Committee during his Oral Evidence on 22 December, 2010:

“Actually in our country about half a dozen tests have so far been done on Bt. cotton, which is the only GM product released in the environment or others that are in the pipeline, like Bt. brinjal. Even these tests have been done either by the company itself or by an accredited laboratory, but on the samples given by the company. In India, we are dealing largely with Monsanto. Please allow me to say that if we were to make a list of unethical companies in all areas of industry around the world, the Monsanto will be the number one. I have given you some material which establishes that. It is known for bribing, for example, in Indonesia. It is known for hiding data, falsifying data or presenting wrong data and so on. All these charges that I am making have been validated over and over again. I have made them publicly also. The Monsanto is free to take me to court for defamation, but they have not done that so far. Not only me, but these charges have been made by a large number of people around the world. So, there is no doubt in my mind that taking these considerations alone in mind, we have to be extremely careful. I am not suggesting or asking that we put a permanent ban on release of all GM organisms. All that I am saying is that they must be adequately tested and we have defined very clearly what adequate testing is.”

2.17 Elaborating further the witness added:

“It is true that the net yield of cotton after we introduced Bt. Cotton in India has increased, perhaps not to the extent it is claimed but there is no question, it has increased substantially. However, we have to recognise the following three facts. First is, when we engage in such an activity, it must be sustainable. We already have reports of resistance to Bt. Cotton to the pests that it is supposed to kill in Gujarat. It is documented in Shri Jairam Ramesh’s report, I have a copy of it. I have also talked to Gujarat farmers. In Punjab, now instead of the pests that normally attacks cotton (the Boll worm) now the mini-bug has come which is resistant to Bt. Cotton. Punjab farmers now say that the yields have stabilised. All this was predictable. Then we also have worrying cases in Andhra Pradesh. I have all the documentation here of several thousand cattle dying after eating the

remnants of the Bt. Cotton plant after the cotton was harvested over two years. Now the Andhra Government has issued a dictum that farmers should not allow their cattle to be fed on the remnants of these plants which could be toxic. In Gujarat, there is also a report that the soil after it has been used for Bt. Cotton for several years becomes incapable of sustaining any other crop possibly because of dehydration and loss of micro-nutrients. So, to the question that we had asked right in the beginning, whether it is going to be sustainable, the answer is no.”

2.18 In response to the concerns of the Committee about human health, the witness stated:

“We refused to do chronic toxicity studies on GM crops in this country. Why? They are scared that if these studies were to be done, they will not be able to market their products. Our nation’s health is being taken to ransom; we must not allow that. When Bt. Cotton came into the market, about that time, Dr. Raj Paroda was the DG of ICAR, a very old friend of mine and Shri Mashelkar was the DG of CSIR; I said to both of them that why do not you together set up a lab in which we can do all the necessary tests for GM crops. I also wrote an article at that time in Economic and Political Weekly; this was before I was nominated by the Supreme Court on the GEAC. I did not understand why they were so reluctant to set up a lab where all these tests can be done so that we do not need to rely on the company for doing the tests. Now, I understand that because they were under pressure not to set up a lab, can you believe that a country like India with all this technological advancements, does not have a lab of our own where we can do all these tests. I gave a proposal when I became a member of the GEAC, saying that this lab should be set up. I gave the whole plan, I have set up several institutions, if I may say so, I set up the CCMB, I set up Sun Pharma Advanced Research Centre in industry. And I have set up other institutions. We know what goes into making an institution. I gave them (GEAC) within seven days, an entire plan of setting up an institution. It has been put into a spin by the GEAC. They do not want to set it up. If we had a lab of our own,

believe me, Bt. Cotton would never have been allowed. Then, we would have forced the Government to do all the tests. Today we do not have a lab of our own. The whole nation does not have a lab where all the required tests could be done on GM organisms.”

2.19 To a pointed query regarding the role of GEAC as the apex regulator of GMOs and related matters the witness replied:

“When Bt cotton was introduced, people were not aware. There was lack of awareness. As I mentioned to you, it was introduced surreptitiously. The nation did not even know that Bt cotton was being tried. As I said, there was a dinner party which I attended; if I had not attended this dinner party in a five star hotel in Hyderabad, the nation probably would not have known for another few years that Bt cotton was being tried in the country. The world-wide information that we have on GM crops also did not exist.

As far as Bt brinjal is concerned, there is new awareness. People understand what it is all about. Large amount of literature has appeared on it. If I may again say so, I became the nominee of the Supreme Court on this Committee and, therefore, I also spent a lot more time than I would have spent otherwise on this matter. I carefully looked at the Report of the Expert Committee Two (EC-II) which recommended the release of Bt brinjal and found that it was a third-rate scientific report. It is not just my opinion. I have sent you material from other people’s opinion. In the document of Shri Jairam Ramesh, several critiques of this Report have been mentioned. At that time the kind of information that we today have was not there. That is what makes it even more suspicious.

Given this information, to come up with that Report on the basis of which the Genetic Engineering Approval Committee hurriedly approved Bt brinjal on 14th October, 2009, was un-understandable. That Report was perhaps written by a PRO of a company as it was not a scientific report.

I have documented that Arjula Reddy, the Chairman of the Committee that wrote that Report, is the Vice Chancellor of one of the universities in my State of Andhra Pradesh. I have known him since

the beginning of his career. He called me one day and told me that this is a confidential conversation when I said: "I would keep it confidential unless a situation arises when I morally feel that conversation may be made public so, please go ahead. If there is anything that you do not want to tell me, feel free not to tell me". He said: "No, I want to tell you. Tests that you have said should be done, which should have been done, have not been done on Bt brinjal, and even the tests that have been done have been done badly". Imagine, this is the Chairman of the Committee calling me and saying to me. And he said: "I am under pressure. I have had calls from industry, from the Genetic Engineering Approval Committee and from the Minister". I did not ask him which Minister. So, I do not know that. He asked me: "What shall I do?" I said: "Follow your conscience".

I must say that after this conversation, I felt that his Committee is not going to approve Bt. brinjal. On the 14th October, 2009, a Wednesday, a GEAC meeting was to be held. When I went to my office in Hyderabad on the 12th October, Monday, my administrator said that a 108 page of EC-II has just come on the e-mail. I looked at the report and said that tonight I will have a look at it because Monday was a very busy day for me. At two o'clock on the night of that Monday I looked at the report cursorily. I have been the editor of many national and international scientific journals. One thing we learn is to pick holes very quickly and I said: "My God, it is a terrible report". I did not get time to go through it and so I said at this meeting to give us one month to go through this report but they were not even prepared to do that and the report was approved on the 14th October. Later on, we commented on it and those comments are with you. It is an amazingly bad report. I do not understand how a group of scientists in 2010 can write such an obviously un-authentic and scientifically irrelevant and poor report. It is not my opinion. Every sensible scientist around the world has said exactly the same thing.

There are simple arithmetical errors in the Report; errors of addition. Things are said in the report which are not there in the original documentation that I have with me here on Bt. brinjal. So, you contradict your own data because it suits you to contradict it at that moment."

2.20 The witness summing up his views on the scientific merits of GEAC functioning stated:

“May I also mention to you that brinjal has alkaloids in it – two major and two minor? Alkaloids are generally toxic. The two major alkaloids’ level in brinjal is just about what man can tolerate. In Bt. brinjal, one of these alkaloids increases by 30 per cent. This is the primary data of Monsanto which available on the net. But EC-II Report, on the basis of which Bt. brinjal was cleared by GEAC on 14.10.2009, says that there is no difference. Now this difference of 30 per cent is a lot of difference. Then, it has two minor alkaloids which are highly toxic. There, even if there is an increase of 20 per cent, it would mean that brinjal becomes toxic. जहाँ तक मुझे मालूम है आप शायद मुझे सही कर सकते हैं। हमारे देश में और अन्य जगह बच्चों को बैंगन नहीं दिया जाता है। उसकी वजह यही है कि उसमें टॉक्सिन होता है। Since it has these toxic alkaloids, should they not have looked at these minor alkaloids before giving approval? They have not done that.”

(v) Renaming of GEAC

2.21 The Genetic Engineering Approval Committee was renamed Genetic Engineering Appraisal Committee in 2010. When asked about changes if any in its mandate, status, role and responsibilities after the renaming, it was submitted that the Genetic Engineering Approval Committee (GEAC) was established by the MoEF under Section 4 (4) of Rules 1989. Apart from according approval of activities involving large scale use of hazardous microorganisms and recombinants in research and industrial production from the environmental angle, the GEAC is also responsible for approval of proposals relating to release of genetically engineered organisms and products into the environment, including experimental field trials (BRL-I and BRL-II).

2.22 MoEF had organized public consultation on Bt Brinjal at seven locations during January-February 2010. The public consultations were chaired by the former Minister for Environment & Forests (I/C), Shri Jairam Ramesh himself. In that consultation, one of the points which came was that when it

is called Genetically Engineered Approval Committee then it creates an impression that its job is to give the "Approval". Therefore, the change in name was to suggest that it is going to appraise the safety of the genetically modified organism. Accordingly, MoEF issued a Notification No. GSR 613 (E) dated 16 July 2010 changing the name of the GEAC to Genetic Engineering Appraisal Committee. There is no change in the mandate after change in name from Genetic Engineering Approval Committee to Genetic Engineering Appraisal Committee.

2.23 Asked further about the role envisaged for GEAC as far as regulation of activities involving and relating to the use of genetically engineered organisms, the products, etc. in the Country are concerned it was stated that the role and responsibility of GEAC is to address only biosafety issues (both environment and health safety) before according approval for environmental release. The GEAC also has the powers to prohibit, revoke, supervise and take punitive action in case of non compliance, furnishing of wrong information or in case of any damage to the environment.

2.24 The GEAC has no role in policy matters related to research and development of GM crops, food security, pricing of GM seeds, commercialization of GM crops and labeling for consumer awareness.

(vi) Role of Ministry of Environment and Forests

2.25 The MoEF (nodal Ministry of GEAC) perception about itself in so far as research into the effects of genetically modified/transgenic crops/edible commodities on bio-diversity, bio-safety, environment, human health, flora and fauna are concerned is that MoEF calls for and also support research into the effects of GM/transgenic crops on biodiversity, biosafety and environment, both as part of pre approval evaluation and post release surveillance. During the course of the safety assessment process of GM crops, the project components are asked to undertake research and generate data on specific effects on case by case basis.

2.26 For example in case of Bt brinjal evaluation, Indian Institute of Vegetable Research, Varanasi was requested to undertake crossability

studies with the related species for two years to understand effect of Bt brinjal on diverse flora of brinjal existing in the country. Similarly as part of the post approval surveillance, Central Institute of Cotton Research, Nagpur has been identified as the agency for studying the development of insect resistance to Bt gene in the target pest across the cotton growing areas. The Ministry is also providing financial support to Central Institute of Cotton Research (CICR) to monitor the baseline susceptibility of Bt gene in bollworms as part of post release surveillance of Bt cotton since 2002.

2.27 Further, the Ministry has schemes and programs to support projects for evolving regulatory guidelines and methodology to assist in evaluating the impact of GM crops on biodiversity, flora and fauna etc. . As part of this initiative, MoEF jointly with DBT has developed (i) Guidelines and SOPs for the conduct of Confined Field Trials of Transgenic Plant, 2008; (ii) Biology documents for five crops namely Cotton, Rice, Okra, Brinjal and Maize; (III) Guidance document on information /data to be generated during Biosafety Research Level trials of Genetically Engineered Crops.

2.28 The safety assessment of Genetically Modified Crops/Commodities with regards to human health is generally on the following aspects:

- (a) direct health effects (toxicity);
- (b) tendency to provide allergic reaction (allergenicity);
- (c) specific components thought to have nutritional or toxic properties;
- (d) the stability of the inserted gene;
- (e) nutritional effect associated with genetic modification; and
- (f) any unintended effects which could result from the gene Insertion.

2.29 The Committee, therefore, asked GEAC as to in how many cases had it performed / contributed /assisted such assessments, if any, In the context of Genetically Modified/transgenic Crops /Commodities introduced /intended for introduction in the Country at various stages of their trials and launch and the results of their such endeavours.

2.30 In response they were informed that the GEAC does not directly perform studies on safety assessment. As per the requirements of the biosafety guidelines, the applicants are required to generate data on food

and environmental safety including (a) to (f) above in the recognized public and private sector laboratories so as to submit the information to RCGM and GEAC. Accordingly the GEAC is involved in the review of the biosafety data submitted by the applicants. Minutes of the GEAC are regularly posted on the MoEF website. Biosafety data submitted by the applicant is also posted on the Ministry's website (<http://moef.nic.in/index.php>) for inviting comments from concerned stakeholders before a final decision on environmental release is taken.

2.31 As of date the GEAC has evaluated the efficacy and biosafety of Bt cotton and Bt brinjal which has been conducted as per the biosafety guidelines under the Rules 1989. The results of the various studies indicate that (i) the insect resistant trait is stably integrated in the crop genome and there is no likely evidence of crop instability, (ii) the products are safe for environmental release both from the health and environmental angle. Reports and findings of the study are available on the MoEF website.

2.32 It was also stated that the practice for data generation by the applicant are in line with the national and international norms followed in case of other products such as pharmaceuticals. When the same query was put to the MoEF, they seconded the version of GEAC. During the Oral Evidence on 28 September, 2010 when director, National Institute of Plant Genome Research was asked to clarify in the matter, he stated:

“On the whole I defend the technology and approach of the GEAC. I agree that most of these tests, particularly in the beginning when we learn about it should be done by the third party rather than by those who are involved parties. Because of that, doubts will arise and it is true that in this case some of the tests have been done by the involved parties. Although at the same time, tests have also been done by State Agricultural Universities or private paid industries to which these tests were outsourced. This requires strengthening of infrastructure so that we are able to provide an intervention from the third party. But GEAC regulations at that point did not forbid those tests to be done by a involved party and therefore, those tests up to that level were done by this party and were found to be satisfactory. This GEAC not only includes scientists. At one time I have also worked

as a Member of GEAC and it also involves other people along with those from agriculture, molecular biology and from protein area and so it is a large panel that has been constituted. That is my view about the approach of GEAC.”

2.33 Asked further about the stand of the Ministry before the competent authority with regard to introduction/field trials/cultivation of GM/transgenic crops in the Country during each of the last five years and the extent to which the stand of the Ministry has been accepted by the competent authority while deciding upon each of these cases, the Ministry stated that the specific views of the Ministry are not solicited by the competent authority (*viz.* GEAC in the instant case) as it involves case by case safety assessment and is regulated under a legal frame work. During the last 5 years, the GEAC had recommended open field trials of various GM crops with new genes/events.

2.34 All field trials are monitored by designated monitoring teams constituted for the purpose by the RCGM/GEAC. Status of GM crops approved for field trials by RCGM/GEAC from 2007 onwards is at **Annexure-I**. There are three stages of trials, namely:

- (i) Event selection trials: Preliminary trials after green-house testing for confirmation of efficacy and gene stability which allows for selection of best events that can be taken forward for purpose of regulatory clearance.
- (ii) Biosafety Research Level Trial-I (BRL-I): For generation of Biosafety data conducted at 2-3 locations in an area of not more than one acre (0.4 ha) per trial per location for two years.
- (iii) Biosafety Research Level Trial-II (BRL-II): For generation of Biosafety data conducted at minimum of 8-9 locations in different agro-climatic zones.

2.35 Approvals for Event selection trials and BRL-I trials are issued by RCGM/DBT after approval of GEAC.

2.36 BRL-II trials fall under the purview of GEAC. As of date, BRL-II trials are being conducted by M/s. Dow Agro Sciences India Ltd. and M/s. Mahyco for GM Cotton Crop and BRL-II trials by M/s. Monsanto with respect to GM Maize.

2.37 The recommendation of the GEAC to accord approval for environmental release of Bt cotton in 2002 was supported by the Ministry. However on the recommendations of the GEAC to approve Bt brinjal event EE-1 the Ministry received strong views (both in favour and against) the release of Bt brinjal. Subsequently, the Ministry organized public consultations chaired by the Minister for Environment and Forests (IC) at seven locations.

2.38 Several concerns emerged during the national consultations which include health issues, loss of biodiversity, dependence on MNCs for seeds, loss of indigenous varieties through contamination of gene pool, sustainability of the technology, consumer choice and labeling, adequacy of regulatory process etc have. In the absence of scientific consensus and opposition from the State Governments and others, the Ministry, on February 09, 2010 decided to impose a moratorium on commercialization of Bt brinjal until all concerns expressed by the public, NGOs, scientists and the State Governments are addressed adequately.

2.39 The Minister for Environment and Forests (IC) while imposing moratorium on Bt brinjal Event EE-1 had also issued the following directions to the GEAC:

1. Identify further studies and tests with appropriate protocols in appropriate laboratories.
2. Review of all materials received by the Minister as part of the consultation process.
3. Interact with all those scientists, institutions and civil society groups who have submitted written representation to the Minister.
4. Consult with scientists like Prof M S Swaminathan, Dr P M Bhargava, Dr G Padmanabhan, Dr M Viyayan, Dr Keshav Kranthi and Dr Madhav Gadgil and others to draw up fresh protocols for specific tests that will have to be conducted to generate public confidence.

2.40 As a follow up to the above directions, a meeting of the GEAC to consult experts and scientists on the issue of Bt. Brinjal during the post-moratorium phase was held on April, 27, 2011. Minutes are at [Annexure-II](#)

(vii) Organisational Set-up

2.41 About the adequacy of the organisational set up available with them for ensuring that the designated role is discharged in conformity with the power vested upon them, GEAC informed the Committee that presently, the GEAC Secretariat in the MoEF comprises of Chairman GEAC (Additional Secretary, MoEF); Vice Chair (Joint Secretary, MoEF), Member Secretary GEAC (Dir –MoEF) and one Research Officer. The secretarial support staff is minimal. The Co-chair a nominee of DBT is an accomplished scientist outside DBT but having independent professional responsibilities. Administrative and technical support for review of the large number of applications is not provided to the Co-Chair and Member Secretary under the present system. To address this issue, GEAC is following a Committee based approach by constituting sub-committees and experts bodies.

2.42 The RCGM under DBT is also functioning with minimum staff and infrastructure. In light of the new developments in the areas of modern biotechnology, the dependence on a committee based review approach needs to be changed with a more robust review mechanism consisting of dedicated staff and infrastructure. It is in this context the Cabinet has approved the Biotechnology Regulatory Authority of India Bill, 2010 under DBT.

2.43 About the extent to which the role of GEAC differed or was in conformity with similar entities functioning in the Countries where substantial activities involving genetically engineered organisms, their products, etc. are being undertaken, as also in the countries which are on the threshold of entering the substantial activities ambit in near future like India, the Committee were informed that countries have different regulatory systems sometimes based on new acts that have been exclusively framed to deal with GMOs or based on regulations under the auspices of existing legal instruments. Further, these regulatory systems are very dynamic responding

to the needs of advancing biotechnology research. While the objective and methodology of biosafety assessment being followed is similar in most countries, the agencies involved in the regulation may differ. Some countries have dedicated 'Authorities' to implement the biosafety regulation whereas others have a 'Biosafety Committee' based system as in India. In several countries the Ministry of Environment and Forests is the nodal ministry for implementing the Biosafety laws.

2.44 The Committee were further informed that whereas the role of GEAC is broadly in conformity with regulatory process adopted in other countries, the responsibilities depend on the type of products and activities being regulated viz drugs, GM food, GM crops, transgenic animals, clinical trials, field trials, etc.

(viii) Antibiotic Resistant Marker Genes

2.45 There is a view point that Gene Transfer from Genetically Modified Crops/Commodities to cells of the body or to bacteria in the gastro intestinal tract would be of concern, if the transferred genetic material adversely affects human health. This would be particularly relevant if antibiotic resistant genes, used in creating GMOs, were to be transferred. In spite of the probability of such transfer being low, the use of technology without antibiotic resistant genes has been encouraged by FAO/WHO expert panel.

2.46 In order to understand the issue in its all ramifications the Committee sought the views of ICAR in the matter. In response, ICAR informed the Committee that antibiotic resistance marker genes have been in wide use by plant molecular biologists to develop transgenic plants since 1983; many of which are present in the GM crops commercially cultivated globally. The biosafety of these genes/enzymes has been well established (Nap et al., 1992; EFSA, 2001 and 2007, USEPA, 2004). Experiments have shown that the likelihood of horizontal transfer of these genes from transgenic plants and foods derived thereof to bacteria and other organisms is extremely negligible. In conclusion, antibiotic resistance marker genes are totally biosafe, environmentally safe and can be continuously used without any adverse consequences. GM crops developed using marker genes have so far

not shown any adverse effect at different stages of development including release at commercial scale.

2.47 The Council further informed the Committee that while the use of antibiotic resistance genes in GM crop development has been verified by experts to be safe, ICAR will be looking for options of developing GM crops free from such antibiotic resistance marker gene as encouraged by WHO and this is being currently pursued by some of the ICAR institutes. There are well established strategies available for development of marker free transgenics. Other options are also available which include excision or segregation of marker genes from the host genome after regeneration of transgenic plants through co-transformation.

2.48 When GEAC was asked to clarify on this issue they informed the Committee through a written reply that antibiotic resistance marker genes have been in wide use by plant molecular biologists to develop transgenic plants since 1983. The selectable marker genes such as *nptII*, *hpt* and *aad* are sourced from ubiquitous bacteria such as *E. coli* (transposon 5), and gram-negative bacteria (Transposons 7 and 21) and are extensively used in the development of transgenic plants/crops/ many which are commercially cultivated globally. It is a matter of policy issue on whether to allow GM crops with antibiotic resistance markers since technology for generating marker free transgenic plants is available.

2.49 The Committee were further informed that the matter was deliberated in the 105th GEAC meeting held on 8.12.2010 wherein it was noted that GM crops in the pipeline have been developed several years ago based on the technology available at that point of time. Further, it takes several years to complete the safety and efficacy assessments of GM crops. Therefore, any decision to disallow release of GM crops with antibiotic resistant genes would make almost all transgenic plants that are under consideration of GEAC/RCGM ineligible for release. Technological interventions and improvements are ongoing process and would be made available for newer products.

2.50 In view of the above, the GEAC decided that the GM crops containing markers for antibiotic resistant genes currently in the pipeline may continue

to be evaluated on a case by case basis unless scientific evidence is established otherwise on the ground. For newer products it was decided to have wider consultations on the matter taking into consideration technologies available and international experience.

2.51 When the same query regarding the antibiotic resistant mark a genes was put forth to the Ministry of Environment and Forests, who are the controlling Ministry of GEAC, they also dittoed the stand of GEAC in the matter.

2.52 The Department of Science and Technology, who are the nodal authority for science and technology in the Country informed the Committee on this aspect that experts in the area generally adopt the general principle of risk minimized strategy in dealing with GM crops and employ scientific tools and techniques for assessing the risk potential prior to field trials. It is true that there are concerns with respect to the risk of gene transfer to the cells in the body or micro-organisms. The perceived views of FAO/WHO expert panels with respect to encouraging technologies without the antibiotic resistant genes emanates from their risk minimization approach. At this stage of development of GM technologies, "minimization rather than total elimination of risks" might form the pragmatic approach. The Department holds a view on this issue that while risk minimization based on rigorous scientific assessment is an acceptable current approach, further research for Zero-risk standards of GM food crops should be supported.

2.53 The Department also stated that they shared the views of RCGM and GEAC on this important issue by virtue of the process adopted by them which are science based regulatory deliberations and they take into account of the current technology paradigm in the world.

2.54 The Department of Biotechnology, who are the nodal Department for RCGM informed the Committee that they endorsed the following views of RCGM and GEAC on this issue which are science based regulatory deliberations in recent period:

"In its 96th meeting of RCGM the issue was discussed in detail. It has been stated by RCGM that markers for antibiotic resistance should

not be 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. Antibiotic resistant 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. GEAC in its 105th meeting on 8.12.2010 has accordingly reviewed and decided that the GM crops containing markers for antibiotic resistant genes currently in the pipeline may continue to be evaluated on a case by case basis unless scientific evidence is established otherwise.”

2.55 Since the Department of Health Research/ICMR under the Ministry of Health and Family Welfare is the nodal Department for all human health related research the Committee wanted to not only know their views on the use of antibiotic resistant marker genes in creating GMOs but they also wanted to know as to whether the Department/ICMR had taken any initiative in this regard with a view to discourage use of antibiotic resistant genes, in case they subscribed to the views of FAO/WHO expert panel.

2.56 In response, the Department informed the Committee that horizontal gene transfer from plants to bacteria has not been demonstrated experimentally under natural conditions and deliberate attempts to induce such transfers have so far not been successful. The likelihood of brinjal genes transferring to humans and other animals perhaps are negligible. Modern biotechnology should develop marker genes other than antibiotic resistance ones though from available scientific data and reports, the possibility of gene transfer is very remote.

2.57 Asked further as to what role DHR/ICMR perceived for themselves in so far as research into the effect of Genetically Modified crops/edible commodities on human health is concerned it was stated that the Department shall critically review all the toxicological data generated during the biosafety research level studies (BRL) relevant to human health and carry out a risk assessment to ensure that the GM food crop would be safe

for human consumption. Department will support research to examine these aspects also.

2.58 However, when the views of Council of Scientific and Industrial Research were sought by the Committee on this issue, it was stated by them that CSIR favours marker free transgenics (i.e. those without antibiotic resistance genes) and molecular breeding is the preferred option for food crops and medicinal plants.

(ix) Conflict of Interest

2.59 Taking note of a media report appearing in a national daily regarding alleged favoritism by GEAC in dealing with case of the kin of a GEAC member, the Committee asked GEAC to submit a factual note on the report. In a written submission GEAC informed that the facts of the case are as follows:

1. The GEAC in its 104th meeting held on 15.11.2010 had allowed event selection trials on seven transgenic rice (*Oryza sativa* L) by the Department of Botany, Calcutta University at Rice Research Station, Chinsurah. The concerned member was not present in the GEAC meeting.
2. The proposal was recommended to the GEAC by the RCGM in its 94th meeting held on 26.10.2010 wherein the prescribed isolation distance was only 10 m. During the GEAC deliberation, the Committee noted that the proposed isolation measure is not in line with the Indian Minimum Seeds Standard Certification (IMSCS) which prescribes 200 m isolation distance. Accordingly the GEAC approved the proposal subject to compliance of 200 m isolation distance. RCGM was also informed to issue the permit letter accordingly.
3. Subsequently the Member Secretary, GEAC received a mail from the concerned member stating "*Please see the 104th meeting of GEAC :a proposal from Calcutta Univ on Event selection of transgenic rice for high iron rice, it was recommended for the 200*

m isolation distance. It should be 3 meter as inbred lines (as per guidelines of IMSCS 1988). It is not hybrid rice. Can you please check this matter?"

4. The matter was placed before the GEAC in the 106th GEAC meeting held on 12.1.2011. The Committee noted that as per IMSCS, 1988, for inbred lines the isolation distance is 3 meter and for hybrids it is 200 m. As the trials conducted by the University of Calcutta with inbred lines, it was observed that 10 m isolation distance is adequate. Accordingly, the GEAC conveyed its 'no objection' to maintain 10 m isolation distance during the event selection trials with transgenic rice developed by University of Calcutta.
5. Meanwhile DBT directed Calcutta University to submit 'no objection' from the State Government for the event selection trials. Directorate of Agriculture, Government of West Bengal vide communication No.210-PS dated 24.3.2011 has given their consent with the condition of plastic barrier to be placed around the GM rice field trial site. DBT has recently issued the approval letter for event selection trials. However, the trials have not been initiated.

2.60 In view of the newspaper report, the GEAC in its meeting held on 6.7.2011, reconsidered the issue of approval given to GM rice trials developed by Calcutta University. The above matter was discussed in the absence of the concerned member. The Committee reconsidered the case and reiterated its earlier decision to allow Calcutta University to conduct event selection trial maintaining an isolation distance of 10 m. In light of the fact that the isolation distance under Indian Minimum Seed Certification Standards (notified under Seed Act 1966) is 3 m for inbred rice lines, the Committee was of the view that the 10 m isolation distance stipulated by GEAC is adequate.

2.61 It may also be noted that the newspaper report states that the GEAC has flouted the SC direction for maintaining 200 m isolation distance. In this regard it may be noted that the order dated 8.5.2007 which stipulates that

an isolation distance of 200 m should be maintained for all GM crop field trials has been waived through an order dated 8.4.2008. As the isolation distance is crop specific, the GEAC had constituted a Sub-Committee to review the SC orders. Based on the recommendations of the sub-committee, the Ministry had filed an application for waiver of the condition. The SC in its order dated 8.4.2008 noted that:

"On 8th May, 2007 this Court had directed that when field trials are conducted, there must be 200 meters isolation distance between the trial fields and the neighbouring fields having cultivation of same crop, to avoid contamination. It is submitted on behalf of the applicants in I.A.s 22 and 23 that the distance to be maintained should depend upon the nature of the crop. It is submitted that some crops may require less than 200 meters and some may require more than 200 meters. GEAC will examine this issue and prescribe the isolation distance depending upon the nature of the crop".

In light of the above, the GEAC has not flouted any of the Supreme Court direction.

2.62 In view of the media reports about conflict of interest of some of the members on the Committee/bodies of GEAC. The Committee sought a detailed note in the matter as also details of action taken in case any of these instance/matter was actionable. In response they were apprised that the GEAC in its 105th GEAC meeting held on 8.12.2010, had adopted the following criteria to address issues related to conflict of interest based on the recommendations of the sub-committee constituted by the GEAC:

- I. A member of the GEAC is either a team leader or member of a team that has developed a transgenic plant which has come up for consideration before the GEAC shall not participate in the discussion regarding such an application.

- II. A member of the GEAC is a consultant for an industry/research foundation that has developed a transgenic plant which has come up for consideration before the GEAC shall not participate in the discussion regarding the said application.

- III. A Member of the GEAC is involved in the development of transgenic plant constituting the same crop/trait of interest that is being considered by the GEAC or is involved in the development of a recombinant vaccine/drug against the same disease. The GEAC member shall not participate in the discussion regarding such an application.
- IV. Further, in all the three situations mentioned above, the GEAC member should not be involved in the conduct or monitoring of field trials/clinical trials with regard to an application being considered by the GEAC.

2.63 The criteria for 'Declaration and Statement of Independence' to be submitted to the GEAC were specific to the involvement of the Member with respect to an application under consideration of the GEAC.

2.64 The matter was reconsidered in the GEAC meeting in light of a recent report. The GEAC has now decided that the 'Conflict of Interest' clause would be triggered if the member or his/her spouse or children are involved in terms of the criteria mandated above.

2.65 The GEAC has also decided to constitute a Sub-Committee to ensure that there is no Conflict of Interest and suggest further measures for avoiding such situations.

2.66 The Committee also sought the views of Prof. N.K. Ganguly, former Director-General, ICMR and Distinguished Biotech Scientist, THSTI on this aspect. He informed the Committee during his Oral Evidence on 19 October, 2010:

"Again, in real terms several of our councils have not done because in agricultural area the public health is weak, in the pure science areas public health is weak. So, many of these are public health concerns and we need to really create a seamless system in our place where such assessments are taught or passed on to appropriate stakeholders. Although, we have something like GEAC, the processes need to be put in place. I have seen about 10 or 15 people are gathered in a place, they come with huge documents which they have

not even read. Many of them read them on the table and sitting for few hours they give their impression and opinion. This is not how the opinions are made. It is a process and each step of the process is very important. So, all these committees, whether it is GEAC or Food Security Authority, etc., should have SOPs for the meeting and these SOPs should also deal with conflict of interest.

We hardly ask conflict of interest. Like, I came here as a witness, perhaps you have called me as a technical expert because I am the Chair of the Food Safety Technical Committee and also chaired the committee on its introduction in India for 10 to 12 years, but you never asked me whether I have a conflict of interest or not; whether I was a consultant on Monsanto or not. Nobody asked me to fill up a form. This is very important in the committees. In India, hardly such declaration is asked for. When I go to attend international meetings, this is the first declaration which is taken from me and the total processes are put in place. Any violation of that process does not complete the meeting. Like, in the stakeholders if we have members of religious bodies, members of the lay public then their opinion is also very important. Sometimes they ask very germane questions which need to be answered. If anyone of them is missing in these committees then nobody accepts the committee's rulings and verdict. So, this will again be my recommendation that composition of these committees should be very deeply looked into and their processes should be in place according to the strict SOPs and they should not deliberate for just few hours and then give a verdict of such an importance."

2.67 Shri Prashant Bhusan, Advocate, Supreme Court of India while emphasizing the need for an independent regulator to eliminate any conflict of interest told the Committee during his Oral Evidence on 28 October, 2010:

"जब इंडिपेंडेंट साइंटिस्ट्स क्रिटिक कर के अपने-अपने कमेंट्स दे दें, तब एक बिलकुल इंडीपेंडेंट रैगुलेट्री बॉडी यह देखे कि इससे कोई खतरा होगा कि नहीं होगा, कुछ एवीडेंस निकला कि नहीं निकला और तब अगर यह दिखे कि हां, कोई खतरा नहीं है, तब उसका रिलीज एलाउ किया जाए। इसके लिए यह

जरूरी है कि जो भी आपकी रैगुलेट्री बॉडी है या रैगुलेट्री अथॉरिटी है, उसमें सारे इंडीपेंडेंट लोग होने चाहिए।

जी.इ.ए.सी. जो थी, उसके को-चेयरमैन थे डॉ. सी.डी. माई। वे आई.एस. ट्रिपल ए के बोर्ड ऑफ डायरेक्टर्स में थे, यानी कि उसी आर्गेनाइजेशन के बोर्ड में थे, जो आर्गेनाइजेशन मौंसेंटो द्वारा फाउंडेड एंड फंडेड थी। जिसे मौंसेंटो चलाता है, उस आर्गेनाइजेशन के बोर्ड ऑफ डायरेक्टर्स में हैं और यहां रैगुलेट्री बॉडी के को-चेयरमैन हैं। इसलिए यह बहुत जरूरी है कि रैगुलेट्री बॉडी ऐसी होनी चाहिए कि उसके कोई कॉन्फ्लिक्ट ऑफ इंटरैस्ट्स न हों। उसके बड़े सख्त मापदंड हों यह देखने के लिए कि इनके कोई कॉन्फ्लिक्ट ऑफ इंटरैस्ट्स तो नहीं हैं। इनका कोई कनेक्शन नहीं है उन कंपनियों से जिनका इसमें कमर्शियल इंटरैस्ट है और उनसे ये लोग पैसे तो नहीं लेते। ये सब ब्रॉड इश्यूज हैं, जिन पर हम लोगों को सोचना और विचार करना है।”

(x) Development of BN Bt/Bt NHH44

2.68 During the currency of the Committee’s examination of the present subject a news item appeared on 30 December, 2011 in a national daily which reported that two Bt cotton variants developed by scientists in public sector were found to be carrying genes from the original patented product of a multinational company. The Committee immediately sought a factual note from the Government in the matter.

2.69 In their explanation in the matter ICAR stated that the Objective was to develop and commercialize low cost alternative Bt cotton varieties and hybrids through public sector institutions. The chronology of events relating to development of Bikaneri Narma Bt cotton variety and Bt NHH44 cotton hybrid is as follows:

1. 2000-2001 : National Research Centre on Plant Biotechnology (NRCPB) provided the cry 1 Ac gene construct to University of Agricultural Sciences, (UAS), Dharwad which was used to transform shoot apex explants of Bikaneri Narma through Agrobacterium mediated transformation to develop the BN Bt event ‘BNLA106’
2. 2003: NRCPB confirmed gene integration and copy number by Southern analysis.
3. 2002-04: The material brought from UAS Dharwad in 2002 was tested by Central Institute for Cotton Research (CICR), Nagpur

and confirmed the expression of Cry 1Ac protein. Subsequently, UAS, Dharwad conducted insect bioassays and advanced the BN Bt to T3 generation..

4. 2005: BN Bt seeds developed at UAS, Dharwad were grown in Glasshouse of CICR, Nagpur in May 2005. Biosafety studies were initiated by CICR, Nagpur.
5. 2006-2007: The work was published in Current Science (I. S. Katageri, H. M. Vamadevaiah, S. S. Udikeri, B. M. Khadi and Polumetla A. Kumar. 2007. Genetic transformation of an elite Indian genotype of cotton (*Gossypium hirsutum* L.) for insect resistance. Current Science, 93, 1843-1847).
6. 2005-2008: Applications to Review Committee on Genetic Manipulation (RCGM) and Genetic Engineering Approval Committee (GEAC) were submitted by Director, CICR, Nagpur. Contained Open Field Trial, Multilocation Research Trials and Biosafety studies were carried out. The BN Bt variety and 'Bt NHH 44' were tested under RCGM "Contained Open Field Trial" at three locations in three cotton growing zones during 2005-2006 and Multi-Location Research Trials (MLRT) in 12 locations in all the three zones in 2006-07 and 2007-08. The BN Bt and Bt NHH 44 showed over-all yield superiority in both seed cotton and lint yield when compared with Non-Bt check and local checks. Biosafety studies were carried out at various institutions through CICR.
7. 2006-07: The BNBt event was characterized by outsourcing the work to M/S Avasthagen, Bangalore.
8. 2008: After completing all the mandatory biosafety testing and field experimentation, the 'BN Bt variety' was approved for commercial cultivation in the 84th meeting of GEAC held on 2nd May 2008
9. 2008: A meeting was held under the Chairmanship of Deputy Director General (Crop Sciences), ICAR regarding the roadmap for the promotion and utilization of BNBt cotton.
10. 2008: To finalize the commercialization modalities of 'BN-Bt' Bt-cotton event, BN-Bt variety and the Bt-cotton hybrids developed using the 'BN-Bt' event, a Meeting was held on 12th December

2008 under the Chairmanship DDG (CS) in New Delhi. Commercialization and seed production plans were finalized.

11. 2008: UAS, Dharwad produced 250 quintal seed in 2008-09 kharif season. The seed was sent to CICR in two lots (165 Q on 4th May and 84 Q on 6th May 2009) at Rs 50 per Kg. The seeds were packed at CICR in 2kg seed bag containing packs of 200g pigeonpea refugia seed and were distributed to various agencies.
12. 2009: The hybrid 'Bt NHH 44' was approved by GEAC on 13th May 2009 for commercial cultivation in the Central and South zones during Kharif season 2009. 'BN Bt' is female parent and AC738 is the male parent for Bt NHH 44. UAS Dharwad produced 15 quintals Bt NHH 44 seed and sent to CICR at Rs 370 per Kg on 28th May 2009. The seeds were packed at CICR in 750 g Bt NHH 44 seeds per bag and were distributed to various institutions
13. 2009: A meeting was convened at New Delhi on 10-12-2009 under the Chairmanship of DDG (CS) to examine the reported presence of Mon 531 in BNBt seeds. Based on the evidence available, it was decided to stop production and commercial sale of BNBt and Bt NHH 44 seeds.
14. 2011: To explore the way forward in utilizing Bt genes from available sources for introgression into elite public sector varieties and hybrids, a meeting was convened at New Delhi on 27-04-2011 under the Chairmanship of DDG (CS). Options were also suggested for purification of the BNBt event.
15. 2011: In view of emerging reports regarding the presence of Mon531 in BNBt cotton, a meeting was held on 27-12-2011 under the Chairmanship of DDG (CS) and it was noted that the seed multiplication of BN Bt and Bt NHH 44 was suspended after 2009. It was suggested that the Vice-Chancellor, UAS, Dharwad may look into the process of BN Bt development, seed multiplication and other related aspects. The authors of the Current Science paper are advised to submit immediately a Corrigendum to rectify the vector map. As a way forward to utilize the Genetically modified (GM) cotton events available with the public sector, concerted efforts may be initiated by CICR to

develop multi-gene stacked elite cotton varieties. The events available with the public sector institutions may be evaluated and the best events may be stacked together through inter-institutional collaborative programmes to be taken up on priority.

16. Indian Council of Agricultural Research (ICAR) is constituting an Expert Committee to examine the entire issue related to BNbt cotton event and Bt NHH44, and suggest appropriate measures.

INSTITUTIONS INVOLVED:

NRCPB, New Delhi

1. Provided Cry 1Ac gene construct
2. Conducted PCR
3. Confirmed gene integration and copy number by Southern blot analyses.

UAS Dharwad

1. Development of BNbt event BNLA106 through genetic transformation of shoot apex explants and regeneration of transformed tissues through tissue culture methods
2. Screening of the transformed events to select the best event
3. Breeding methods to carry forward the best event plant progeny through 5 generations to obtain homozygous plants of BNLA106 event
4. Conducted insect bioassays
5. Conducted ELISA tests
6. Multiplied and provided seeds for all bio-safety studies and field trials
7. Provided 'BNbt' seed to plant breeder in 2005 for gene introgression into elite varieties

CICR, Nagpur

1. Coordinated the biosafety studies for BNbt seeds provided by UAS, Dharwad institutions)
2. Conducted biosafety testing on soil micro-organisms and studies on pollen-flow

3. Conducted Institute Biosafety Committee meetings regarding BNBt
4. Applied for RCGM permission and GEAC approval
5. Submitted application for registration to PPV-FRA
6. Distribution of the seeds from UAS Dharwad during May 2009 to the seed corporations

Review Committee on Genetic Manipulation (RCGM) :

Review Committee on Genetic Manipulation in its 53rd meeting in year 2007 noted that the applicant has not completed the biosafety studies. The feeding studies in large animals viz., cows and goats are not complete. The committee also observed that the applicant has not complied with the Supreme Court directive "Prior to bringing out the GM material from the green house for conduct of open field trials, the approved institution should submit a validated event specific test protocol at an LOD of at least 0.01% to detect and confirm that there has been no contamination". However, the Committee also felt that the applicant has already completed most of the biosafety studies as per the DBT guidelines and no adverse effects have been observed in the studies conducted so far. Moreover, the feeding studies on cows and goats will be completed within the next six months. In view of this, the Committee recommended the case to GEAC to take a view on the request of the applicant.

Genetic Engineering Approval Committee (GEAC)

Genetic Engineering Approval Committee approved BNBt and Bt NHH 44 for commercial release in the meetings of 2-5-2008 and 13-05-2009, respectively.

Current Status

- Seed production of BNBt and Bt NHH44 has been suspended after 2009
- University of Agricultural Sciences, Dharwad was requested to consider reviewing the process of BNBt development and also the reported presence of Monsanto's gene/event in BNBt seeds

- The ICAR is constituting an Expert Committee of Scientists to examine the entire issue of BNBT and Bt NHH44 and suggest appropriate measures.

2.70 With a view to acquire further clarity in the matter the Committee sent a list of points to Government on this issue. The said list of points alongwith replies of ICAR is at **Annexure - III**.

2.71 The Department of Biotechnology submitted the following information in the context of role of RCGM in the matter:

1. As per the information submitted by UAS, Dharwad to RCGM on 21.06.2005, the task of making the hybrid NHH-44 (Bt version) was assigned to Agricultural Research Station, Dharwad farm under NATP in collaboration with NRCPB, IARI, New Delhi by ICAR. As per this information, cry1Ac gene belongs to NRCPB, IARI, New Delhi which was transferred to Bikaneri Narma, a female parent of NHH-44 by following genotype independent transformation technique developed at ARS, Dharwad farm.
2. The Department has not funded any project to UAS, Dharwad or CICR, Nagpur for development of Desi Bt cotton i.e. Bikaneri Narma (BN) Bt Cotton indigenous variety with cry1Ac gene. The Biosafety Reports on Bt transgenic cotton hybrid NHH 44 Bt conducted during 2006-07 [toxicity, allergenicity and feeding studies in small laboratory animals (rats, rabbits & guinea pigs); livestock animals (cows & goats), birds (chicken), fish; and other environmental parameters including gene flow, out crossing, non-target organism and soil biota] by Central Institute of Cotton Research (CICR), Nagpur was evaluated by RCGM in its 53rd meeting held on 22.5.2007. The extracts from the recommendations of RCGM are reproduced below:

“The committee deliberated on the issue and observed that the applicant has not completed the biosafety studies. The feeding studies in large animals viz., cows and goats are not

complete. The committee also observed that the applicant has not complied with the Supreme court directive 'Prior to bringing out the GM material from the green house for conduct of open field trials, the approved institution should submit a validated event specific test protocol at an LOD of at least 0.01% to detect and confirm that there has been no contamination". However, the Committee also felt that applicant has already completed most of the biosafety studies as per the DBT guidelines and no adverse effects have been observed in the studies conducted so far. Moreover, the feeding studies on cows and goats will be completed within the next six months. In view of this, the committee recommended the case to GEAC to take a view on the request of the applicant".

GEAC in its 93rd meeting held on 13.5.2009 considered the application from CICR, Nagpur for commercial release and taking into consideration the fact that NHH-44 Bt was developed by using BN Bt as female parent which contains the same cry 1AC gene and event that has already been approved for commercial cultivation, the Committee approved commercial release of NHH-44 Bt cotton hybrid developed by CICR, Nagpur. The detailed decisions are available at GEAC website <http://moef.nic.in/divisions/csurv/geac/decision-may-93.pdf>.

2.72 The Report on 'Animal Feeding Trial on Bio-Safety Studies with Biotechnologically Transformed Bt cotton Crop Seed Meal obtained by the Committee from ICAR is placed at **Annexure - IV**. The study which was funded by CICR was conducted by Division of Animal Nutrition, Central Sheep and Wool Research Institute, Avikanagar, Rajasthan.

2.73 The MoEF furnished the following information in respect of bio-safety approvals granted in the instant case(s) by GEAC:

(1) Regulatory Mechanism of Genetically modified organisms (GMOs)

All Genetically modified organisms (GMOs) and products thereof including GM crops are regulated products in India 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 through their Notification No. 621 in Official Gazette of Govt. of India on December 5, 1989 under the provisions of the 'Environment (Protection) Act', 1986 with a view ensure sound application of biotechnology making it possible to accrue benefits arising from modern biotechnology while minimizing the risks to environment and human health. The Rules 1989 also define the competent authorities and composition of such authorities for handling of various aspects of the Rules.

(2) Functions of various committees

(i) The functions of the Review Committee on Genetic Manipulation (RCGM) established under the DBT are to monitor the safety related aspects in respect of on-going research projects and activities (including small scale field trials) and bring out manuals and guidelines specifying procedure for regulatory process with respect to activities involving genetically engineered organisms in research, use and applications including industry with a view to ensure environmental safety.

(ii) The Genetic Engineering Appraisal Committee (GEAC) established by the MoEF under Section 4 (4) of Rules 1989 is the apex body to accord approval of activities involving large scale use of hazardous microorganisms and recombinants in research and industrial production from the environmental angle. The GEAC is also responsible for approval of proposals relating to release of genetically engineered organisms and products into the environment, including experimental field trials (Biosafety Research Level trial-I and II known as BRL-I and BRL-II).

(iii) The GEAC is following a policy of case by case event based approval in case of Genetically Modified (GM) foods or food crops. Evaluation of the safety of GE crops and regulatory approval process takes place right from the research stage. This includes generation and documentation of relevant biosafety information/data and its elaborate

analysis to ensure food, feed and environmental safety. The development of GM crops at the laboratory stage, confined multi-location trials for generation of biosafety data known as biosafety research trials – I and biosafety research trials-II (BRL-I and BRL-II) require prior approval of the RCGM and the GEAC set up under the Rules, 1989 respectively. The compliance of the regulatory procedures during GM crop field trials is monitored by the Monitoring Committees set up by the RCGM/GEAC.. The GEAC takes into consideration the findings of the biosafety and agronomic studies as well as recommendations of the RCGM before according approval for environmental release. Only those transgenic crops which are found to be safe for human consumption as well as the environment are recommended for environmental release.

(3) Initiation of multi-location trials/ large scale trials (LST) of Bikaneri Narma (BN) Bt (Variety) and NHH- 44 Bt

In view of the above process and procedures laid down under Rules 1989, the research and development of Bikaneri Narma (BN) Bt (variety) and NHH 44 Bt including multi-locational field trials by CICR was initiated with the approval of RCGM. The proposal for large scale trials (LST) was referred to the GEAC by the RCGM only in 2007. The recommendation of RCGM was based on the biosafety data presented by Director CICR, Nagpur with respect to toxicity, allergenicity and feeding studies in small laboratory animals (rats, rabbits & guinea pigs); livestock animals (cows & goats), birds (chicken), fish; gene flow, out crossing, impact on non-target organism and soil biota in the RCGM meeting held on 22.5.2007. While recommending the proposal for LST and ICAR trials and seed production in the North, Central and South zone, RCGM also observed that the applicant has not completed the following requirements:

- (i) Feeding studies in large animals (cows and goats);
- (ii) The Institute has not submitted a validated event-specific test protocol at a LoD of at least 0.01 % as per the requirement of Supreme Court Order;

As the above information will be available within six months, the RCGM recommended that the GEAC may consider according approval for LST and ICAR trials and seed production.

(4) Chronological sequence of events subsequent to RCGM recommendation falls under the purview of the GEAC.

- a. The recommendations of RCGM and application submitted by CICR, Nagpur was considered by the GEAC in its meeting held on 22.6.2007 wherein it was noted that (i) BN Bt (variety) and NHH 44 Bt indigenously developed transgenic cotton developed by CICR expresses Bt cry 1 Ac (Truncated and codon-modified) gene which is very similar to the Cry 1Ac toxin expressed by MON 531 event developed by M/s Monsanto as well as event 1 of IIT, Kharagpur both of which are already under commercial cultivation; (ii) The Bt technology has been deployed for the first time in a known varietal background; (iii) BN Bt (variety) was developed by CICR in accordance with the prescribed protocol and procedures and after obtaining the approval of RCGM; and (iv) The biosafety studies conducted by the Institute so far indicate that there is no adverse effects on the environment and human health. However, the GEAC after detailed deliberation recommended that the request for LST and ICAR trials and seed production will be recommended only after completion of the biosafety studies and submission of event specific test protocol at LoD of 0.01%.
- b. On completion of the feeding studies and submission of event-specific test protocol, the request of CICR for LST and ICAR trials and seed production of BN Bt (variety) and NHH44 Bt in the North zone was considered by the GEAC meeting held on 2.4.2008. During the deliberations, the following points emerged:
 - Bt technology has been for the first time introduced in a varietal background whereby the farmers can save the seeds.

- Bt technology has been introduced in a popular and well established agronomic background.
 - No cost to the trait value which would provide cheaper options to the farmers.
 - Adequate data on Cry 1Ac protein is available.
 - The seeds generated during the trials would be made available to the farmers free of cost.
- c. In the above meeting, the Supreme Court invitee, Dr P.M. Bhargava opined that since the Bt crops expressing cry1 Ac toxin is already under commercial cultivation and in the national interest, he suggested that as an exceptional and unique situation, the GEAC may consider commercial release of the BN Bt (variety). However, CICR, Nagpur informed that currently seeds are available only for LST and ICAR trials. The GEAC further opined that several public sector institutions are developing new GM crops with new traits and therefore it is advisable that the regulatory procedure is complied with in all cases.
- d. In light of the above discussions, the GEAC in its meeting held on 2.4.2008 approved the LST and ICAR trials and seed production in an area of 100 hectares in the North zone.
- e. In the GEAC meeting held on 2.5.2008, the request of CICR for LST and ICAR trials and seed production of BN Bt (variety and NHH 44 Bt in the Central and South zones was considered by the GEAC wherein it was felt that there is a need for review of the decision directing CICR to conduct larger scale trials with the BN Bt (variety) on the following grounds:
- Bt technology has been for the first time introduced in a varietal background whereby the farmers can save the seeds;
 - Bt technology has been introduced in a popular and well established agronomic background; and
 - No cost to the trait value which would provide cheaper options to the farmers and

- Approvals for LST for a variety and a hybrid have different implications because in the case of a variety, approval for large scale trials would tantamount to commercial release as the farmers can save the seeds for planting in the next season.

(5) Approval of BN Bt (Variety)

In light of above discussions, the GEAC in its meeting held on 2.5.2008 approved the commercial release of BN Bt (variety) developed by CICR in the North, Central and South zones.

(6) Approval for Large scale field trials (LST) and ICAR trials for NH-44 Bt

In the same meeting NHH 44 Bt was approved for LST and ICAR trials and seed production in an area of 100 ha in the Central and South zones.

(7) Approval of GEAC for commercial release of NHH 44 Bt

On completion of the LST and ICAR trials, the GEAC approved the commercial release of NHH 44 Bt in the meeting held on 13.5.2009.

(8) Discontinuation of Seed Production of BN Bt (Variety)

Subsequent to the approvals granted by the GEAC, the Committee has not received any complaint or information from CICR/ICAR indicating that seed production of BN Bt (variety) has been discontinued as it contains Cry 1Ac gene MON 531 event; which is a proprietary of M/s Monsanto.

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.

2.75 The Committee further note that the regulatory mechanism to enforce these rules consists of six committees. The chain begins with the Institutional Bio-Safety Committee, which is established under the institution engaged in GMO research for oversight and to interface with Review Committee on Genetic Manipulation (RCGM). RCGM functions under the Department of Biotechnology and is mandated with the responsibility of monitoring and regulating safety related aspects of ongoing research projects and activities including small scale field trials. There is a recombinant DNA Advisory Committee (RDAC) which is of an advisory nature and which recommends suitable and appropriate safety regulations in recombinant research, use and applications from time to time. The Genetic Engineering Appraisal Committee (GEAC) previously known as Genetic Engineering Approval Committee is the apex body to accord approval of activities involving large scale use of hazardous micro-organisms and recombinants in research and industrial production from environmental angle. More importantly it is also mandated with the authority for approving release of genetically engineered organism and products into the environment including

experimental field trials. GEAC functions under the Ministry of Environment and Forests. Then there are State Biotechnology Coordination Committees (SBCCs) who are mandated with the power of State level monitoring. SBCCs also have powers to inspect, investigate and take punitive action in case of violations. The last tier of the regulatory mechanism are the District Level Committees (DLCs) who are tasked with the role of monitoring the safety regulations in installations engaged in the use of GMOs/hazardous microorganisms and their applications in the environment. Apart from these six Committees, the Committee note there is a Monitoring-cum-Evaluation Committee which monitors the compliance of regulatory procedures during field trials of GM crops.

2.76 The procedure in vogue preceding approval is that the company involved in development of GM crop undertakes in containment, several biosafety assessment including environmental safety, food and feed safety assessments. This is followed by Biosafety Research Trials in two stages BRL-I and BRL-II which require prior approval of RCGM and GEAC respectively. Approval for environmental release is accorded by GEAC after taking into consideration the findings of bio-safety and agronomic studies as well as recommendations of RCGM, ICAR and MEC. Finally commercial release is permitted by GEAC for only those transgenic crops which are found to be safe for human consumption as well as the environment. Committee note that the Government have also put a strict regimen in place at all stages of assessment and evaluation procedure.

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

2.78 Furthermore, Dr. Bhargava has also pointed out that the growing failures of Bt. cotton on the front of resistance to pests it was supposed to kill, increasing attacks of secondary pests, etc. prove that the technology is not sustainable. The death of cattle and other livestock in Andhra after grazing on Bt. cotton fields, which apart from Dr. Bhargava was also brought to the notice of the Committee by Dr. Sagari Ramdas of Anthra and Ms. Kavitha Kuruganti of Kheti Virasat Mission, also raise doubts about the safety of Bt. cotton as feed. Similarly, how the regulatory mechanism has missed the 30 % increase in toxic alkaloid content in Bt. brinjal and approved it for environmental release are all

perplexing questions which need honest answers, as all these developments could have devastating effects on environment and human and livestock health.

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

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.

2.81 These contradictory stances are not restricted to the renaming issue only, but permeate in several other aspects. To say the least, the demarcation of roles and responsibilities between MoEF and GEAC seems to be hazy. While Rules 1989 are very clear and unambiguous about the authority of according approval for environmental and commercial release vesting with GEAC, the information submitted to the Committee by MoEF and GEAC from time to time, for and in connection with the examination of the subject, conveyed an intent to obfuscate the matter. At some places the authority of GEAC to accord approvals was truly reflected, at others it was couched as 'recommendation of GEAC to accord

approval' and at still others it was stated that GEAC accorded approval for environmental release and had no role in commercialization of GM crops. The Committee, therefore, strongly feel that this uncertainty is not in the interest of the regulatory mechanism in place for such a sensitive matter. They, therefore, recommend the Government to come up with a detailed statement clarifying on all aspects of the matter so as to put the ongoing controversies to rest.

2.82 The Committee note with concern that both GEAC and RCGM who are in existence for several years now and are mandated with very very sensitive functions have no organizational set-up and infrastructure worth mentioning. Due to these severe and debilitating impediments, both the agencies have to depend on a Committee based approach, which in the opinion of the Committee, is not the most optimal way of functioning for agencies tasked with such sensitive responsibilities. The Committee are in full agreement with GEAC that the ever evolving dynamics of modern biotechnology cannot be kept fully tracked of with the Committee based review approach and a more robust and dedicated review mechanism is urgently called for. The Committee, therefore, recommend that an immediate review of the organizational set-up and infrastructure of GEAC and RCGM be got done by the Government and necessary augmentation, both in terms of men and material be carried out immediately and without linking it to the proposed omnibus regulatory authority that may still take years to come into existence.

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

2.84 The Committee note that FAO/WHO expert panel, IAASTD report and several other studies have recommended the use of anti-biotic resistant marker free genes technology while creating GMOs. According to such studies though the possibility of such a transfer is low but any transfer of such genes from GM crops/commodities to cells of the body or to bacteria in the gastro-intestinal tract would be of concern. In our context, while GEAC has stuck to the argument that such possibilities are remote, most of the other ministries/departments whose views were sought by the Committee have shown a marked inclination for technologies without antibiotic resistant marker genes. Most of the independent scientists and

other witnesses appearing before the Committee have also expressed their concern on use of anti-biotic resistant marker gene in developing GMOs.

2.85 In spite of some of the stakeholders emphasising about the remote possibility of the antibiotic resistant marker gene transferring from GM crop or commodity to cells of body or to bacteria in gut, an overwhelming majority of stakeholders who appeared before the Committee are in favour of use of anti-biotic marker resistant gene free technology. GEAC has, however, taken the stand that since technology for generating marker free technology is available it is a matter of policy whether to allow GM crops with antibiotic resistance markers. Side by side GEAC has also informed the Committee that it had taken note of this matter in its meeting held on 8 December, 2012 and had found that any decision to disallow release of GM crops with antibiotic resistant genes would make almost all transgenic plants that are under consideration of GEAC/RCGM ineligible for release. GEAC has further given its mind on this crucial matter by stating that technological interventions and improvements are ongoing process and would be made available for newer products.

2.86 The Committee cannot but express their extreme displeasure at this mindset of a regulatory agency which is mandated with ensuring safety of environment, human health, food and feed of the Country. The above-cited response of GEAC betrays a complete lack of concern towards its role and responsibility. Rather it conveys in unequivocal terms its strong inclination towards the benefit of

industry. The Committee, therefore, recommend the Government to not leave such a crucial decision in the hands of GEAC but come up with a clear-cut policy in this regard without any further loss of time.

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.

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.

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

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

expert committee comprising of eminent scientists from ICMR, pathologists, veterinarians and nutrition experts.

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

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.

CHAPTER - III

PRACTICES ELSEWHERE

Regulatory Framework in Various Countries

3.1 A brief overview of the international practices for release of GM crops and bio-safety regulations in various countries as furnished by DAC is given below:

(i) USA:

3.2 The US regulatory system operates in a coordinated framework involving three government agencies as given in Table below:

US regulatory authorities for crop biotechnology products

Agency	Jurisdiction	Laws
USDA	Plant pests, plants, veterinary biologics	Federal Plant Pest Act (FPPA)
FDA	Food, feed, food additives, veterinary drugs, human drugs, medical devices	Federal Food, Drug and Cosmetic Act (FFDCA)
EPA	Microbial and plant pesticides, new uses of existing pesticides, novel microorganisms	Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); FFDCA; Toxic Substances Control Act (TSCA)

3.3 The USDA's Animal and Plant Health Inspection Services (APHIS) is the lead agency for the regulation of genetically engineered plants including the experimental evaluation of these products in confined field trials. The Environmental Protection Agency (EPA) is responsible for assuring the human and environmental safety of pesticidal substances engineered into plants, and the Food and Drug Administration (FDA) is responsible for assuring that foods and drugs derived from genetic engineered are as safe as their traditional counterparts. Products are generally regulated according to their intended use, with some products being regulated under more than one agency e.g. pesticidal plants.

3.4 It may be noted that no new laws have been enacted in USA for regulation of GMOs products thereof and provisions have been made in

existing laws only. However, the products developed using genetic engineering are subjected to much higher degree of scrutiny as compared to those derived through traditional breeding, selection or accelerated mutagenesis. All the three regulatory agencies have the legal power to demand immediate removal from the market place of any product post commercialization if any new and valid data indicates a question of safety for consumers or the environment.

3.5 Regarding research and development activities, the National Institutes of Health (NIH) have developed guidelines to describe facilities and practices intended to prevent unintended release or inadvertent exposure to GMOs or products thereof. Compliance with NIH guidelines is mandatory for working with GMOs for all scientists receiving federal funding or working for federal agencies.

3.6 Shri Ajay Kanchan of Forum for Biotechnology and Food Security while sharing his experience about the situation obtaining in USA stated during this Oral Evidence on 15 September, 2010:

“There are three problems related to GM food. One is basically acute toxicity. आपने अभी खाया, आपके ऊपर उसका तुरंत असर होगा।

दूसरा सब-क्रोनिक टोक्सिसिटी होता है। आप उसे तीन-चार साल खायेंगे तो आपकी किडनी, लीवर, कैंसर आदि की प्रॉब्लम बढ़ेंगी और फिर क्रोनिक टोक्सिसिटी होता है। इस तरह से क्रोनिक टोक्सिसिटी और सब-क्रोनिक टोक्सिसिटी के लिए कोई भी जीएम फूड को कहीं पर भी 180 दिन से ज्यादा टैस्ट नहीं किया गया है। जब हम लोग उसे अपनी पूरी लाइफ साइकिल में खायेंगे, जब तक आप उसे किसी मैमल पर टैस्ट नहीं करेंगे, तब तक पता नहीं चलेगा। यदि एक चूहे की उम्र केवल 24 महीने होती है और उसे हम 24 महीने पूरी तरीके से नहीं खिलाते हैं, उसकी मल्टी जनरेशन को नहीं खिलाते हैं, आपको इस बात का कभी पता नहीं लगेगा कि यह आपके लिए हार्मफुल है या नहीं। सिर्फ कुछ साइंटिस्ट्स ने इंडिपेन्डेंट स्टडीज की हैं और आस्ट्रिया में एक स्टडी हुई है, जिसमें उन्होंने मल्टी जनरेशन ट्रायल किये हैं और उसमें उन्होंने यह साफ दिखा दिया कि थर्ड जनरेशन तक आते-आते जनरेशन पूरी तरह से इनफर्टाइल हो जाती है। उसके अंदर पूरी इंसेनिटी, जो आपके लैब एनिमल्स हैं, उसके अंदर बढ़ जाती है। अगर आप उन देशों के बारे में देखें जहां पर लोग काफी समय से इसे खा रहे हैं, अमेरिका में वर्न 1996 के बाद से एलर्जीज में 1500 परसेंट का इंक्रीज हुआ है, अल्जाइमर और डिमेन्सिया में 9000 परसेंट का इंक्रीज हुआ है। अब आप कह सकते हैं कि हमारे पास कहीं भी इस बात का कोई प्रमाण नहीं है कि यह सब जेनेटिकली मोडिफाइड क्रॉप की वजह से हो रहा है, लेकिन कोई इस बात से इन्कार भी नहीं कर सकता है कि यह उसकी वजह से नहीं हो रहा है। यह उसके सामने सबसे बड़ा प्रमाण है और देखिये अमेरिका में सबसे ज्यादा जेनेटिकली मोडिफाइड फूड जानवरों को खिलाया जाता है। इन्डिपेंडेंट साइंटिस्टों ने अपनी स्टडीज में दिखाया है

कि इसका सबसे ज्यादा बुरा असर लीवर पर पड़ता है। हमारे शरीर में अगर टॉक्सिसिटी बढ़ेगी तो उसका सबसे बुरा असर लीवर पर होगा। मैंने अभी वहां पर अमेरिका में कम से कम डेढ़ से दो महीने तक बहुत सारे वेटेनेरियन्स से बात की। उन्होंने कहा कि पिछले चार-पांच साल से जब हम लोग जानवरों का पोस्टमार्टम करते हैं या उन्हें काटते हैं तो देखते हैं कि उनका लीवर ऐसे नजर आता है जैसे उसके अंदर किसी तरह की कलस्टर बाम्बिंग हुई है। जब तक आपने एक फूड को 180 दिन से आगे टैस्ट ही नहीं किया है और सबसे बड़ी चीज यह है कि हम लोगों से यह कहा जाता है कि एफडीएनएस को प्रमाणित किया हुआ है। एफडीए का एक भी सिंगल लॉ ऐसा नहीं है जो किसी भी कंपनी को मजबूर करता हो कि आप इसे टैस्ट कीजिये। अल्टीमेटली यह हमारे बीच में एक इस तरह का फूड लाने की कोशिश की जा रही है। केवल कंपनियां इतना तय कर लेती हैं कि आप उसे खाकर तुरन्त न मर जायें। वर्न 1989 में अमेरिका में एलट्रिप्टो फैन के नाम से एक बहुत बड़ी ट्रेजेडी हुई थी। एलट्रिप्टो फैन पिछले कम से कम सौ साल से एक ऐसा हैल्थ टॉनिक था, जिन्हें नींद नहीं आती थी, जिन्हें डिप्रेशन था, वे उसे लेते थे। एक कंपनी ने जब उसे बनाना शुरू किया तो उसे लेने के बाद एकदम से कम से कम 100 के आसपास लोग मर गये और कम से कम 10 से 15 हजार लोग हमेशा के लिए क्रपल हो गये। मैं बहुत सारे ऐसे लोगों से मिला हूँ, जोकि उसे खाने के बाद क्रपल हुए हैं। इससे यह बात जाहिर है कि जब तक आपने उसे एक लांग टर्म और इंडिपेंडेंटली टैस्ट नहीं किया है, तब तक आप कभी भी उसके बारे में यकीन से नहीं कह सकते हैं। मेरे ख्याल से इसके साथ जो मुझे सबसे बड़ी दिक्कत नजर आती है, वह यह है कि इसे हम सभी खायेंगे। अल्टीमेटली यह हम सभी की जिम्मेदारी होती है कि कम से कम हम लोग दूसरों के अभी तक के एक्सपेरीमेंट से, लोग जिस अनुभव से गुजरे हैं, उनके अनुभव से हम लोग कुछ सीख लें। अमेरिका में पिछले दस साल से सबसे ज्यादा तेजी से जो चीज बढ़ी है, वह ऑर्गेनिक फूड का एडॉप्शन है। लोग वहां पर नॉन जीएमओ सर्टीफाइड कर रहे हैं, लोग वहां पर नॉन जीएमओ सील लगाकर अपना खाना खा रहे हैं। हम लोग ऐसा फूड अपने यहां पर उस समय ला रहे हैं, जब लोग उस तरफ से हट रहे हैं।”

(ii) European Union

3.7 Since 1990, European Union states have had a harmonized approach to address the issues of GMOs and genetically modified microorganisms (GMMs) under the Directive 90/220/EC. A new framework under the Directive 2001/18/EC, replaced this Directive on April 17, 2001. The new EU directive sets forth regulations governing the deliberate release into the environment of GMOs. The Directive puts in place a step by step approval process on a case by case assessment of the risks to human health and the environment before any GMO or product consisting of, or containing GMOs can be released into the environment or placed on the market.

3.8 Essentially the approval process requires submission of the notification to the competent authority in a member state where the GMO will be field tested/marketed. The competent authority produces a summary/assessment report which is forwarded to the commission and competent authorities of all member states. In addition to the member states, public is also provided

an opportunity to provide comments which are discussed in an attempt to reach agreement. At the end of review process, the competent authority provides a written consent for marketing the GMO for a period of no more than 10 years. The period of validity, the conditions for marketing the product, the labeling and monitoring requirements are all specified in the consent. The Directive requires that the labeling include the words 'this product contains genetically modified organisms'.

3.9 Some of the other provisions which are noteworthy in Directive 2001/18/EC include the following:

- The phasing out of antibiotic resistance genes;
- The use of the precautionary principle' when assessing GMO effects;
- The authority for the competent authority to conduct inspections and compliance measures;
- The requirement to trace the GMO at all stages to market;
- The ability to keep confidential sensitive business information while providing the public information about the GMO and its environmental risk assessment.
- The ability of a Member State to restrict or prohibit use of an approved GMO if new or additional information provides 'detailed grounds for considering that a GMO ...constitutes a risk to human health and/or the environment';
- A statement that Member States may take into consideration ethical aspects' when reviewing GMO.

(iii) Canada

3.10 In Canada, the regulations of the biotechnology products is coordinated by Canadian Food Inspection Agency (CFIA), Health Canada and Environment Canada. The CFIA is responsible for regulating the import, environmental release, variety registration and use in livestock feeds of plants with novel traits. Health Canada is solely responsible for assessing the human health safety of foods. Environment Canada is responsible for administering the new substances notifications regulations and for performing environmental risk assessment of toxic substances, including

organisms and microorganisms that may have been derived from biotechnology. These agencies regulate biotechnology products under the authority derived from at least ten pieces of preexisting legislation that have been amended time to time to deal with new products. A list of regulatory responsibilities of these agencies along with the relevant legislation is given below for agriculture biotechnology products:

Regulatory agencies for agricultural biotechnology products in Canada and the products regulated

Department/ Agency	Products regulated	Relevant legislation	Regulations
Canadian Food Inspection Agency	Plant and seeds, including those with novel traits; animal vaccines and biologics; fertilizers; livestock feeds	Consumer packaging and labelling act Feeds Act Fertilizers Act Food and Drugs Act Health of Animals Act Seeds Act Plant Protection Act	Feeds Regulations Fertilizers Regulations Health of Animals Regulations Food and Drug Regulations
Environment Canada	Biotechnology products under CEPA. Such as microorganisms used in bioremediation; waste disposal, mineral leaching of enhanced oil recovery	Canadian Environmental Protection Act	New Substances Notification Regulations (These regulations apply to products not regulated under other federal legislation)
Health Canada	Food; drugs; cosmetics; medical devices; pest control products	Food and Drugs Act Canadian Environmental Protection Act Pest Control Products Act	Cosmetic Regulations Food and Drug Regulations Novel Foods Regulations Medical Devices Regulations New Substances Notification Regulations Pest Control Products Regulation
Fisheries and Oceans	Potential environmental release of transgenic aquatic organisms	Fisheries Act	Under Development

3.11 Canada is the only country where regulatory oversight is triggered solely by the novelty of traits of the means by which the novel traits were introduced, The Canadian regulatory system refers to plants with novel traits (PNT) and novel foods in place of GM plants or GM foods.

3.12 Under this regime, all agricultural commodities and food products, whether they are produced using conventional technologies or biotechnologies, are governed under the same acts. Depending on the type of product, the relevant piece of legislation is applied i.e. Seeds Act, Feeds Act, Fertilizers Act, Food and Drugs Act, Health of Animals Act, or the Canadian Environmental Protection Act (CEPA). For example, a herbicide tolerant Canola produced using genetic engineering or accelerated mutagenesis (more established plant breeding tool) are subject to same environmental or food safety risk assessment although the later has been in use for about 70 years and is not subject to stringent regulations in other countries.

(iv) Australia

3.13 In Australia, research, manufacture, production, commercial release and import of GMOs are regulated under the Gene Technology Act 2000 by Gene Technology Regulator (GTR). Every dealing with a GMO needs to be licensed by GTR, unless the dealing is an Exempt Dealing, a Notifiable Low Risk Dealing or on the Register of GMOs. Three advisory committees, the Gene Technology Technical Advisory Committee (GTTAC), the Gene Technology Community Consultative Committee (GTCCC) and the Gene Technology Ethics Committee (GTEC), provide advice to GTR and the Ministerial Council.

3.14 Dealings with GMOs and GM products are also regulated by a number of other regulatory agencies where they are to be used for specific purposes. These include the National Registration Authority (NRA) for agricultural and veterinary chemicals; the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) for industrial chemicals; the Food Standards Australia New Zealand for foods intended for human consumption; the Therapeutic Goods Administration (TGA) for therapeutic goods; and the Australian Quarantine and Inspection Service (AQIS) for the import of plants, animals and biological.

National Gene Technology Regulatory System in Australia

(v) Argentina

3.15 Argentina regulates biotechnology, including transgenic plant and genetically engineered food products through a combination of GMO-specific legislation and pre existing laws covering seeds and veterinary products. Approvals for the environment release of GMOs and their use in human food or livestock feed are administered by the Secretary of Agriculture, Livestock, Fisheries and Food (SAGPyA) created the Commission Nacional Asesora de Biotecnología Agropecuaria (The National Advisory Committee on Agricultural Biosafety or CONABIA) as a mechanism to provide advice on technical and biosafety requirements for environmental releases, human food, and livestock feed uses of genetically engineered plant and animal materials. CONABIA's membership is composed of both public and private sector representatives with a wide range of expertise in agricultural biotechnology. Members are selected according to a transparent process and are approved by SAGPyA. Argentina regulations concerning the environmental release of GMOs were developed by CONABIA and are based in guidelines in the form of non-legislative resolution that are integrated in the overall regulatory system and there is no specific law that makes the resolutions legally binding.

(vi) South Africa

3.16 In 1997, the Genetically Modified Organism Act was passed in 1997 as a new legal instrument specifically to regulate GMOs in South Africa. The Act which came into force in 1999 created an executive council, a scientific advisory committee and an inspectorate for implementation of its provisions. The Act has been developed to promote the responsible development, production, use and application of GMOs. In addition, all imports and exports for agriculture material required a permit issued under the Agricultural Pests Act 1983, The safety of all foods, including foods derived from biotechnology, is regulated under the Foodstuff, Cosmetic and Disinfectants Act, 1972.

(vii) Japan

3.17 Japan uses a series of voluntary guidelines administered through four governmental agencies to ensure safe use and application of recombinant technologies. These include Ministry of Science and Technology for lab level work, Ministry of International Trade and Industry for industrial applications, Ministry of Agriculture, Forestry and Fisheries to oversee the safety of animal feeds, feed additives and environmental release of GMOs and Department of Health and Welfare for food and food additives produced by rDNA technology. These guidelines are not legally binding but are followed on a voluntary basis.

(viii) China

3.18 China's first biosafety guidelines were produced by the State Science and Technology Commission in December 1993, under which the administrative responsibility for biosafety of various products has been assigned to the relevant administrative departments. In 2002, China has established rules on GMOs to strengthen the safety and management of GMO products. Besides other detailed procedures, these rules require all GM products to be labeled.

3.19 In South-east Asia, Philippines and Malaysia have completed their biosafety guidelines. Thailand has approved field testings after finalizing its

regulations in 1993. India has notified rules for manufacture, import, use, etc. of GM products in 1989 under Environment Protection Act, 1986.

3.20 A comparison of principle features and components of regulatory regimes in different countries is presented below with respect to GMO applications in agriculture:

Comparison of principal features of regulatory regimes in different countries for GMO applications in agriculture

Parameter	Countries						
	USA	Canada	EU	Australia	Argentina	South Africa	India
Use of existing legislation	Yes	Yes	No	No	Yes	No	Yes
New legislation and/or regulations	New regulations only	No	Yes	Yes	New resolutions and decrees	Yes	New regulation only
States involved	Plant Protection Act; FIFRA, FFDC	10 pieces of legislation	EU Directed 2001/18/EC (2001); EC regulation 258/97(1997)	Gene Act 2000	Numerous laws, resolutions and decrees	Genetically Modified Organisms Act (1997)	Rules for handling GMOs, (1989) under Environment Protection Act 1986
Agencies involved	USDA, FDA and EPA	Canadian Food Inspection Agency, Health Canada and Environment Canada	Members states competent authorities and European Commission	Office of the Gene Technology Regulator	Secretariat of Agriculture, Fisheries and Foods	Agriculture Ministry	Ministry of Environment & Forests and Department of Biotechnology
Products covered	Plants that could become plant pest, plants engineered to produce pesticides, plants intended as food	Plants with novel traits	All genetically modified organisms; all novel foods and novel food ingredients	All genetically modified organisms	All genetically modified organisms	All genetically modified organisms	All genetically modified organisms and products thereof
Established safety standard in legislation	Yes (for example unreasonable adverse effects on the environment)	-	Yes (for example foods must not present a danger to consume)	-	Yes	No	-
Transparency (Information about regulatory process)	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Transparency (Application and	EPA provides partial information,	-	Summary information made	-	No	Summary information is provided	-

supporting data for field trial and commercialization)	USDA sometimes provide information, FDA does not		available for commercialization, legislation silent on information about field trials or food safety assessment				
Public participation (On individual applications)	Yes for applications to EPA and commercial releases at USDA otherwise no	-	Yes for environmental release, no for food safety	-	No	Yes	No Regulators. If desired, can call for public opinion.
Use of outside scientific experts	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Post-approval activities	Partial conducted by EPA but not by USDA or FDA	-	Yes	-	Unknown	Not required by legislation	Yes
Enforcement authority	Yes but it is not used on regular basis	-	Yes	-	Yes and all field trials are inspected	Yes and inspections are carried out	Well defined mechanism for enforcement
Inclusion of other societal concerns	No	-	Yes	-	Yes	Yes	Yes

(ix) Norway

3.21 Apart from the information submitted by DAC on this issue the Committee have also been given to understand that Norway also has a very comprehensive and bio-safety friendly law for regulation of GMOs. The purpose of the legislation is very clearly laid down in the first Chapter this Act No.38 of 2 April, 1993 relating to the Production and Use of Genetically Modified Organisms, etc. as follows:

Purpose of the Act

The purpose of this Act is to ensure that the production and use of genetically modified organisms and the production of cloned animals take place in an ethically justifiable and socially acceptable manner, in accordance with the principle of sustainable development and without adverse effects on health and the environment.

Substantive scope of the Act

The act applies to the production and use of genetically modified organisms. The Act also applies to the production of clone vertebrates and crustaceans. The provisions of the Act relating to genetically

modified organisms also apply to substances and products that consist of or contain genetically modified organisms.

The Norwegian Law also contains separate provisions for impact assessment; making public methods and plans for monitoring and emergency response and also assessment of foreseeable effects; public consultation; compensation; coercive fines; penal measures; etc.

(x) EU Directive

3.22 From the material furnished to them the Committee found that the European Union have the Directive 2001/18/EC of April 17, 2001 to address the issues of GMOs and genetically modified organisms. Amongst other stipulations the Directive prescribed that the public policy provided an opportunity to provide comments before any GMO or products consisting of Genetically Modified Microorganisms can be released in the environment or placed on the market.

3.23 About the situation obtaining in this regard in India as far as agriculture is concerned, GEAC stated that in the matter of biosafety laws and policies, India was one of the early movers in the developing world, having introduced the national biosafety rules even before the Convention on Biological Diversity (CBD) was adopted at Rio de Janeiro in 1992. The introduction of the biosafety rules in 1989 spelling out the implementation mechanism involving various committees at institutional, district, state and central levels was a pioneering step that was enabled by the Environment (Protection) Act, 1986.

3.24 Rules 1989 was framed based on the global best practices available at that point of time. Therefore, public hearing is not a mandatory component. However, since 2004, all information related to biosafety regulations in India including minutes of the GEAC meeting and biosafety data on Bt cotton & Bt brinjal is available in the public domain and may be viewed at <http://moef.nic.in/modules/project-clearances/geac-clearances/> and <http://igmoris.nic.in/>

3.25 Comments from the public/stakeholders are invited on policy issues, guidelines, and biosafety issues before any decision is taken by the GEAC.

In case of Bt Brinjal, the biosafety data was posted on the website for public comments. The concerns/public views were considered by an Expert Committee (EC-I) before the GEAC allowed large scale trials with Bt brinjal event EE-I. Subsequent to the large scale trials, the GEAC again constituted another Expert Committee (EC-II) to address concerns received from the public and other relevant stakeholders. Further, the decision of GEAC dated 14 October 2009 to allow Bt Brinjal event EE-I for release and the EC-II Report was again posted on the Ministry's website for comments. The Minister for Environment & Forests also obtained views of both national and international experts as well as views of the State Governments. Based on the outcome of the public consultation, a moratorium was issued on 9 February 2010.

3.26 It is therefore submitted that a mechanism has been put in place to integrate public opinion in the decision making process even though it is not mandatory under Rules 1989. However, this aspect has been addressed in the new Biotechnology Regulatory Authority of India Bill where it is mandatory for the authority to consult the public.

3.27 The same EU Directive also stipulates that at the end of the review process the competent authority provides consent only for marking of GMO for a period of no more than 10 years.

3.28 About reasons due to which consent is only provided for marketing the GMO for a period of no more than 10 years in the European Union, GEAC informed the Committee that as per Article 15(4) of the Directive 2001/18/EC of April 17, 2001, the consent for marketing the GMO is given for a period of no more than 10 years in accordance with Council Directives 70/457/EEC and 70/458/EEC, which are applicable to all plant varieties including GMOs. It has been indicated in these directives that the acceptance of a variety shall be valid until the end of the tenth calendar year following acceptance and may be renewed at given intervals if it is still cultivated on such a scale as to justify this and provided that the requirements as to distinctness, uniformity and stability are still satisfied. It may be noted that the system for granting marketing approval for a period of no more than 10 years in EU is not specific for GMOs but applicable to all plant varieties.

3.29 When queried about the position in this regard in India as far as such products in agriculture sector are concerned it was stated that in India under the system of notified varieties by the Ministry of Agriculture, a variety is notified for 15 years and is subject to renewal after that. However, the notification of varieties is not mandatory, and the seeds can be marketed as truthfully labeled. Therefore, this limitation is not applicable to marketing of seeds in general.

3.30 In case of GMOs, as per clause 13(ii) of Rules, 1989, the approval is given for four years followed by renewal of two years. Accordingly, the first approvals for Bt cotton was given for three years followed by renewal on a two year basis. Subsequently, following the adoption of recommendations of Task Force on Agricultural Biotechnology under the chairmanship of Prof. M.S. Swaminathan and Sub-Committee on Bt cotton and related issues under the chairmanship of Dr. C.D. Mayee, GEAC has adopted an event based approval system. In view of the new policy, the requirement of subsequent renewal of each variety/hybrid is no longer applicable.

3.31 However, the New Seed Bill, 2004 which is under consideration prescribes mandatory registration of all seeds including GM seeds for a specific period of 15 years.

3.32 Some of the other provisions of the Directive 2001/18/EC are as follows:

- (i) The phasing out of antibiotic resistance genes;
- (ii) The use of the 'precautionary principle' when assessing GMO effects;
- (iii) The authority for the competent authority to conduct inspections and compliance measures;
- (iv) The requirement to trace GMO at all stages to market;
- (v) The ability to keep confidential sensitive business information while providing the public information about the GMO and its environmental risk assessment;
- (vi) The ability of a Member State to restrict or prohibit use of an approved GMO if new or additional information provides 'detailed

grounds for considering that a GMO ... constitutes a risk to human health and /or the environment’;

- (vii) A statement that ‘Members States may take into consideration ethical aspects’ when reviewing GMO.

3.33 GEAC when asked about the position obtaining in India, in so far as agriculture sector is concerned, in the context of all seven provisions mentioned above stated that in the matter of biosafety laws and policies, India was one of the early movers in the developing world, having introduced the national biosafety rules even before the Convention on Biological Diversity (CBD) was adopted at Rio de Janeiro in 1992. The introduction of the biosafety rules in 1989 was a pioneering step that was enabled by the Environment (Protection) Act, 1986. Therefore, Rules 1989 was framed based on the global best practices available at that point of time. Subsequently, scientific developments in the area of biotechnology have progressed exponentially resulting in newer challenges. Recognizing this, the Government of India has formulated the Biotechnology Regulatory of India Bill 2010 which is in accordance with the best practices available globally and national experiences.

3.34 Keeping in view the above, the India’s position on the seven provisions mentioned above is as follows:

- (i) The phasing out of antibiotic resistance genes

Antibiotic Resistance Marker Genes have been in wide use by plant molecular biologists to develop transgenic plants since 1983. The selectable marker genes such as *nptII*, *hpt* and *aaD* are sourced from ubiquitous bacteria such as *E. coli* (transposon 5), and gram-negative bacteria (Transposons 7 and 21) and are extensively used in the development of transgenic plants/crops/ many of which are commercially cultivated globally.

It is a matter of policy issue on whether to allow GM crops with antibiotic resistance markers since technology for generating marker free transgenic plants is available.

The matter was deliberated in the 105th GEAC held on 8.12.2010 wherein it was noted that GM crops in the pipeline have been developed several years ago based on the technology available at that point of time. Further, it takes several years to complete the safety and efficacy assessments of GM crops. Therefore, any decision to disallow release of GM crops with antibiotic resistant genes would make almost all transgenic plants that are under consideration of GEAC/RCGM ineligible for release. Technological interventions and improvements are ongoing process and would be made available for newer products.

In view of the above, GEAC decided that the GM crops containing markers for antibiotic resistant genes currently in the pipeline may continue to be evaluated on a case by case basis unless scientific evidence is established otherwise. For newer products it was decided to have wider consultations on the matter taking into consideration technologies available and international experience.

(ii) The use of the 'precautionary principle' when assessing GMO effects

As a precautionary approach, the Government of India is following a case by case approval of assessing the safety of a GMO even if it is approved for commercial release in other countries.

GEAC has taken the 'Precautionary Approach' in attaching conditions to the approval of each GM crop on a case- by- case for environmental release and cultivation. For example, while approving Bt cotton, GEAC conditions *inter alia* included (a) every cotton field where Bt cotton is planted shall be fully surrounded by a belt of land called 'refuge' in which the same non-Bt cotton shall be grown; (b) develop plans for Bt based Integrated Pest Management and include this information in the seed packets. (c) undertaking awareness and education programs for farmers, (d) recording impact on non-target insects

and crops, (e) providing testing procedures for identifying the transgenic varieties by DNA and protein methods, etc. and (f) Monitoring of susceptibility of bollworms to be undertaken by CICR, Nagpur.

It may be stated, however, that there are many GM crops with new gene conferring traits in regulatory pipeline posing technical and organizational challenges in near future for monitoring and surveillance. Therefore, there is a need to strengthen the existing system in terms of investments, human resource, and infrastructure providing new institutional frame work for pre and post release monitoring and management

(iii) The authority for the competent authority to conduct inspections and compliance measures

As per Clause 4 (v) & (vi) of Rules 1989, the State Biotechnology Coordination Committee and District level Committees are the competent authorities to conduct inspection and compliance measures.

(iv) The requirement to trace GMO at all stages to market

Labeling of GM seeds or food or food products derived from them is to provide information required to address market and consumer preference.

The labeling of GM/transgenic seeds, food crops and commodities derived from them do not fall under the purview of GEAC. However, for sale of GM seeds (in case of Bt cotton), GEAC has prescribed labeling conditions related to a) packing, b) labeling, c) physical and genetic description of the seeds, d) information on sowing pattern in packets in addition to complying with the requirements for regulating the quality of certain seeds for sale in accordance with Seed Act 1966 and Seed Control Order, 1983 and subsequent amendments implemented by Ministry of Agriculture.

According to Food Safety and Standards Act, 1986, no person shall manufacture, distribute, sell or expose for sale or dispatch or deliver to any agent or broker for the purpose of sale, any packaged food products (including genetically modified or engineered food or food containing such ingredients) which are not marked and labeled in the manner as may be specified by regulations. The regulations for labeling of GM foods are being formulated by Food Safety and Standards Authority.

Globally different countries follow voluntary or mandatory labeling system for products derived from GM crops. In some countries, the threshold levels of adventitious presence of GM ingredients in non-GM products have also been notified and are usually in the range of 0.9 to 5 percent depending upon the stage of processing and the state of final product.

- (v) The ability to keep confidential sensitive business information while providing the public information about the GMO and its environmental risk assessment

Issues pertaining to keep confidential sensitive business information are dealt with as per the RTI Act. However, GEAC does not post confidential, sensitive business information on GEAC website.

It is submitted that this aspect has been addressed in the new Biotechnology Regulatory Authority of India Bill, 2010.

- (vi) The ability of a Member State to restrict or prohibit use of an approved GMO if new or additional information provides 'detailed grounds for considering that a GMO... constitutes a risk to human health and/or the environment'

Clause 13 (ii) of Rules 1989 pertaining to grant of approval states:

“(ii) All approvals of the Genetic Engineering Approval Committee shall be for a specified period not exceeding four years at the first instance renewable for 2 years at a time. The

Genetic Engineering Approval Committee shall have powers to revoke such approval in the following situations:

- (a) If there is any new information as to the harmful effects of the genetically engineered organisms or cells.
- (b) If the genetically engineered organisms or cells cause such damage to the environment, nature or health as could not be envisaged when the approval was given, or
- (c) Non compliance of any condition stipulated by Genetic Engineering Approval Committee.”

Therefore, the biosafety regulation in India provides for revoking the approval in case of either non compliance or any new information pertaining to harmful effects which was not envisaged at the time of approval.

- (vii) A statement that 'Members States may take into consideration ethical aspects' when reviewing GMO

The role and responsibility of GEAC is to address only biosafety issues (both environment and health safety) before according approval for environmental release. GEAC has no role in policy matters related research and development of GM crops, food security, pricing of GM seeds, commercialization of GM crops, labeling for consumer awareness or ethical issues, etc.

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.

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

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

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.

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, Foresteries and Fisheries oversees the safety of animal food, feed and environmental release of GMOs and the Department of Health and Welfare is responsible for food and food additives produced by recombinant DNA technology.

3.40 The Committee have been informed that Norway has a very comprehensive law for regulation of GMOs and products thereof. The primary focus of the Act No. 38 of 2 April, 1993 relating to the production and use of Genetically Modified Organisms is biosafety,

ethics and sustainable development without any adverse effects on the health and the environment. It also has separate provisions for impact assessment; making public methods and plans for monitoring and emergency response and also assessment of foreseeable effects; public consultation; compensation; coercive fines; penal measures; etc..

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

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

3.43 As has been stated previously in this Report the regulatory mechanism in India derives its authority from Rules 1989 and the guidelines and regulations made thereunder from time to time. As the Rules 1989 were drafted more than two decades ago based on the then prevalent global best practices modifications have been

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

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

3.45 Under such circumstances when the stakes are so high, the Committee have strong reasons to agree with the apprehensions expressed by several stakeholders who deposed before the Committee that the basic assessments and data generation by IBSC as also the evaluation of these assessments and data by the accredited laboratories and regulatory agencies based on the samples provided by the company cannot be relied upon fully. The case of Bt BN and Bt NHH44 mentioned in the Report is a case in point. Another tier in the regulatory mechanism viz. the RCGM functions under the administrative control of DBT which is the promoter Department for biotechnology particularly modern biotechnology in the Government of India. Quite obviously inspite of their best efforts to do justice with their mandate to assess biosafety, environmental safety, human health safety, food and feed safety, there is a strong possibility of conflict of interest creeping in.

3.46 RDAC, which is an advisory committee incidentally also functions under the administrative control of the Department of Biotechnology. Coming to GEAC, as the Committee have also mentioned in the previous Chapter, it is headed by a civil servant who is also functioning in another capacity in the Ministry of Environment and Forests, the controlling authority of GEAC. The Co-Chairman of GEAC is a biotechnologist who though purportedly from outside, is nominated by DBT, the promoter Department. The Vice-Chairman is again a civil servant, simultaneously discharging a few more responsibilities in another role in the Ministry of Environment and Forests. By its very composition, the Committee does not have

regular existence and meets monthly, only when some decisions are to be taken. It is also a sad reality that modern biotechnology being a nascent discipline in the Country, we have a serious dearth of scientists of eminence in sufficient numbers, therefore, more or less the same set of people sit on both the sides i.e. to develop technologies and products as also to assess, evaluate and approve them.

3.47 The Government time and again justified, before the Committee, the existing regulatory mechanism as based on best global practices and systems which are followed successfully in the pharmaceutical sector also. It is common knowledge that the regulatory mechanism in the pharmaceutical industry is beset with several problems and shortcomings. In fact the Department Related Standing Committee on Health and Family Welfare in their 59th Report on "The Functioning of the Central Drugs Standard Control Organisation (CDSCO)" presented to the Parliament on 8 May, 2012 have severely criticized CDSCO for several malpractices including working against the interest of patients, collusion with industry and numerous other acts of omission and commission and have recommended to the Government a complete overhaul of the regulatory mechanism for the pharmaceutical industry. Since the Government have drawn a parallel between the regulatory mechanism for GMOs and products thereof with the regulatory mechanism for the pharmaceutical industry, the Committee are of a very strong view that the former also requires to be overhauled, even created *de novo* in the interest of biosafety, environmental

safety, human and livestock health safety. Albeit, it is to be ensured that due concern is paid to the interest of the industry. From their examination of the subject the Committee have found that, hitherto, the tendency of the regulatory mechanism in the absence of specialized infrastructure and R&D facilities in the Country is to base their decision making on practices and studies elsewhere, as also on the assessments and data generated by the company concerned. This type of precautionary approach has lot of scope for mistakes, errors, misrepresentation and misinterpretation. It is, therefore, not at all an ideal regulatory mechanism for a Country like India which is the centre of origin, as also one of the richest centres of biodiversity in the world. We should also not forget that we are the second most populous country in the world and have a huge population of livestock, as well. The present state of our health services and various other social sector services also does not inspire confidence that remedial action, post commercialization would be forthcoming, with any degree of alacrity. In such a situation what the Country needs is not a biotechnology regulatory legislation but an all encompassing umbrella legislation on biosafety which is focused on ensuring the biosafety, biodiversity, human and livestock health, environmental protection and which specifically describes the extent to which biotechnology, including modern biotechnology, fits in the scheme of things without compromising with the safety of any of the elements mentioned above. The Committee, therefore, recommend to the Government with all the power at their command to immediately evolve such a legislation after due consultation with all stakeholders and bring it before the Parliament without any further

delay. In this context the Committee would advise Government to duly consult the Norwegian Law which emulates this spirit to a large extent.

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

CHAPTER - IV

INTERNATIONAL REGULATIONS

4.1 The Committee desired to be apprised about the major International agreements/conventions/protocols pertaining and/or relevant to the matter, to which India is a signatory and the salient features and the binding conditionalities imposed by them on the signatory nations. In their reply the Ministry of Environment and Forests informed the Committee that India is a signatory to the following International Conventions and Protocols pertaining to biodiversity and biosafety:

I. Convention on Biological Diversity (CBD)

4.2 CBD is a legally binding agreement adopted during Rio Earth Summit in 1992. India signed the CBD on 5th June, 1992 and ratified it on 18th February, 1994. CBD has near universal membership with 193 countries as Parties. USA is the only major country which is a non-Party to this Convention.

4.3 While reaffirming sovereign rights of nations over their natural resources, this Convention establishes three goals: conservation of biological diversity, sustainable use of its components, and fair and equitable sharing of benefits arising from the use of genetic resources. Provisions relating to the third objective of CBD, also called access and benefit sharing (ABS) form the core of the CBD.

4.4 Ten meetings of the Conference of the Parties (CoP) to the CBD held so far. India is hosting CoP-11 to the CBD to be held in Hyderabad in October 2012, which is the year of 20th anniversary of Rio Earth Summit.

4.5 There are two unqualified obligations on all Parties to the CBD, including developing country Parties. One relates to the preparation of a National Biodiversity Strategy and Action Plan (Article 6), the other relates to preparation of national reports to the CoP on measures taken for implementation of the Convention (Article 26). India prepared 'National Policy and Macrolevel Action Strategy on Biodiversity' in 1999, which was revised as the 'National Biodiversity Action Plan' that was approved by the

Cabinet in November 2008. Towards fulfilment of reporting obligations, India has submitted its first, second, third and fourth national reports in January 1999, August 2001, November 2005 and May 2009 respectively.

4.6 In pursuance of the CBD India has also enacted the Biological Diversity Act in 2002, and notified Biological Diversity Rules in 2004, to give effect to the various provisions of the CBD, including those relating to ABS.

4.7 In this regard, ICAR, clarifying further informed the Committee that the Convention on Biological Diversity, in its Article 19.3 provides for the safe transfer, handling and use of LMOs in recognition of the potential risk arising from living modified organisms (LMOs). The Article 8 (g) of the Convention directs the members to establish or maintain means to regulate, manage or control the risks associated with the use and release of LMOs resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.

II. Cartagena Protocol on Biosafety (CPB).

4.8 The CPB, the first international regulatory framework for safe transfer, handling and use of LMOs was negotiated under the aegis of the Convention on Biological Diversity. The Protocol was adopted on 29th January 2000. India has acceded to the Biosafety Protocol on 17th January 2003. The Protocol has come into force on 11th September 2003. As of date 162 countries are Parties to the Protocol. Five meetings of the Conference of Parties serving as Members of the Parties to the Cartagena Protocol (COP-MOP) on Biosafety have been held so far.

4.9 The objective of the Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of LMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

4.10 The Protocol promotes biosafety by establishing rules and procedures for the safe transfer, handling, and use of LMOs, with specific focus on transboundary movements of LMOs. It establishes an advance informed agreement (AIA) procedure for ensuring that countries are provided with the information necessary to make informed decisions before agreeing to the import of such organisms into their territory. The Protocol contains reference to a precautionary approach and reaffirms the precaution language in Principle 15 of the Rio Declaration on Environment and Development. The importing country is required to make its decisions in accordance with scientifically sound risk assessments as outlined in Article 15 & 16 and Annex-III of the Protocol. To facilitate its implementation, the Protocol establishes a Biosafety Clearing-House for Parties to exchange information, and contains a number of important provisions, including capacity-building, financial mechanism, compliance procedures and public awareness and participation. The Protocol attempts to reconcile the respective needs of trade and environmental protection in the light of rapidly growing biotechnology industry.

4.11 As a Party to the Protocol, the first and foremost requirement is the setting up of a National Biosafety Regulatory Framework. In the matter of biosafety laws and policies, India was one of the early movers in the developing world, having introduced the national biosafety rules even before the Convention on Biological Diversity (CBD) was adopted at Rio de Janeiro in 1992. The second commitment relates to fulfillment of the reporting obligations. India has submitted its First National Report on Implementation in February 2008 and is in the process of preparing the Second National Report which is due for submission on September 30, 2011.

4.12 Even though the text of the Protocol has been adopted, several critical issues such as risk assessment, liability and redress, documentation and identification of LMOs for Food Feed and Processing, etc are still being discussed in the meetings of COP-MOP. Therefore, globally, progress in the implementation of the Protocol is slow due to the complexity of the issues involved and lack of capacity.

4.13 Elaborating on the salient features of Cartagena Protocol, (ICAR informed the Committee) which regulates transboundary movement of LMOs as follows:

- The Protocol comprising 40 articles is a legally binding agreement to ensure adequate levels of protection for safe transfer, handling and use of LMOs resulting from modern biotechnology that may have adverse effects on human health and conservation & sustainable use of biological diversity.
- It covers transboundary movement, transit, handling and use of LMOs but does not cover non-food or non-feed products derived from LMOs (e.g. paper from GM trees) and LMOs that are pharmaceuticals for humans.
- It allows the members to take decisions on the import of LMOs intended for direct use as food or feed, or for processing (LMOsFFPs), under their domestic regulatory framework.
- The Protocol also promotes cooperation to help developing countries acquire resources and capacity to use biotechnology safely and more efficiently and encourages training to promote safe transfer of technology.

III. Nagoya Protocol on Access and Benefit Sharing

4.14 The CoP-10 to the CBD held in Nagoya, Japan in October 2010 adopted the Nagoya Protocol on ABS after six years of intense negotiations, and nearly 18 years after adoption of CBD. India has made significant positive contributions in finalisation of the Nagoya Protocol, which is being considered as a milestone achievement in multilateral environmental negotiations. India is a megadiverse country rich in biodiversity and associated traditional knowledge. Hence, implementation of the ABS provisions of CBD is of special interest to us.

4.15 The Protocol has been opened for signature from 2 February, 2011 to 1 February, 2012. As on date, 24 countries have signed the Protocol. India has signed the Protocol on 11 May, 2011 after obtaining approval of the Cabinet on 20 April, 2011. The Nagoya Protocol will enter into force 90 days after its 50 ratification. In case 50 ratifications are received by 10 July,

2012, the first CoP- MoP of the Protocol will be held in Hyderabad in October 2012 along with the CoP-11 to the CBD.

4.16 The objective of Nagoya Protocol is the fair and equitable sharing of benefits arising from utilisation of genetic resources. The Protocol establishes a clear framework on how researchers and companies can obtain access to genetic resources and to associated traditional knowledge, and how benefits arising from the use of such material or knowledge will be shared. The Protocol also sets out clear obligations for Parties to provide that users of genetic resources within their jurisdiction respect the domestic regulatory framework of Parties from where the resource has been accessed. The ABS Protocol is expected to address the concerns of biodiversity rich countries such as India relating to misappropriation of genetic resources and associated traditional knowledge and lead to a more balanced implementation of CBD.

4.17 The domestic regulatory framework on ABS is already in place in India in the form of Biological Diversity Act and Rules. There is therefore no need to enact any new legislation or set up a separate national regulatory authority to implement the Nagoya Protocol. If required, necessary changes may be made in the Act or Rules to align it with the Protocol.

IV. Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress in the Context of Cartagena Protocol on Biosafety

4.18 The COP-MOP 5 to the CPB held at NAGOYA, Japan in October 2010 has adopted the Nagoya Kuala Lumpur Supplementary Protocol on Liability and Redress to the CPB after six years of intense negotiations. India is centre of origin/ diversity to several crops. India also has a strong research base and qualified scientist involved in the research and development of products from modern biotechnology in agricultural and health care sector both of which are critical to India. Hence, implementation of the provisions of the Supplementary Protocol on liability and redress is of special importance to us.

4.19 The Supplementary Protocol fulfils the commitment set forth in Article 27 of the Cartagena Protocol to elaborate international rules and procedures

on liability and redress for damage to biodiversity resulting from transboundary movements of LMOs.

4.20 The Supplementary Protocol aims to contribute to the conservation and sustainable use of biodiversity by providing international rules and procedures for liability and redress in the event of damage resulting from LMOs. The Supplementary Protocol reaffirms the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development and recognizes the need to provide for appropriate response measures where there is damage or sufficient likelihood of damage, consistent with the CPB.

4.21 The Scope of the Supplementary Protocol applies to damage resulting from LMOs which find their origin in a transboundary movement. It applies to damage resulting from any authorized use of LMOs as well as illegal and unintentional transboundary movement that started after the Supplementary Protocol has come into force. The domestic law implementing the Supplementary Protocol shall also apply to damage from transboundary movements from non-parties. The Supplementary Protocol specifies the measures that need to be taken in response to damage resulting from LMOs that find their origin in a transboundary movement. In the event of damage or sufficient likelihood of damage to biological diversity, a Government, through a competent authority, would require the person in control of the LMO, i.e. the operator, to take appropriate response measures, or would take such measures itself with a right of recourse against the operator. The right of Parties to provide for financial security is also enshrined in the Supplementary Protocol. Financial security is important to ensure that, if for any reason, the responsible party cannot pay for the damage caused by an LMO, there will be some means available to do so.

4.22 The Supplementary Protocol takes an "administrative approach" whereby response measures are required of the operator (person or entity in control of the LMO) or the competent authority if the operator is unable to take response measures. This would cover situations where damage has already occurred, or when there is a sufficient likelihood that damage will

result if timely response measures are not taken. However, countries can still provide for civil liability in their domestic law.

4.23 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 be enacted to meet the obligations under the Supplementary Protocol as the EPA 1986 and Rules 1989 and the proposed BRAI Bill do not address the concept of (i) damage and sufficient likely hood of damage from LMOs and (ii) response measures including financial security to take preventive measures.

4.24 The Protocol has been opened for signature at the United Nations Headquarters in New York from 7th March, 2011 to 6th March 2012. As of date 23 countries are signatories to the Supplementary Protocol. The Protocol will enter into force on the ninetieth day after the date of deposit of the 40th instrument of ratification, acceptance, approval or accession. MoEF is in the process of seeking approval of the Cabinet for signing the Supplementary Protocol.

4.25 Apart from the above regulations/institutions, ICAR informed the Committee that the following other international institutions were also involved in the regulation of trade of GM crops and GM food:

1. ***The World Trade Organization (WTO)-1995:*** The WTO Agreement on Application of Sanitary and Phytosanitary (SPS) Measures is related to procedures of risk analysis of plant and animal pests and diseases, and food safety. This Agreement concerns the application of food safety and animal and plant health regulations, which should be based on science, applied only to the extent necessary and not discriminate between countries with similar conditions. The guidelines for pest risk analysis (PRA) ensure that all restrictions in trade are based on the assessment of risks and are not arbitrary or discriminate against any exporting country with the same pest status.
2. ***The International Plant Protection Convention (IPPC)-1952:*** The IPPC develops International Standards on

Phytosanitary Measures (ISPMs) against pests of plants and plant products including GMOs. The guidelines include phytosanitary risks that might be associated with LMOs as they are included within the scope of pests and hence, should be considered for PRA to make decisions regarding their risk management. The potential of risk from LMO pests depends in part on the intended use. As for other organisms, certain intended uses (such as high security contained use) may significantly manage risk. For LMOs, as with other pests, options within the country also include the use of emergency measures related to phytosanitary risks.

3. ***The Codex Alimentarius Commission (CAC)-1972:*** The CAC develops international standards including those for food safety and food labeling. The Codex's aim is to anticipate not only the direct risks, but also the indirect/ unanticipated risks that the products of modern agriculture might pose for human health. It states that all the methods including protoplast fusion and/or recombinant DNA technology have the potential to generate unanticipated effects in plants.
4. ***The World Organization for Animal Health (OIE)-1924:*** The OIE harmonizes trade regulations for animals and animal products, and develops standards on animal health including for infectious animal diseases. It ensures *transparency* in the global animal disease situation to improve the legal framework and resources of national *veterinary services*. It establishes standards, guidelines and recommendations relevant to animal diseases and zoonoses in accordance with its statutes and as defined in the WTO-SPS Agreement.
5. ***The Organization for Economic Cooperation and Development (OECD)-1961:*** The OECD undertakes harmonization of international regulations, standards and policies. The OECD was the first to set international safety guidelines for industrial, agricultural and environmental applications of biotechnology. It presents scientific principles that

could underlie risk management for the release of GMOs into the environment. The 1992 OECD report follows from this and defines "Good Development Principles" for the design of safe, small-scale field trials of GM plants and microorganisms.

4.26 On the aspect of major international agreements/conventions/protocols pertaining to/relevant to bio-diversity to which India is a signatory, the National Biodiversity Authority informed the Committee that India has participated in major international events on environment and biodiversity conservation since 1972. India has also contributed to developing the agreed texts, ratified, and complied with the commitments in various international conventions relating to biodiversity. These agreements are: Bonn Convention on Migratory Species (CMS), Convention on International Trade in Endangered Species of flora and fauna (CITES), Ramsar Convention on Wetlands, World Heritage Convention. Some other international agreements which have bearing on biodiversity to which India is a Party include United Nations Framework Convention on Climate Change (UNFCCC), United Nations Convention to Combat Desertification, International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and UN Convention on the Law of the Seas (UNCLOS).

4.27 The Authority further drew the attention of the Committee to the following Conventions/Treaties which pertain to bio-diversity and to which India as a signatory is obliged to follow:

1. Convention on Migratory Species

The Convention acknowledges the importance of migratory species being conserved and of Range States agreeing to take action to this end whenever possible and appropriate, paying special attention to migratory species the conservation status of which is unfavourable, and taking individually or in co-operation appropriate and necessary steps to conserve such species and their habitat. The Convention also acknowledges the need to take action to avoid any migratory species becoming endangered.

In particular, the Parties are requested to promote, co-operate in and support research relating to migratory species; endeavour to provide immediate protection for migratory species included in Appendix I (individual species) and endeavour to conclude Agreements covering the conservation and management of migratory species included in Appendix II (groups of species) respectively of the convention.

2. Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)

The CITES focuses on regulating and prohibiting trade in endangered species, within an International context. Appendix I of the convention includes all species threatened with extinction which are or may be affected by trade. Trade in specimens of these species must be subject to particularly strict regulation in order not to endanger further their survival and must only be authorized in exceptional circumstances. Similarly, Appendix II includes (a) all species which although not necessarily now threatened with extinction may become so unless trade in specimens of such species is subject to strict regulation in order to avoid utilization incompatible with their survival; and (b) other species which must be subject to regulation in order that trade in specimens of certain species referred to in (the convention) may be brought under effective control. Appendix III includes all species which any Party identifies as being subject to regulation within its jurisdiction for the purpose of preventing or restricting exploitation, and as needing the co-operation of other Parties in the control of trade. Parties shall not allow trade in specimens of species included in Appendices I, II and III except in accordance with the provisions of the present Convention.

3. Ramsar Convention

The Convention on Wetlands (Ramsar, Iran, 1971) -- called the "Ramsar Convention" -- is an inter-governmental treaty that embodies the commitments of its member countries to maintain the ecological character of their wetlands of international importance

and to plan for the "wise use", or sustainable use, of all of the wetlands in their territories. Unlike the other global environmental conventions, Ramsar is not affiliated with the United Nations system of Multilateral Environmental Agreements, but it works very closely with the other MEAs and is a full partner among the "biodiversity-related cluster" of treaties and agreements.

4. Convention Concerning the Protection of the World Cultural and Natural Heritage

Each State Party to this Convention recognizes that the duty of ensuring the identification, protection, conservation, presentation and transmission to future generations of the cultural and natural heritage situated on its territory, belongs primarily to that State. It will do all it can to this end, to the utmost of its own resources and, where appropriate, with any international assistance and co-operation, in particular, financial, artistic, scientific and technical, which it may be able to obtain.

5. United Nations Framework Convention on Climate Change

The ultimate objective of this Convention and any related legal instruments that the Conference of the Parties may adopt is to achieve, in accordance with the relevant provisions of the Convention, stabilization of greenhouse gas concentrations in the atmosphere at a level that would prevent dangerous anthropogenic interference with the climate system. Such a level should be achieved within a time frame sufficient to allow ecosystems to adapt naturally to climate change, to ensure that food production is not threatened and to enable economic development to proceed in a sustainable manner.

6. United Nations Convention to Combat Desertification

The objective of this Convention is to combat desertification and mitigate the effects of drought in countries experiencing serious drought and/or desertification, particularly in Africa, through effective action at all levels, supported by international cooperation and partnership arrangements, in the framework of an integrated

approach which is consistent with Agenda 21, with a view to contributing to the achievement of sustainable development in affected areas. Achieving this objective will involve longterm integrated strategies that focus simultaneously, in affected areas, on improved productivity of land, and the rehabilitation, conservation and sustainable management of land and water resources, leading to improved living conditions, in particular at the community level.

7. International Treaty on Plant Genetic Resources for Food and Agriculture

The objectives of this Treaty are the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security.

8. UN Convention on the Law of the Seas

Recognizing the desirability of establishing through this Convention, with due regard for the sovereignty of all States, a legal order for the seas and oceans which will facilitate international communication, and will promote the peaceful uses of the seas and oceans, the equitable and efficient utilization of their resources, the conservation of their living resources, and the study, protection and preservation of the marine environment.

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.

4.29 The Convention on Biological Diversity (CBD) adopted at Rio Earth Summit was signed by India on 5 June, 1992 and ratified on 18 February, 1994. CBD very unambiguously reaffirms sovereign rights of nations over their natural resources and establishes three clear

goals *viz.* conservation of biological diversity, sustainable use of its components and fair and equitable sharing of benefits arising from the use of genetic resources. The access and benefit sharing objective forms the core of CBD. CBD also directs the members to establish or maintain means to regulate, manage or control risks associated with the use and release of LMOs resulting from biotechnology, which are likely to have adverse environmental impacts affecting the conservation and sustainable use of biodiversity as also human health.

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.

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.

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 be enacted 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.

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.

4.34 Apart from these major conventions and treaties there are several more conventions/protocols/treaties/agreements pertaining to the subject. The Committee note that other than the WTO whose primary focus is facilitation of trade, all other relevant treaties, conventions, protocols and agreement very unambiguously underline the need for ensuring biological diversity and sustainability and eliminating any risk to the human health due to use of LMOs, GMOs and products thereof. The Committee are however appalled by the existing state of affairs in these matters in the Country. While we have become signatories to these conventions/protocols/agreements/treaties with alacrity, we have simultaneously not ensured that the necessary wherewithal, scientific expertise, infrastructure and manpower for ensuring compliance is also created. As the succeeding narrative will prove, the Biological Diversity Authority and PPV and FRA could have played a crucial role as an advisor and regulator in several matters pertaining to safety and sustainability of biodiversity but they are just a cosmetic presence. The Committee need not reiterate their observation regarding the state of affairs in the extant regulatory mechanism for the LMOs and products thereof, as it has been already commented upon in one of the previous chapters. However, hugely concerned with the situation on the ground, the Committee cannot but reiterate that the Country requires an all encompassing Bio-safety Authority without any further loss of time.

CHAPTER - V

SCIENTIFIC STUDIES AND REPORTS

(i) IAASTD Report

5.1 The Committee have been apprised that in August, 2002, the World Bank and the Food and Agriculture Organization (FAO) of the United Nations initiated a global consultative process to determine whether an international assessment of agricultural knowledge, science and technology (AKST) was needed. This was stimulated by discussions at the World Bank with the private sector and NGOs on the state of scientific understanding of biotechnology and more specifically transgenics. During 2003, eleven consultations were held, overseen by an international multistakeholder steering committee and involving over 800 participants from all relevant stakeholder groups, e.g., governments, the private sector and civil society. Based on these consultations the steering committee recommended to an Intergovernmental Plenary meeting in Nairobi in September 2004 that an international assessment of the role of AKST in reducing hunger and poverty, improving rural livelihoods and facilitating environmentally, socially and economically sustainable development was needed. The concept of an International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD) was endorsed as a multithematic, multi-spatial, multi-temporal intergovernmental process with a multistakeholder Bureau cosponsored by the FAO, the Global Environment Facility (GEF), United Nations Development Programme (UNEP), United Nations Educational, Scientific and Cultural Organisation (UNESCO), the World Bank and World Health Organization (WHO).

5.2 About 400 of the world's experts were selected by the Bureau, following nominations by stakeholder groups, to prepare the IAASTD Report (comprised of a Global and five Sub-Global assessments). These experts worked in their own capacity and did not represent any particular stakeholder group. Additional individuals, organizations and Governments were involved in the peer review process.

5.3 The IAASTD development and sustainability goals were endorsed at the first Intergovernmental Plenary and are consistent with a subset of the UN Millennium Development Goals (MDGs): the reduction of hunger and poverty, the improvement of rural livelihoods and human health, and facilitating equitable, socially, environmentally and economically sustainable development. Realizing these goals requires acknowledging the multifunctionality of agriculture: the challenge is to simultaneously meet development and sustainability goals while increasing agricultural production.

5.4 Meeting these goals has to be placed in the context of a rapidly changing world of urbanization, growing inequities, human migration, globalization, changing dietary preferences, climate change, environmental degradation, a trend toward biofuels and an increasing population. These conditions are affecting local and global food security and putting pressure on productive capacity and ecosystems. Hence there are unprecedented challenges ahead in providing food within a global trading system where there are other competing uses for agricultural and other natural resources. AKST alone cannot solve these problems which are caused by complex political and social dynamics, but it can make a major contribution to meeting development and sustainability goals.

5.5 The following Governments accepted the Executive Summary of the Synthesis Report as also the Synthesis Report:

Armenia, Azerbaijan, Bahrain, Bangladesh, Belize, Benin, Bhutan, Botswana, Brazil, Cameroon, People's Republic of China, Costa Rica, Cuba, Democratic Republic of Congo, Dominican Republic, El Salvador, Ethiopia, Finland, France, Gambia, Ghana, Honduras, India, Iran, Ireland, Kenya, Kyrgyzstan, Lao People's Democratic Republic, Lebanon, Libyan Arab Jamahiriya, Maldives, Republic of Moldova, Mozambique, Namibia, Nigeria, Pakistan, Panama, Paraguay, Philippines, Poland, Republic of Palau, Romania, Saudi Arabia, Senegal, Solomon Islands, Swaziland, Sweden, Switzerland, United Republic of Tanzania, Timor-Leste, Togo, Tunisia, Turkey, Uganda, United Kingdom of Great Britain, Uruguay, Viet Nam, Zambia (58 Countries).

5.6 The following Governments did neither fully accept the Executive Summary of the Synthesis Report nor the Synthesis Report.

Australia, Canada, United States of America (3 Countries).

5.7 The reservations of these three Countries on the IAASTD Synthesis Report are given hereunder:

Australia: Australia recognizes the IAASTD initiative and reports as a timely and important multistakeholder and multidisciplinary exercise designed to assess and enhance the role of AKST in meeting the global development challenges. The wide range of observations and views presented however, are such that Australia cannot agree with all assertions and options in the report. The report is therefore noted as a useful contribution, which will be used for considering the future priorities and scope of AKST in securing economic growth and the alleviation of hunger and poverty.

Canada: In recognizing the important and significant work undertaken by IAASTD authors, Secretariat and stakeholders on the background Reports, the Canadian Government notes these documents as a valuable and important contribution to policy debate which needs to continue in national and international processes. While acknowledging the valuable contribution these Reports provide to our understanding on agricultural knowledge, science and technology for development, there remain numerous areas of concern in terms of balanced presentation, policy suggestions and other assertions and ambiguities. Nonetheless, the Canadian Government advocates these reports be drawn to the attention of Governments for consideration in addressing the importance of AKST and its large potential to contribute to economic growth and the reduction of hunger and poverty.

United States of America: The United States joins consensus with other Governments in the critical importance of AKST to meet the goals of the IAASTD. We commend the tireless efforts of the authors, editors, Co-Chairs and the Secretariat. We welcome the IAASTD for

bringing together the widest array of stakeholders for the first time in an initiative of this magnitude. We respect the wide diversity of views and healthy debate that took place.

5.8 As we have specific and substantive concerns in each of the reports, the United States is unable to provide unqualified endorsement of the reports, and we have noted them.

5.9 The United States believes the Assessment has potential for stimulating further deliberation and research. Further, we acknowledge the reports are a useful contribution for consideration by Governments of the role of AKST in raising sustainable economic growth and alleviating hunger and poverty.

5.10 The Report has an exclusive theme devoted to biotechnology. Some of the major observations in the Report are as follows:

- Conventional biotechnologies, such as breeding techniques, tissue culture, cultivation practices and fermentation are readily accepted and used. Between 1950 and 1980, prior to the development of GMOs, modern varieties of wheat may have increased yields up to 33% even in the absence of fertilizer. Even modern biotechnologies used in containment have been widely adopted. For example, the industrial enzyme market reached US\$1.5 billion in 2000. Biotechnologies in general have made profound contributions that continue to be relevant to both big and small farmers and are fundamental to capturing any advances derived from modern biotechnologies and related nanotechnologies. For example, plant breeding is fundamental to developing locally adapted plants whether or not they are GMOs. These biotechnologies continue to be widely practiced by farmers because they were developed at the local level of understanding and are supported by local research.
- Much more controversial is the application of modern biotechnology outside containment, such as the use of GM

crops. The controversy over modern biotechnology outside of containment includes technical, social, legal, cultural and economic arguments. The three most discussed issues on biotechnology in the IAASTD concerned:

- Lingering doubts about the adequacy of efficacy and safety testing, or regulatory frameworks for testing GMOs ;
 - Suitability of GMOs for addressing the needs of most farmers while not harming others, at least within some existing IPR and liability frameworks;
 - Ability of modern biotechnology to make significant contributions to the resilience of small and subsistence agricultural systems.
- Some controversy may in part be due to the relatively short time modern biotechnology, particularly GMOs, has existed compared to biotechnology in general. While many regions are actively experimenting with GMOs at a small scale, the highly concentrated cultivation of GM crops in a few countries (nearly three- fourths in only the US and Argentina, with 90% in the four countries including Brazil and Canada) is also interpreted as an indication of a modest uptake rate. GM crop cultivation may have increased by double digit rates for the past 10 years, but over 93% of cultivated land still supports conventional cropping.
 - The pool of evidence of the sustainability and productivity of GMOs in different settings is relatively anecdotal, and the findings from different contexts are variable, allowing proponents and critics to hold entrenched positions about their present and potential value. Some regions report increases in some crops and positive financial returns have been reported for GM cotton in studies including South Africa, Argentina, China, India and Mexico. In contrast, US and Argentina may have slight yield declines in soybeans, and also for maize in US. Studies on GMOs have also shown the potential for decreased

insecticide use, while others show increasing herbicide use. It is unclear whether detected benefits will extend to most agroecosystems or be sustained in the long term as resistances develop to herbicides and insecticides.

- Biotechnology in general, and modern biotechnology in particular, creates both costs and benefits, depending on how it is incorporated into societies and ecosystems and whether there is the will to fairly share benefits as well as costs. For example, the use of modern plant varieties has raised grain yields in most parts of the world, but sometimes at the expense of reducing biodiversity or access to traditional foods. Neither costs nor benefits are currently perceived to be equally shared, with the poor tending to receive more of the costs than the benefits.
- Biotechnologies affect human health in a variety of ways. The use of DNA-based technologies, such as microchips, for disease outbreak surveillance and diagnostics can realistically contribute to both predicting and curtailing the impacts of infectious diseases. The application of these technologies would serve human health objectives both directly and indirectly, because they could be applied to known human diseases and to plant and animal diseases that might be the source of new human diseases or which could reduce the quantity or quality of food.
 - Other products of modern biotechnology, for example GMOs made from plants that are part of the human food supply but developed for animal feed or to produce pharmaceuticals that would be unsafe as food, might threaten human health. Moreover, the larger the scale of bio/nanotechnology or product distribution, the more challenging containment of harm can become.
 - All biotechnologies must be better managed to cope with a range of ongoing and emerging problems.

Holistic solutions may be slowed, however, if GMOs are seen as sufficient for achieving development and sustainability goals and consequently consume a disproportionate level of funding and attention. To use GMOs or not is a decision that requires a comprehensive understanding of the products, the problems to be solved and the societies in which they may be used. Thus, whatever choices are made, the integration of biotechnology must be within an enabling environment supported by local research and education that empowers local communities.

- How agriculture is conducted influences what and how much a society can produce. Biotechnology and the production system are inseparable, and biotechnology must work with the best production system for the local community. For example, agroecosystems of even the poorest societies have the potential through ecological agriculture and IPM to meet or significantly exceed yields produced by conventional methods, reduce the demand for land conversion for agriculture, restore ecosystem services (particularly water), reduce the use of and need for synthetic fertilizers derived from fossil fuels, and the use of harsh insecticides and herbicides.
- Plant breeding and other biotechnologies (excluding transgenics discussed below) have made substantial historical contributions to yield. While yield may have “topped out” under ideal conditions, in developing countries the limiting factor has been access to modern varieties and inputs instead of an exhaustion of crop trait diversity, and therefore plant breeding remains a fundamental biotechnology for contributing to sustainability and development goals.
 - Biotic and abiotic stresses, e.g., plant pathogens, drought and salinity, pose significant challenges to yield. These

challenges are expected to increase with the effects of urbanization, the conversion of more marginal lands to agricultural use and climate change. Adapting new cultivars to these conditions is difficult and slow, but it is again plant breeding perhaps complemented with MAS, that is expected to make the most substantial contribution. Genetic engineering also could be used to introduce these traits. It may be a way to broaden the nutritional value of some crops. If GM crops were to increase productivity and prevent the conversion of land to agricultural use, they could have a significant impact on conservation. However, the use of some traits may threaten biodiversity and agrobiodiversity by limiting farmers' options to a few select varieties.

- Breeding capacity is therefore of great importance to assessments of biotechnology in relation to sustainability and development goals. In developing countries, public plant breeding institutions are common but IP and globalization threaten them. As privatization fuels a transfer of knowledge away from the commons, there is a contraction both in crop diversity and numbers of local breeding specialists. In many parts of the world women play this role, and thus a risk exists that privatization may lead to women losing economic resources and social standing as their plant breeding knowledge is appropriated. At the same time, entire communities run the risk of losing control of their food security.
- The decline in numbers of specialists in plant breeding, especially from the public sector, is a worrisome trend for maintaining and increasing global capacity for crop improvement. In addition, breeding supplemented with the use of MAS can speed up crop development, especially for simple traits. It may or may not also significantly accelerate the development of traits that depend on multiple genes.

Provided that steps are taken to maintain local ownership and control of crop varieties, and to increase capacity in plant breeding, adaptive selection and breeding remain viable options for meeting development and sustainability goals.

- GM plants have been adopted mainly in high chemical input farming systems thus far, the debate has focused on whether the concomitant changes in the amounts or types of some pesticides that were used in these systems prior to the development of commercial GM plants creates a net environmental benefit. Regardless of how this debate resolves, the benefits of current GM plants may not translate into all agroecosystems. For example, the benefits of reductions in use of other insecticides through the introduction of insecticide-producing (Bt) plants seems to be primarily in chemically intensive agroecosystems such as North and South America and China.
- Biotechnology must be considered in a holistic sense to capture its true contribution to AKST and achieving development and sustainability goals. On the one hand, this may be resisted because some biotechnologies, e.g., genetic engineering, are very controversial and the particular controversy can cause many to prematurely dismiss the value of all biotechnology in general. On the other hand, those who favour technologies that are most amenable to prevailing IP protections may resist broad definitions of biotechnology, because past contributions made by many individuals, institutions and societies might undermine the exclusivity of claims.
- A problem-oriented approach to biotechnology R&D would focus investment on local priorities identified through participatory and transparent processes, and favour multifunctional solutions to local problems. This emphasis replaces a view where commercial drivers determine supply. The nature of the commercial organization is to secure the IP

for products and methods development. IP law is designed to prevent the unauthorized use of IP rather than as an empowering right to develop products based on IP. Instead, there needs to be a renewed emphasis on public sector engagement in biotechnology. It is clearly realized that the private sector will not replace the public sector for producing biotechnologies that are used on smaller scales, maintaining broadly applicable research and development capacities, or achieving some goals for which there is no market. In saying this, an IP-motivated public engagement alone would miss the point, and the public sector must also have adequate resources and expertise to produce locally understood and relevant biotechnologies and products.

- A systematic redirection of AKST will include a rigorous rethinking of biotechnology, and especially modern biotechnology, in the decades to come. Effective long-term environmental and health monitoring and surveillance programs, and training and education of farmers are essential to identify emerging and comparative impacts on the environment and human health, and to take timely counter measures. No regional long-term environmental and health monitoring programs exist to date in the countries with the most concentrated GM crop production. Hence, long-term data on environmental implications of GM crop production are at best deductive or simply missing and speculative.

5.11 Since India has accepted IAASTD Report, the Committee was desirous of knowing the considered views of the Department of Agriculture and Cooperation on the Report. They also desired to know that based on their views on the said Report, what policy initiatives have been taken by the Department or what inputs for policy initiatives have been provided by the Department to Government for ushering necessary correctives in the extant policy framework. The Committee further desired to be apprised of the specific action been taken by DAC as the nodal Department on the recommendations contained in the Report.

5.12 In a written reply the Department informed the Committee that the IAASTD study was initiated in 2002 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. DAC 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, DAC follows the policy guidelines of NPF 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.

5.13 Dwelling upon the Report ICAR informed the Committee that IAASTD Report has laid emphasis in its section on 'Biotechnology' on IPR, investment in R&D in modern biotechnology and other agricultural research. The report has shown concern on concentration of ownership of agricultural resources as a result of IPR frameworks; however, IPR is a good instrument to attract investment in agriculture and to claim ownership. According to the IAASTD Report, "biotechnology should be used to maintain local expertise and germplasm so that the capacity for further research resides within the local community." With regard to improvement in agriculture, ICAR has prepared recently its own document on Vision-2030. ICAR takes into consideration the feedback from each State/region in the country through the Regional Committees, AICRIP workshops, etc.

5.14 When queried about the policy initiatives taken by the ICAR and inputs for policy initiatives provided by them to Government for ushering necessary correctives in the extant policy framework ICAR stated that in addition to IAASTD report, ICAR/DARE along with DAC are constantly making efforts to develop strategies for achieving sustainable agriculture which include the following:

1. Integrated Natural Resource Management - INRM practices are based on the addition of ecological principles to more widely recognized areas of agronomy, livestock husbandry and natural resources management.
2. Integrated Pest Management - IPM emphasizes cultural and biological controls and selective application of chemicals where necessary that do not harm human health, biodiversity or populations of pest predators, parasitoids and other standing of agro-ecosystems as complex webs of in crop protection.
3. Organic agriculture (wherever possible and applicable) - Organic Agriculture encompasses practices that promote environmental quality and ecosystem functionality. Organic systems are knowledge-intensive and based on replacing the use of synthetic inputs with ecologically based approaches to soil fertility and pest management.
4. Conservation Agriculture - Reduced tillage and conservation agriculture are low-cost systems that include reduced wind and water erosion, and enhanced conservation of soil organic matter.

5.15 The Committee also sought the views of Department of Science and Technology on the Report. Through a written reply they were informed that the Department agree with the recommendations of IAASTD. It is observed that development and sustainability goals should be placed in the context of:

- (1) current social and economic inequities and political uncertainties about war and conflicts;
- (2) uncertainties about the ability to sustainably produce and access sufficient food;
- (3) uncertainties about the future of world food prices;
- (4) changes in the economics of fossil-based energy use;

- (5) the emergence of new competitors for natural resources;
- (6) increasing chronic diseases that are partially a consequence of poor nutrition and poor food quality as well as food safety; and
- (7) changing environmental conditions and the growing awareness of human responsibility for the maintenance of global ecosystem services.

5.16 The Committee were further informed that the Department are of the view that the study has made a case for an international assessment of agricultural knowledge, science and technology. Such studies are particularly important in the wake of globalized economy and trade as well as sustainability goals of the countries in the world. However, policies of the Governments are derived on the basis of national goals and needs and are contextual. India needs to enunciate clearly national policies on the subject. The Department of Science & Technology have not formulated any policies as the subject is not in the Business of Allocation of the Department. However, the Department are committed to provide scientifically assessed inputs for derivation of policies on GM food as a part of the inter-ministerial consultation mechanism as and when such a policy formulation process for regulation is initiated.

5.17 The opinion expressed by the Ministry of Environment and Forest before the Committee was that the Report covers a wide range of issues which is broadly coming under the purview of Ministry of Agriculture. As and when issues concerning environment are referred to this Ministry, necessary action would be initiated. While the Ministry are not directly involved in policy matters related to poverty alleviation, food security and health care issues, they recognize the importance of these issues in the context of conservation and sustainable use of biological diversity. In matters related to modern biotechnology, the overall objective is to promote the safe use of modern biotechnology by enhancing the effectiveness and efficiency of regulatory procedures and promote responsible use of biotechnology for safeguarding the health and safety of the people of India and to protect the environment. In this context, the Ministry have provided constructive inputs to the proposal to set up Biotechnology Regulatory Authority of India under the aegis of the DBT which has been approved by the Cabinet on November

18, 2010 with a view to streamline the existing regulatory process and ensure compliance with international norms and commitment. The Ministry have also provided inputs to the New Seed Bill, 2004 and the Food Safety and Standards Act 2005.

5.18 When this question was put to GEAC by the Committee it dittoed the views of its nodal Ministry *viz.* Ministry of Environment and Forests. In a written submission to the Committee it stated that the Report covers a wide range of issues which is broadly coming under the purview of Ministry of Agriculture. As and when issues concerning environment are referred to this Ministry, necessary action would be initiated. While the GEAC is not directly involved in policy matters related to poverty alleviation, food security and health care issues, it recognizes the importance of these issues in the context of conservation and sustainable use of biological diversity. In matters related to modern biotechnology, the overall objective is to promote the safe use of modern biotechnology by enhancing the effectiveness and efficiency of regulatory procedures and promote responsible use of biotechnology for safeguarding the health and safety of the people of India and to protect the environment. In this context, the MoEF which serves the GEAC have provided constructive inputs to the proposal to set up Biotechnology Regulatory Authority of India under the aegis of the DBT which has been approved by the Cabinet on November 18, 2010 with a view to streamline the existing regulatory process and ensure compliance with international norms and commitment. The MoEF have also provided inputs to the New Seed Bill, 2004 and the Food Safety and Standards Act 2005.

5.19 The opinion of CSIR was that Report deals with thematic areas such as poverty and livelihoods, food security, environmental sustainability, human health and nutrition, equity, investments, themes such as bio-energy, biotechnology, climate change, human health, natural resource management, trade and markets, traditional and local knowledge and community based innovation and women in agriculture. CSIR are generally in agreement in particular to approach in the Report where R&D investment is prioritized as per local needs, which get identified through participatory & transparent process. However, every nation is to evolve its own approach. At the same time Department must look for inclusive solutions. It is for this

reason that CSIR in 2008 launched CSIR – 800 program to empower the farmers through technology intervention. As regards the policy initiatives taken by them for ushering necessary correctives in the extant policy framework, it was stated that CSIR launched CSIR – 800 in 2008 and extensively supported marker assisted selection technology and R&D on apomixes technology which is the technology of the future. While deposing before the Committee on 10 June, 2011, Secretary, DSIR and DG, CSIR stated in regard to IAASTD Report and related matters:

“I think it is all market-demand driven, when we get connected globally. But the nation’s responsibility is to protect its people and do what is best for the people of the Country. However, so far, farmer option, it is like this. It is a western concept of giving consent. When the genome was done, the western world wanted saying that you take the written consent of the people. So, I used to tell them that the last time a poor man or a farmer has signed, he lost his property. In India, it does not work. He does not even understand what you are getting his signature for. So, it is important that you tell all the world, in WHO in the United Nations, I got them convinced on genome that the informed consent of the people has to be video recorded that you actually explain them correctly that this taking of blood sample has this benefit and the benefit of those research must go back to the people. Today world has accepted it and India is the first country to implement and put that.

The United Nations has given a guideline and we are all signatory in that except three countries, America, Canada and Australia. I think, you must be having a copy of that guideline that the United Nations guideline is very clear. It clearly tells and the major thrust of the report is that the technology that is developed should be responsive to local needs and should involve participation of farmers. This is IAASTD, that is called, Report on International Assessment of Agricultural Knowledge, Science and Technology for Development. This report has been signed by all except three countries of America, Canada and Australia. I think, this guideline is very good guideline. And there is no reason for India which is also the signatory and that is

a good guideline. That is what I feel. It is like this. It is important as consent, option and freedom to choose is there. But if the person is not educated enough, his choice does not make any sense. It is a responsibility of the educated people to understand. That is why I sit here, it is my job. That is why I have said that I have my loyalty towards my profession and to my people before it is to my Government or to my Department or to my scientist because ethics and people are first and that is what I believe. I have expressed it very clearly. It is very important that we stay with high technology but it is also very important that we take all precautions correctly."

5.20 Dwelling further on the Subject he added:

"All drugs and medicines we take, has some side effect. Therefore before we take the medicine, we are aware that it may cause nausea, it may cause vomiting. But you asked a question, by not taking a medicine, I will die out of heart trouble and by taking a medicine I may have some swelling in my leg. This risk benefit has been done by human for health care. As I mentioned, the genetic modifications are of many types. First I gave you the suggestion which is safe, that is, scheme using molecular breeding not by modifying what is not there in the nature. Next take from one food item to another food item, both exist in the nature is also all right. This has been going on by classical trial and error. Now you can go it more smartly and fast. Introducing antibiotic resistance marker is not acceptable, according to me. It should be marker free. In this case, there is already a marker. That is what bothers me because marker is not a good idea – two drug marker. The last is, even if we are using GM, it has gone for cotton and things which are not eatable. So, therefore, technology is not bad but as you said correctly, until each technology is proved safe in the laboratory - hundred per cent. Science is never 100 per cent truth. It is an approach to truth. Every day new results will come. Anytime, the medicine you have consumed, and you get a new report that it is having a problem. So, that medicine gets withdrawn. Unfortunately, when you withdraw medicine, it is taken out of the market. But when you withdraw a black or bacteria is gone, it is very difficult to take it back from earth. So, pollens have gone.

Therefore, it is this query that all tests must be completed before it is commercially released to the public. That is my view. But technology should not be thrown. I am only telling this because tomorrow what will happen is, if you give a signal, the technology is bad, and India is not with this new technology, world will look at us, we are behind.”

5.21 The Department of Biotechnology informed that Committee that they agreed with the recommendations of IAASTD Report. About the policy initiatives taken by the Department and the inputs for policy initiatives provided by them to Government for ushering necessary correctives in the extant policy framework they stated that several of these policy directives are also reflected in the Eleventh Plan approach and continue to be pursued in formulation of Twelfth plan proposals. The Biotechnology Development Strategy formulated by the Department for implementation from 2006 onwards also has a Overall Vision of the Department to “create biotechnology tools and technologies that address the problems of agricultural productivity, food production, nutrition security, health care and environmental sustainability affecting the large section of the society, provide new and emerging products and services at affordable prices, generate employment opportunities and make India globally competitive in the emerging bio-economy”. In line with these principles, the Department is now revising the strategy to include recent developments and principles of use of biotechnology in the changing global scenario. In making the Biotechnology Regulatory Authority of India Bill 2011 through consultative process, the elements of autonomy, accountability, transparency, inclusiveness in terms of organized public consultation, inter ministerial opinion, role of stakeholders in governance of the authority, participation of State Governments have also been adequately addressed with an overall goal to promote the safe use of modern biotechnology by enhancing the effectiveness and efficiency of regulatory procedures and promote responsible use of biotechnology for safeguarding the health and safety of the people of India and to protect the environment.

(ii) Report of Six Science Academies

5.22 In view of serious objections from several quarters to the release of Bt. Brinjal the then Minister of State (I/C) of the Ministry of Environment and

Forests had asked the six science academies to submit their report on Bt. Brinjal. The Report, however, became controversial as reportedly some of its content has been plagiarized. It was stated that the portions relating to regulatory tests carried out on Bt. Brinjal and its effects on animals were taken from a newsletter of Department of Biotechnology and some other sources. DBT is the promoter of transgenics technologies in the Country. The six apex science academies, thereafter, came up with a revised report. Giving the background to the Committee in the matter Director National Institute of Plant Genome Research, New Delhi stated during the Oral Evidence on 28 September, 2010:

“I am a fellow of the four National Academies of Sciences and also of the Third World Academy of Sciences. So, being a member of these national academies, I am aware a little bit of the overall process. When the Minister Shri Jairam Ramesh visited the Indian National Science Academy, he had asked the scientists to give the views of the scientific community about the GM technology. That was the letter which was sent. So, an effort was made to bring all the six academies, which includes the three science academies, engineering, medical and agricultural academies, together, which, if you allow me to say, is a rare event. Normally scientists pursue their field of activity individually, but they try to come together. So, letters were sent to all the fellowships, which may amount almost to 2000, as of now, from India collectively, from all the academies. Those who could express their views had communicated their views through the email system and then a meeting was arranged in the Indian National Science Academy in which almost everyone who was present there, gave his view. Let me say that the situation was like this that except for two, most of the members were in favour of release of GM crops in India. When the report was submitted, it was considered that there should be a communication with the people at large and therefore, a highly technical report is not what has been presented. It is a consolidated view which has been presented, which is in a simplified language, giving the impression of the community and it has also been mentioned that like any scientific endeavour, there is room for improvement and there is room for re-examination and

there is also due recommendation given as to how we could proceed. So, certainly the report says that there is need to strengthen the infrastructure to evaluate the GM technology, there is a need to communicate with the public more effectively, there is need also to do surveillance after the release. So, it is not that the Academies have said that you may just release it and forget it. Academies have said that there are several precautions which need to be taken, but as per the existing requirements of the regulatory process, all the requirements have been fulfilled. So, Bt. Brinjal is a product which is ready for release. Now, regarding the controversy, if you allow me to say and it is my personal view, I was aware of it that there would be several questions because the subject is so sensitive. So, it was not unexpected, but something unexpected has happened and we should admit this – it has been reported in the Media – the views of one of the scientists who works on Bt. Brinjal were also taken. It seems that the views that he expressed are also printed somewhere else by him, which have been incorporated into this report as well. So, the Press is saying, why two views are so similar or is it that the views are of an individual rather than a combined opinion of the scientists. But in the overall wisdom that part was included, not because it is the view of an individual scientist, but because the contents which were a part of that were considered to be appropriate for inclusion into the report. So, that is the larger controversy which is, in a sense, a matter of ethics rather than of science. Scientifically, that part which is considered to have been repeated is also reflecting the views which are scientifically correct, which is my opinion about that particular report.

I should tell you that today at 11 o'clock, the President of the Indian National Science Academy has certainly regretted this event and has sent letters to all of us. He had said that we should not throw the baby with the bath water and we should improve it which we will do. The first thing was that we will admit that there is a mistake and that mistake should be corrected. That will be done for sure. The scientists will correct that part as well. He has also said that as far as the recommendation and the general consideration of the subject of

GM crop technology is concerned, the views of the scientists have been reflected in that report.”

5.23 In view of the fact that the report had been commissioned by the then Minister with a view to assess the environmental and bio-safety aspects of the Bt. Brinjal crop, the Committee sought the opinion of several stakeholders on the report.

5.24 In response, DARE/ICAR informed them that the report by the six science academies advocated the release of Bt-brinjal event EE1 after considering the guidelines and regulation norms of releasing a GM crop in the country. The Committee were further informed that the Department fully endorses the recommendations of the above report on GM Crops. The recommendation pertaining to Bt brinjal as reproduced below is in consonance with the views of the Department:

“The issue of Bt brinjal deserves special attention in terms of its immediate relevance. The overwhelming view is that the available evidence has shown, adequately and beyond reasonable doubt, that Bt brinjal is safe for human consumption and that its environmental effects are negligible. It is appropriate now to release Bt brinjal for cultivation in specific farmers’ fields in identified states. Appropriate distance isolation needs to be maintained, although no deleterious environmental effect is anticipated. The performance in the field, in all its aspects, should be monitored by an independent committee which should not include the suppliers or their representatives”.

5.25 The Department of Biotechnology stated in a written submission that Bt. brinjal contains the same gene as that of Bt cotton approved for commercial use by the same regulatory frame work under EPA 1986 (Rules, 1989), however, with more stringent internationally harmonized revised safety guidelines. The recommendations of RCGM and GEAC on safety assessment were further examined by two more Expert Committees (EC-I and EC-II) constituted by the Ministry of Environment and Forests. The findings of the independent Report of the six science academies (GEAC

Report) on Bt. Brinjal further reiterated the food and environmental safety of the product without ambiguity. The Department therefore endorses the Report of the six science academies (GEAC Report) on Bt. Brinjal.

5.26 The Department of Science and Technology virtually echoing the views of the Department of Biotechnology stated that the Bt Brinjal contains the same gene as that of Bt cotton approved for commercial use by the same regulatory frame work under EPA 1986 (Rules, 1989), however, with more stringent internationally harmonized revised safety guidelines. The recommendations of RCGM and GEAC on safety assessment were further examined by two more Expert Committees (EC-I and EC-II) constituted by the Ministry of Environment and Forests. The findings of the independent report of the six science academies (GEAC Report) on Bt. Brinjal further reiterated the food and environmental safety of the product without ambiguity. The Department therefore endorses the report of the six science academies (GEAC Report) on Bt. Brinjal.

5.27 When the views of the Ministry of Environment and Forests were sought in the matter they opined that as a follow-up to the moratorium on Bt brinjal, the Ministry have received several reports from both national and international experts on the merits and demerits of GM crops in general and Bt brinjal in particular. GEAC in consultation with eminent experts and scientists are examining the contents of the report.

5.28 The Department of Health Research were of the opinion that the report of the science academies seems to be a balanced view based on scientific data available. However chronic toxicity and other associated tests need to be carried out as per requirement, independently after exposure for sufficient period.

5.29 When the views of the Department of AYUSH were sought on the Report, initially they stated that there are two reports viz. (1) Report on the Expert Committee (E-II) on Bt. Brinjal Event EE-1, October, 2009 and (2) Inter-Academy Report on GM Crops under the auspices by six Academics (December 2010). Department of AYUSH is examining at present both the reports from the perspective of medicinal values of GM crops.

5.30 In a subsequent detailed note to the Committee, they informed that there are two reports viz. (1) Report on the Expert Committee (E-II) on Bt. Brinjal Event EE-1, October, 2009 and (2) Inter-Academy Report on GM Crops under the auspices by six Academics (December 2010). The food, agriculture and bio-safety issues with respect to GM crops in general and Bt. Brinjal in particular, have been duly dealt in these reports. Each report contains a set of recommendations. The expert Committee (EC-II) concluded that the benefits of Bt. Brinjal event EE-I developed by Ms Mahyco far outweigh the perceived and projected risks. According to the Committee, Bt. Brinjal event EE-I is safe for environmental release in India and no additional studies/review are necessary. Inter-Academy report on GM crops sought to enunciate a national strategy on GM Crops and recommended release of Bt. Brinjal for cultivation in specific farmer's fields in identified States. However, these reports did not cover medicinal values perspective in comprehensive manner, particularly comparative compositional analysis of the GM Crops *vis-a-vis* traditionally cultivated crops and corresponding selective bio-activity should have been incorporated. Therefore, in the view of the Department, the following studies should have also been incorporated/recommended with respect to medicinal values of GM Crops including Bt. Brinjal:

1. Compositional Comparative Analysis: Compositional comparative analysis will reveal the chemical profile of both traditional and Genetically modified crops. On comparison of chemical profiles, the chemical changes will be observed. The compositional change may alter the medicinal values.
2. Bio-activity: Some transgenic crops may be used in the preparation of medicines of traditional systems. Therefore, the bioactivity study of cultivated transgenic crops particularly with reference to known therapeutic uses may reveal the potential, differences and new bioactivity. This study may be undertaken by selecting suitable *in-vitro* and *in-vivo* models. The study shall provide necessary information about the medicinal values of transgenic crops.

5.31 To avoid any conflict of interest, the aforesaid studies may be undertaken by Public Sector Scientific Institutions.

5.32 CSIR's view on the report was that the academies have studied in detail the subject and prevailing scenario. Thus they have arrived to some recommendation which requires due deliberation. India has rich biodiversity and agro climatic zones; detailed studies are required now to arrive at a policy decision.

(iii) Report of Prof. David A. Andow on Bt. Brinjal

5.33 Several of the stakeholders seeking a ban on transgenics in food crops and on Bt. Brinjal release, etc. have cited before the Committee the Report of Prof. David A. Andow on Bt. Brinjal in support of their plea. The said report is a scientific evaluation of the scope and adequacy of Environmental Risk Assessment for hybrid EE-1 Bt. Brinjal.

5.34 When the Committee sought the views of Department of Biotechnology on the said report they informed the Committee that according to Dr. Andow "GEAC set too narrow a scope for environmental risk assessment (ERA) of hybrid Bt brinjal, and it is because of this overly narrow scope that the EC-II is not an adequate ERA.most of the possible environmental risks of Bt brinjal have not been adequately evaluated; this includes risks to local varieties of brinjal and wild relatives, risks to biological diversity, and risk of resistance evolution in brinjal fruit and shoot borer (BFSB)". In the report a detailed account of environmental and socio-economic issues have been enumerated. The contents of the report are also discussed and analyzed by GEAC. The Department have examined the report. The report is an independent scientific review based on available literature. The Department is of the view that regulation while from ideal standpoint has to consider application of every scientific concepts, tool and technique for assuring that new genetic modifications in crops are safe, however, one has to be careful to assure whether the suggested tools and concepts are possible to interpret and are unambiguous. The regulatory systems are developed globally, based on scientific evidence and experimentation with measurable end points that are reproducible and can be interpreted under various circumstances. Concepts, methods, tools encountered in scientific literature in this context

need to be tested and adequately validated so that interpretation of results is not beset with ambiguity while interpreted by others. If simple, reproducible, cost effective and interpretable scientific processes and procedures are able to assess and predict possible risk, it is time consuming and expensive to use concepts and tools which are not validated and have no rationale for the purpose.

5.35 The Department of Science and Technology more or less repeated the reply of Department of Biotechnology and stated that in the report it is stated that *"GEAC set too narrow a scope for environmental risk assessment (ERA) of hybrid Bt Brinjal, and it is because of this overly narrow scope that the EC-II is not an adequate ERA"*. --*"most of the possible environmental risks of Bt Brinjal have not been adequately evaluated; this includes risks to local varieties of Brinjal and wild relatives, risks to biological diversity, and risk of resistance evolution in Brinjal fruit and shoot borer (BFSB)"*. In the Report a detailed account of environmental and socio-economic issues have enumerated. The Department is aware of this report. The report is an independent scientific review based on available literature. The Department is of the view that GEAC has adopted adequate scientific tools for assessing the specific case of Bt. Brinjal and does not suffer from infirmity of scientific rationales. The process is based on general principle of risk minimization rather than elimination as an approach. It is true that regulation should flow from an ideal standpoint and may have to consider application of every known scientific concepts, tool and technique for assuring that new genetic modifications in crops are safe as enshrined in the said report. However, decision support systems should also be careful to take into account that the suggested tools and concepts are pragmatic and is sure to lead to interpretable and unambiguous conclusions.

5.36 The regulatory systems are developed globally based on scientific evidence and experimentation with measurable end points that are reproducible and can be interpreted under various circumstances. Concepts, methods, tools encountered in scientific literature in this context need to be tested and adequately validated so that interpretation of results is not beset with ambiguity while interpreted by regulators. Systems used by regulators cannot afford to be depend vulnerably on super specialist and interpretable

scientific processes and procedures are able to assess and predict and measure possible risk. It is not advisable to employ procedures which are time consuming and expensive and use concepts and tools which are not yet validated. Therefore, the Department is not in discomfort with the recommendations of GEAC with respect to Bt. Brinjal, in spite of its awareness of the report of Professor Andow.

5.37 DSIR/CSIR were of the view that it is a good report. However, further work needs to be carried out to ensure that a balanced approach gets evolved in Indian context.

5.38 DARE/ICAR were of the opinion that Professor David Andow report deals with the scope and adequacy of GEAC environmental risk assessment of Bt-brinjal and mentions the incomplete environmental risk assessment by the Expert Committee (EC-II) on the Bt-brinjal. The Andow report is a sharp critique on the EC-II of GEAC and the concerned firm.

5.39 They further stated that the Department differ with the views expressed by Professor David Andow that the potential advantages of hybrid EE-1 Bt brinjal seem marginal and uncertain for most Indian farmers, and the environmental risks (including socioeconomic risks) to Indian farmers and consumers remain very uncertain. On the contrary, the recent report (Policy Brief No. 34) issued by National Centre for Agricultural Economics and Policy Research (2010) of ICAR projected significant socioeconomic benefits of Bt brinjal cultivation by small and marginal vegetable farmers of India. Other environmental risks such as development of resistant insects have been considered and suitable resistant management strategies such as deployment of refugia will be kept in place.

5.40 When the views of the Ministry of Environment and Forests were sought on the report of Prof. Andow they stated that as a follow-up to the moratorium on Bt brinjal, the Ministry has received several reports from both national and international experts on the merits and demerits of GM crops in general and Bt brinjal in particular. The GEAC in consultation with eminent experts and scientists are examining the contents of the report.

5.41 GEAC also preferred an identical response in the matter and stated that as a follow-up to the moratorium on Bt. brinjal, the Ministry has received several reports from both national and international experts on the merits and demerits of GM crops in general and Bt. brinjal in particular. The GEAC in consultation with eminent experts and scientists are examining the contents of the report.

5.42 In their written submission on the report of Prof. Andow the Department of Agriculture and Cooperation submitted that the report of Prof. David Andow on Bt Brinjal is a scientific report that evaluates the scope and adequacy of Environmental Risk Assessment (ERA) for hybrid EE-1 Bt. Brinjal. DAC also submitted that MoEF and GEAC were examining the report of Prof. Andow alongwith other reports on the Subject. Furthermore, they also conveyed that ICAR differed from the views of Prof. Andow.

IAASTD REPORT

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.

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.

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.

5.46 A significant finding made in the Report is about modern technology creating both costs and benefits, depending upon the manner in which it has been incorporated into societies and eco-

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

waiver scheme of the Government in 2009 and several other financial packages for the indebted farmers.

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

5.48 The Report has also drawn attention towards the threat of IP and globalization to public plant breeding institutions in developing countries as privatization fuels transfer of knowledge away from commons. There is a contraction both in crop diversity and numbers of local breed. In many parts of the world, women play this role and thus a risk exists that privatization will lead to woman losing economic resources and social standing as their plant breeding

knowledge is appropriated, simultaneously the entire communities run the risk of losing their control over the food security. Based on their Study Visit to Vidharba the Committee are fully in agreement with these apprehensions of IAASTD Report and desire the Government to take immediate steps to remedy the situation in the Country. This Committee find this very true in the context of India also.

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

5.50 The IAASTD Report, has therefore, very rightly concluded about the need for a systematic direction of AKST including a rigorous rethinking of biotechnology and specially modern biotechnology in the decades to come, effective long term environmental and health monitoring and surveillance programmes and training and education of farmers to identify emerging and comparative impacts on the environment and human health and to take timely counter measures. According to IAASTD Report no regional long term environmental and health monitoring programmes exist to date in the countries who are most concentrated with GM foods. Hence long term data on environmental implications of GM crop production are at best deductive or simply missing and speculative.

5.51 The Committee's interactions with the various ministries/departments/agencies of the Government who were

examined for and in connection with the subject have revealed that while there is awareness and appreciation of the various findings contained in IAASTD Report and a lot of preparatory action is available in documents, purposeful and definitive action towards adopting and implementing sustainable and environment friendly practices and technologies in agriculture and allied sectors which will conserve biodiversity and also ensure safety of human health and livestock health is unfortunately yet to be initiated in right measures.

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

Report of Six Science Academies

5.53 The Committee also examined the report of the Six Science Academies on Bt. Brinjal. This report had been prepared on the instructions of the then Minister of Environment and Forests (I/C) in order to assess the environmental and bio-safety aspects of Bt. brinjal. The report got mired in controversies at the outset itself as

allegations of plagiarism were leveled about some of its content. A revised report had to be, thereafter, brought out. The report has given an emphatic clearance for commercial release of Bt. brinjal on the basis of 'the overwhelming view (amongst members of academies) that the available evidence has shown, adequately and beyond reasonable doubt that Bt. brinjal is safe for human consumption and that its environmental effects are negligible'. While doing so, inexplicably the six academies relied upon available data which had become suspect in view of other scientific reports prepared on the Subject. Doubts had already been expressed about the environmental risk assessment performed in respect of Bt. brinjal, it was also being pointed out that chronic toxicity tests had not been performed. Moreover, all the recommended tests and protocols had also not been followed. Several stakeholders were of the opinion that Bt. brinjal being the first GM food crop in the Country ought to have been put through a far more vigorous assessment and evaluation regime by the regulatory authorities in view of the human health dimensions as also the fact that India is the centre of origin of brinjal. Due to very strong opposition to the commercial release of Bt. brinjal the then Minister of Environment and Forests (I/C) had seven consultations across the Country with stakeholders from all walks of life and after careful evaluation a moratorium on Bt. brinjal was placed. The Committee find that inspite of these developments DARE/ICAR have fully endorsed the report of six science academies. That too when two of their own events for cotton *viz.* BN Bt and Bt NHH44 which were generated through their own in house efforts and assessed in their own

network of institutions, have been embroiled in controversies. As referred to in previously in this Report, ICAR is now setting a Committee of outside experts to investigate the entire matter pertaining to BN Bt and Bt NHH44. DBT and DST have also inexplicably come in support of the report of six science academies ignoring several glaring lapses pointed out by various stakeholders in the evaluation and assessment of Bt brinjal. The Department of Health Research without being overtly critical of the report have clearly advised the need for chronic toxicity and other associated tests, independently after exposure for sufficient period. The Department of AYUSH who, inspite of their huge stake in the Subject, had been kept out of loop by GEAC as mentioned previously in this Report, have also brought to the notice of the Committee the need for several further studies in the matter as brinjal is used in several medicinal preparations under the Indian System of Medicine. They have also emphasized the need for having these studies being undertaken in Public Sector Scientific Institutions to avoid any conflict of interest.

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.

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

5.56 The Committee would also like to say a word about the examination of the various reports on the merits and demerits of GM crops by GEAC in consultation with eminent experts and scientists. GEAC had approved the commercial release of Bt. brinjal on the basis of its own assessments as the apex regulatory body for the purpose in the Country. The same agency is now sitting on the judgment of its own decision and also of the various reports on the merits and demerits of GM crops in general and Bt. brinjal in particular. In the opinion of the Committee, it is a clear case of conflict of interest. They, therefore, recommend that evaluation of the various reports on this matter should be done by some other agency such as CSIR, since they not only have sufficient expertise in this regard but also have minimum conflict of interest in the matter amongst the various public sector scientific institutions. The Committee also feel that the examination of various reports has to be expedited and results conveyed to the them at the earliest so that a final view in the matter is facilitated without any further delay.

Report of Prof. David A. Andow on Bt. brinjal

5.57 The Committee note that the report of Prof. David A. Andow on Bt. brinjal is a scientific evaluation of the scope and adequacy of environmental risk assessment of transgenic EE-1 Bt. brinjal. This report had been cited before the Committee by several stakeholders who are against transgenics in crops. The report has criticized GEAC for setting too narrow a scope for environmental risk assessment of Bt. brinjal due to which the assessment of Bt. brinjal by Expert Committee-II was not adequate. Amongst the possible environmental risks that have not been adequately evaluated include risks to local varieties and wild relatives, risk to biological diversity and risk of resistance evolution in brinjal fruit and shoot borer.

5.58 The Committee also note the views of various ministries and departments on this report. Most of them have expressed their disagreement with the observations made in the report regarding the shortcomings in the parameters set out by GEAC for the Experts Committee-II to conduct environmental risk assessment of Bt. brinjal. Some of them have even gone to the extent of justifying their views on the report on the ground that 'if simple, reproducible, cost effective and interpretable scientific processes and procedures are able to assess and predict possible risks it is time consuming and expensive to use concepts and tools which are not validated and have no rational for the purpose'. It has also been put forth before the Committee that 'it is true that regulation should flow from an ideal standpoint and may have to consider application of every known scientific concept, tool and technique for assuring that new

genetic modifications in crops are safe as enshrined in the said report. However, decision support systems should also be careful to take into account that the suggested tools and concepts are pragmatic and is sure to lead to interpretable and unambiguous conclusions.'

5.59 In the opinion of the Committee the above justifications betrays hint of a cavalier attitude towards this highly sensitive issue. Bt. brinjal, unlike Bt. cotton is a food crop and it would have been the first such endeavour in India of a technology on whose safety and sustainability the last word is yet to be heard. Moreso, the contents of the report are still under examination as post moratorium follow-up. In the considered opinion of the Committee since the matter pertains to as a vital issue as human health safety any amount of time and money spent on any number of studies and analysis to evaluate the product is perfectly justified. And taking refuge behind global best practices and internationally laid down norms would not at all suffice. The Government also ought not forget the admission of one of the witness before the Committee that his having put one gene into a rice plant is affecting 600 other genes as well. The Committee, therefore, recommend that the Government should come out of this stereotyped mindset and for the reason enumerated previously in this Chapter get all these reports evaluated and examined by any agency other than GEAC like CSIR, etc., strictly in national interest on the basis of sheer scientific merits.

CHAPTER - VI

SYSTEM PREPAREDNESS

6.1 As is evident from the preceding Chapters, transgenics in agriculture sector is regulated by GEAC which functions under the Ministry of Environment and Forests. The policy matters pertaining to the subject are in the domain of Department of Agriculture & Cooperation under the Ministry of Agriculture while the Research and Development aspects are in the domain of Department of Agricultural Research and Education under the same Ministry. Transgenics being a bio-technology driven phenomenon, the Department of Biotechnology plays a crucial role as the promoter Department in these matters. Research on the subject is also undertaken in some of the research institutions.

6.2 Food, a basic necessity, has a vital bearing on human and livestock health, likewise the technologies and practices adopted for growing food have a profound impact on the environment, bio-diversity, bio-safety, flora and fauna, etc. In this complex scenario the Government and its various agencies which are entrusted with the regulation, induction, post release surveillance, impact assessment, course-correction, etc. have a crucial and decisive role to play.

6.3 In case of this jurisdiction issue assumes a lot more significance that transgenics in food crops as it is a comparatively new technology and there are diverse viewpoints about both, its pros as well as cons.

6.4 The Committee, therefore, examined the Government of India (Allocation of Business) Rule, 1961 to find out whether other ministries/ departments/agencies had some responsibility or the other to oversee or assess the likely impact of the introduction of transgenics in agriculture sector in general and in food crops in particular. They also assessed the role of some of these ministries/departments/agencies during assessment and regulation stages, post release marketing and surveillance, monitoring cost and benefit analysis, consumer rights protection and a host of other issues.

(i) Department of Agriculture & Cooperation

6.5 The Committee in the first instance asked the Department of Agriculture & Cooperation about their direct as also collective responsibilities in so far as the application of science & technology including modern biotechnology to agriculture sector in general and seed production, cultivation and relevant aspects in particular is concerned. The Department replied that basing on the recommendations of the National Commission on Farmers under the chairmanship of Dr.M.S Swaminathan, Government of India approved the National Policy on Farmers, 2007 (NPF). As per NPF, as far as application of science & technology including modern biotechnology to agriculture sector is concerned, major responsibilities vested with DAC are to protect and improve land, water, biodiversity and genetic resources, to develop 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.

6.6 NPF, 2007 specifies that efforts will be made to conserve as well as to develop bio-resources to ensure their sustainable use with equitable sharing of benefits. Two major legislations – the Protection of Plant Varieties and Farmers’ Rights (PPV&FRA) Act, 2001 and the Biological Diversity Act, 2002 – are in place to achieve some of these objectives.

6.7 Further, NPF elaborates importance of science & technology as the key drivers of change in farm operations and outputs and application of frontier technologies like biotechnology, ICT, renewable energy technologies, space applications and nano-technology for improving productivity in agriculture. The responsibility of DAC also is to ensure that technologies that are developed by agricultural research systems, are available to farmers through training and demonstrations, etc.

6.8 As regards the production of seeds, the mandate of DAC includes notification of seeds developed by the breeders and scientists with a view to facilitate its production and multiplication by seed producers, so that it is available to farmers at affordable prices. Through various schemes, DAC is

encouraging investment in infrastructure related to production and processing of quality seeds as per the National Seeds Plan.

6.9 Asked further as to what extent are these responsibilities enshrined in the mandate of DAC as per Allocation of Business Rules 1961, they stated that Allocation of Business Rules, 1961 Part I, Para 5(a) gives the responsibility to DAC for "development of Agricultural Industries including machinery, fertilizer and seeds but excluding cotton, ginning and pressing with the limitation that in regard to the development of agricultural industries, including machinery and fertilizer, the function of DAC do not go further than the formulation of demands and fixation of targets".

6.10 About the powers vested with the Department to facilitate the discharge of such responsibilities by them, they informed the Committee that the Department formulate various schemes and programmes for promotion and development of seed sector in the country. The Seeds Act, 1966. Seeds Rules made there under and Seeds (Control) Order, 1983 vest powers with the DAC to regulate and control the quality of seeds, notify new plant varieties and take steps for development of new plant varieties. The new plant varieties, extant varieties and farmers' varieties are registered under the provisions of the PPV&FR Act, 2001. The PPV&FR Authority has been established in October 2005 to implement the provisions of the PPV&FR Act, 2001.

6.11 The National Seeds Policy, 2002 lays down guidelines on transgenic plant varieties and states that all genetically engineered crops/ varieties will be tested for environment and bio-safety before their commercial release as per the regulations and guidelines under the Environment (Protection) Act (EPA), 1986. Seeds of transgenic varieties for research purposes can be imported only through National Bureau of Plant Genetic Resources(NBPGR). Before commercial release, transgenic crops/varieties are to be tested to determine their agronomic value for at least two seasons under the ICAR coordinated trials along with environment and bio-safety trials as per EPA and these need to be evaluated by GEAC constituted by MoEF under EPA, 1986.

(ii) Department of Food and Public Distribution

6.12 The Department through a detailed Background Note informed the Committee that as per the allocations of Business Rules, 1961, the Department of Food & Public Distribution has the main function of procurement of foodgrains for Central Pool at the fixed Minimum Support Price (MSP) of the Government through FCI and agencies of the State Governments, making arrangements for safe storage of foodgrains in FCI's/CWC's own/hired godowns and distribute the foodgrains through the Public Distribution System by involvement of concerned State Governments to the most vulnerable segments of Indian population at affordable prices. The Department of Food & Public Distribution through Food Corporation of India, moves wheat and rice from procuring States to consuming States. The movement of foodgrains from procuring States to consuming States is meant for distribution to the targeted groups covered under Targeted Public Distribution System and Other Welfare Schemes. Under the MSP operations, wheat, rice and coarsegrains are procured by FCI and State Governments and their agencies in surplus States which are then required to be moved to deficit / consuming States for distribution under PDS. There is no inter-State trade involved on commercial lines other than what is done for meeting PDS requirements.

6.13 The mechanism of quality control of foodgrains followed by Department of Food & Public Distribution is as follows. *For the quality control of foodgrains, uniform specifications are formulated every year for Rabi and Kharif crops by inviting suggestions from every State/UT Governments in a Committee which meets under the Chairmanship of Joint Secretary (Policy) in this Department with Food Secretaries of some procuring States and some consuming States represented on it, Director (CFTRI) and representative of Food Corporation of India's quality control wing.* These specifications must conform to the PFA standards fixed by Department of Health which are now governed under the FSS Act, 2006 being implemented by FSSAI. This Act now governs all food safety measures including regulations of GM foods in India. They will notify necessary guidelines which will include GM foods. It is also incumbent upon FSSAI to create the capacities required for the propose.

The Department of Food & Public Distribution will also follow all the guidelines formulated for GM foods by FSSAI.

6.14 Although, under the Allocation of Business Rules, the Department of Food & Public Distribution is entrusted with the task of attending International Conferences pertaining to Food, and the Department has attended about 59 Conferences since 2006, but none of these Conferences had any agenda items on any policy issues concerning transgenic/genetically modified foodgrains or other food stuffs, except that in six meetings of the Market Conditions Committee of International Grains Council, they have been asking the member countries to report commercial production figures of any genetically modified food crops in which India's information has been nil regarding wheat and rice. Also in the 37th Session of the International Sugar Organisation at Morocco in June, 2010, they had discussed the prospects of genetically modified crops of wheat and cane where again they had asked about commercial production figures in respect of these two crops if any. They had also discussed the status of Research in respect of these two crops, but there was no discussion on any policy issues and no country position on the desirability etc. of genetically modified crops was asked from any country. Since none of the meetings at the international fora attended by the Department ever asked about the country position on any aspect of GM food crops, the Department has not been asked to formulate its position in this matter and so has no such stated position.

6.15 As far as the views of Department of Food & Public Distribution regarding the transgenic/genetically modified foodgrains are concerned, the Department feels that its role will only start after a policy has been formulated by the country for growing genetically modified crops in respect of foodgrains after having made an evaluation about the safety of these foodgrains for human consumption. It is felt that there is already an established and proper regulatory mechanism for making such an evaluation by the competent committees working under the Ministry of Environment & Forests and Department of Bio-Technology assisted by Indian Council for Agricultural Research and Indian Council for Medical Research (ICMR) and recently created Food Safety Standards Authority of India. The Department is of the view that "Rules for the Manufacture/Use/Import/Export and

Storage of Hazardous Micro-organisms, Genetically Engineered Organisms or Cells, 1989" being implemented by the Ministry of Environment and Forests are elaborate enough to deal with the process of evaluation of benefits or harms of genetically modified crops including foodgrains.

6.16 Although the Department of Food & Public Distribution is not a part of the six main committees i.e., (i) Recombinant DNA Advisory Committee (RDAC), (ii) Review Committee on Genetic Manipulation (RCGM), (iii) Genetic Engineering Appraisal Committee (GEAC), (iv) Institutional Biosafety Committees (IBSC), (v) State Biosafety Coordination Committees (SBCC), and (vi) District Level Committees (DLC), but the view of the Department is that it does not have to participate in the day to day working of these technical committees rather it will, at a later date, implement the quality or safety standards or specifications issued by the FSSAI in respect of genetically modified foodgrains as and when the nation starts growing them and deal with its procurement, storage and distribution.

6.17 With the promulgation of FSS Act, 2006, FSSAI has been empowered to regulate genetically modified foods and accordingly the Ministry of Environment & Forests has published their notifications in the Gazette of India to that effect. FSSAI now intends to meet its regulatory obligations by implementing the safety assessment and approval process for genetically modified foods that leverages existing regulatory capacity within the Government of India within Department of Bio-Technology, Ministry of Environment & Forests and ICMR. FSSAI will also establish the expert committee of genetically modified foods which will oversee a public consultation process. FSSAI will also issue guidelines that clearly describe the regulatory framework for genetically modified foods and provide details about the interim process for regulation of these foods. For this purpose, they will also, if necessary adopt and implement the existing guidelines approved and issued by GEAC and RCGM.

6.18 Based on their experience of the various international fora and views formed in the light of the obligations cast upon by the various treaties and agreements with foreign countries in force, the Department were asked about the action taken by them in order to apprise the Government about their concerns or otherwise so that they are factored in while taking a final

decision in the matter of cultivation of GM/Transgenic food crops in the Country.

6.19 In a detailed response it was stated that the Department do not have information about the general perception prevailing at the international fora regarding the cultivation, trade and commerce of genetically modified/transgenic food crops and derived products because the Department have not attended any such Conferences having agenda items on any policy issues in this regard and so far the Department has not been asked to formulate its view on any of the policy issues for any international fora or any national level bodies. However, the Department are aware of the fact that genetically modified foods have the potential to solve the hunger and mal-nutrition problems to some extent and can help protect and preserve the environment by increasing yield and reducing reliance on chemical pesticides and herbicides but the Department also feel that genetically modified foods may pose various challenges in the following areas:

- (i) Food labelling
- (ii) Segregation & identify Preservation at procurement and storage points.
- (iii) Testing facilities of the Genetically Modified crops.
- (iv) Provision of separate storage infrastructure and handling practices.
- (v) Regulation of policies regarding Genetically Modified crops.

6.20 The Genetically Modified foodgrains are required to be labelled as per the Government regulations and segregated from non Genetically Modified foodgrains right from the time of sowing in the field of harvesting, procurement in the mandis and storage in the godowns, in order to avoid contamination. Due care is required for providing labelling of the Genetically Modified crops at all stages, which will require special efforts to separately procure transport and store in a designated storage space. Therefore, before considering allowing genetically modified foodgrains crops, it is required to develop Standard Operating Procedures (SOP), testing facility

and exclusive storage and transportation facilities for such Genetically Modified foodgrains.

6.21 As far as the Department of Food & Public Distribution is concerned, the main mandate of the Department is for procurement of specified quality foodgrains for central pool at fixed MSP through FCI and State Government agencies, making arrangements for safe storage and ensuring the quality intact and thereafter getting the foodgrains distributed to the vulnerable segments of population at fixed affordable prices through Public Distribution System. These quality specifications were earlier as per the PFA Standards fixed by the Ministry of Health and now it is as per the Standards fixed by FSSAI under FSS Act, 2006. This will also be in respect of Genetically Modified foods which also now fall under the purview of FSSAI for their regulation. We have no role to play in respect of Genetically Modified crops as that will fall under the purview of Ministry of Agriculture as well as under the Ministry of Environment and Forests and Department of Bio-Technology. Our role will only start after a policy has been formulated by the country for growing Genetically Modified crops in respect of foodgrains after having made an evaluation about the safety of these foodgrains for human consumption. Once these crops come into existence and we get Genetically Modified foodgrains, then the Department will have to ensure proper labelling, safe storage, etc. as prescribed by the FSSAI in this regard. The role of the Department of Food does not start before the aforesaid events have happened.

6.22 As far as the desirability or safety of GM foods, since this is a highly technical matter and the Department does not have any expertise in this, we are not in a position to state whether the country should have Genetically Modified foods or not. However, if all the above stated technical bodies/authorities decide in future the desirability of Genetically Modified crops/foods, the Department shall have no objection to implementing any actions enjoined upon it in this regard for ensuring the safety and quality of foodgrains at all stages.

6.23 Under the Government of India (Allocation of Business) Rules, 1961,

the Department are amongst other things responsible for the following:

- (i) Matters relating to the Food Corporation of India and the Central Warehousing Corporation.
- (ii) Purchase of foodstuffs for civil requirements and their disposal and also for military requirements of sugar, rice and wheat.
- (iii) Inter-State trade and commerce in respect of foodgrains and other foodstuffs including sugar.
- (iv) Trade and commerce in, and supply and distribution of, foodgrains.
- (v) Trade and commerce in, and the production, supply and distribution of sugar and foodstuffs other than foodgrains.
- (vi) Public Distribution System.

6.24 As is evident all these responsibilities involve dealing in/with colossal amounts of foodgrains and foodstuffs. Furthermore, their sister Department i.e. Department of Consumer Affairs administer 'The Consumer Protection Act, 1986'. Moreover, conclusive evidence on the side/after effects of cultivation of genetically modified/ transgenic food crops and the products derived from them is still awaited leading the Government to put on hold the field trials of a transgenic crop. Furthermore, the Committee have been given to understand by the Departments of Agriculture & Cooperation and Agricultural Research & Education and the Genetic Engineering Appraisal Committee that given the conditions prevailing in the Indian agricultural sector right from farm to the market, segregation of GM/transgenic food crops and their produce and the non-GM food crops and their produce is impossible.

6.25 The Committee, therefore, sought the views of the Department of Food and Public Distribution from the point of view of 'The Consumer Protection Act, 1986' and the issues concerning consumer rights, consumer interests, informed consumer choice and related aspects? They were also asked as to whether they had taken up these matters with the Department of Consumer Affairs and/or any of the entities mentioned above to put forth

their point of view or have they suggested any course correction/ remedial measures to take care of the scenario referred to above. In response it was submitted that Department of Food and Public Distribution does not handle foodgrains produced from GM/transgenic food crops and as such has no view on the issue.

6.26 When asked about the perception of the Department about movement of foodgrains and foodstuffs between the GM free States and those which allow field trials/cultivation of GM/Transgenic crops and whether involvement/intervention of the Department to ensure any remedial/corrective measures in this matter was required it was again stated that Department of Food & Public Distribution do not handle foodgrains produced from GM/transgenic food crops.

6.27 During the course of Oral Evidence of the representatives of Department of Food & Public Distribution on 4 March, 2011, the Committee gathered a distinct impression that for various reasons including that of jurisdiction, the Department were not adequately sensitised and aware of various issues that may crop up, once the question of genetically modified transgenic food crops is settled either way. The Committee, therefore, pointed out to the Department that since introduction of genetically modified transgenic food crops would be an irreversible process their attitude of crossing the bridge when it comes is neither prudent nor advisable. In response a representative of the Department stated:

“we would like to submit that you rightly mentioned that in the past we had imported wheat. Of course, from the data available on the net and others, there has been no research on GM in the case of wheat crop. In any case, whatever imports are there, there has to be a system in place at the port for testing against the GM. Once India takes a decision in principle whether to allow the wheat with GM, the facility to test the samples at the port has to be developed. There are food safety officers under the Ministry of Health. They are responsible to draw the samples from the imported food items and subject those to various tests; it may be quarantine for pest or pathogens or for GM. Then only, they will be allowed. Once that is allowed, this Department can take over such imported consignments for further inward

movement and distribution. So, that testing facility has to be developed.”

(iii) Department of Consumer Affairs

6.28 As per the Government of India (Allocation of Business) Rules “Internal Trade” is a subject of Department of Consumer Affairs. However, the subject of “Inter-State Trade and Commerce” in respect of food-grains and other foodstuffs including sugar is allocated to Department of Food and Public Distribution which is in the same Ministry. Marketing of agricultural produce, setting up of rural marketing etc. are allocated to the Department of Agriculture and Cooperation.

6.29 The Committee were informed that in view of the above, the role of Department of Consumer Affairs in internal trade in foodgrains and agricultural commodities is to work in coordination with these two departments. The State Governments are mainly concerned with the subject.

6.30 The Committee note that conclusive evidence on the side/after effects of cultivation of genetically modified/ transgenic foodcrops and the products derived from them is still awaited. The Committee have also been given to understand by the Ministry of Agriculture (Departments of Agriculture & Cooperation and Agricultural Research & Education) and the Genetic Engineering Appraisal Committee that given the conditions prevailing in the Indian Agricultural Sector right from farm to the market, segregation of GM/transgenic food crops and their produce and the non-GM foodcrops and their produce is impossible. They further note that the Department of Consumer Affairs also administer ‘The Consumer Protection Act, 1986’.

6.31 Keeping the above scenario in view the Committee sought considered views of the Department of Consumer Affairs from the point of view of ‘The Consumer Protection Act, 1986’ and the issues concerning consumer rights, consumer interests, informed consumer choice and related aspect. In their written response the Department informed the Committee that under the Consumer Protection Act, 1986 one of the rights of the Consumer is the right to be informed about the quality, quantity, potency, purity, standard and

price of goods or services, as the case may be so as to protect the consumer against unfair trade practices. (Sec. 6 (b) of the Act)

6.32 Though there is no specific mention about Genetically Modified Food Crops in the Consumer Protection Act, 1986, when a consumer buys any goods for a consideration, he can file a complaint in the appropriate consumer forum if:

Goods which will be hazardous to life and safety when used, are being offered for sale to the public,--

- (a) in contravention of any standards relating to safety of such good as required to be complied with, by or under any law for the time being in force;
- (b) if the trader could have known with due diligence that the goods so offered are unsafe to the public. (Sec. 2 (v) of the Act)

6.33 According to the Department the existing provisions of Consumer Protection Act are adequate to tackle harmful GM products which can be covered under "unethical trade practice" and penal action can be taken against the manufacturers if the matter is taken to the consumer court. No separate specific provision or any amendment to Consumer Protection Act appears necessary at this stage. However, in response to persistent queries of the Committee during the Oral Evidence on 22 October, 2011, Secretary of Department of Consumer Affairs admitted:

"इसके बारे में मैं बहुत ऑनेस्टली बताऊंगा कि हम लोगों ने इस तरह से आज तक कोई रिकमेंडेशन नहीं की है। परंतु अब जब यह बात समिति की मार्फत हम लोगों के ध्यान में आ गई है तो हमारे विभाग के संयुक्त सचिव, फूड सेफ्टी एंड सिक्युरिटी अथारिटी जो समिति के मैम्बर हैं, हम उन्हें इंस्ट्रक्शन देंगे कि यह इश्यु वह अगली मीटिंग में जरूर उठायें कि इसके बारे में नियम बनाना बहुत आवश्यक है, क्योंकि हमारे कंज्यूमर्स के हितों के लिए ये आवश्यक नियम हैं और ये नियम इस अथारिटी द्वारा जल्दी से जल्दी बनाये जाने चाहिए। जैसे ही ये नियम बनेंगे, अपने आप वे इसमें लागू हो जायेंगे।

दूसरी बात आपने एक बहुत व्यापक मुद्दा उठाया है कि जहां ये सभी चीजें बिना पैकेजिंग के बेची जाती हैं, वहां उपभोक्ताओं के हितों की रक्षा कैसे की जायेगी। मैं तुरंत इस बारे में कोई उत्तर नहीं दे सकता। लेकिन मैं यही कह सकता हूँ कि उपभोक्ता मामलों का विभाग इस वि-य में संबंधित विभागों और राज्य सरकारों से जरूर चर्चा करेगा और हम कंसैन्सस लाकर पालिसी इवोल्व करने की कोशिश करेंगे। वैसे

आपने जो मुद्दा उठाया है, वह बिल्कुल सही है। परंतु इस पर किस तरह से काम किया जाए और किस तरह से ग्राहकों की रक्षा हो, जिससे कि उन्हें इस बारे में मालूम हो सके। क्योंकि हमारे ग्राहक संरक्षण अधिनियम में राइट टू एजुकेशन बहुत महत्वपूर्ण राइट है। जब यह एक इतना महत्वपूर्ण नियम है तो लोगों को यह पता होना चाहिए कि वे जो खा रहे हैं, वह जेनेटिकली मोडिफाइड है या परम्परागत तरीके से उत्पादित किया हुआ खाद्यान्न है। अब इसके लिए क्या किया जाए। इसके लिए हम संबंधित विभागों और राज्य सरकारों से विचार-विनिमय करके जरूर कोई पालिसी बनाने का प्रयत्न करेंगे।”

6.34 He further admitted:

“मैं समिति को बताना चाहता हूँ कि इस बारे में अभी तक कोई विचार-विमर्श या चर्चा नहीं हुई है, यह बात बिल्कुल सही है। मैं समझता हूँ कि इस वि-य में आप विभाग को कम से कम तीन महीने का समय दें तो हम लोग सारी राज्य सरकारों और संबंधित विभागों से चर्चा करके इस बारे में जो भी सर्वसम्मति बनती है, उससे समिति को अवगत करा देंगे।.....इसका लीगल फ्रेमवर्क के बारे में विभाग को मालूम नहीं है कि अगर मान लीजिए कि केरल ने कहा है कि हम जीएम फ्री so how they have done it, whether they have passed some legislations or whether they have used some existing legislations? If that is done, then whether it can be done in the other States also? These are the issues, which have to be discussed with the State Governments. Then, we will be able to arrive at some policy in this regard.”

6.35 The witness also assured the Committee:

“In India, there is a voluntary code for vegetarian products. There is a green dot for it. So, it is not mandatory. But, I appreciate your point that any food product, which is coming in the market, should contain some indication on it that it is GM free. We will definitely work on it.

I assure you that there is no effort to scuttle the safety issue. We definitely appreciate what you were saying. If, a person does not want to consume GM food, then he has every right to be informed that this food either has GM or it is free from GM content. We will see that what can be done about it. We will definitely work on it. We are taking whatever suggestions and instructions are coming from you. We take them very seriously.”

6.36 In India a typical scenario prevails presently, as several States have declared themselves as GM Free States while several others are not averse

to field trials/cultivation of GM/transgenic crops. Asked as to how the Department perceived would the rights and interests of the consumers of GM free States be ensured and protected in such a situation, it was stated that the Department of Consumer Affairs will consult with all State Governments and other stake holders to develop policy in this regards in the best interest of consumers.

6.37 As per the Allocation of Business Rules, 1961, the Department are also mandated with the task of regulation of packaged commodities. In view of the reports that commodities derived from transgenic food crops are coming into the Country and the fact that there are divergent opinions on transgenic/genetically modified food crops and the products derived from them, the Department were asked about the action taken under this mandate of theirs with regards to the food commodities/items having transgenic origin.

6.38 In a written submission it was stated that this Department deals with the packaged commodities. The following mandatory declaration on packages are required under the Legal Metrology (Packaged Commodities) Rules 2011.

- (a) Name & address of the manufacturer/Packer/Importer.
- (b) Common or generic named of the commodity.
- (c) Net content
- (d) Month and year of packing
- (e) The retail sale price of the package
- (f) Consumer care details.

6.39 There is no stipulation regarding mandatory mention of any transgenic nature of food in the existing Rules. It is understood that the labelling provisions under Food Safety and Standards act, 2006 provide for the same. This Department will coordinate with Ministry of Health and concerned authorities to ensure that all relevant information is made available to consumers. The Packaged Commodities Rules will be amended, if necessary, to make it mandatory for manufacturers to indicate whether the product is a GM product.

6.40 The Department also enforce the Bureau of Indian Standards Act 1986 as a part of other responsibilities. Given the reports emanating from certain

sections that we are lacking in a well laid out regulatory and monitoring framework for the purpose were asked as to whether they have explored the likelihood of bringing these commodities under the BIS Act, 1986 for ensuring quality control and standardization. The Department replied that BIS has set up technical committee 'Biotechnology for Food and Agriculture' Sectional committee, FAD 23 under Food & Agriculture Division council in 2006 for standardization in the field of food & Agriculture products derived from modern biotechnology. The Committee is also involved in international standardization as an active member of the International Standards Organizations/TC 34/SC 16 'Horizontal methods for molecular biomarker analysis' Subcommittee. The present Scope and Programme of work of FAD 23 is given as below:

Scope of the Committee:

"To develop standards, guidelines or recommendations, as appropriate, for food and agriculture products derived from modern biotechnology or traits introduced into food and other articles of human and animal consumptions, by modern biotechnology, on the basis of scientific evidence, risk and analysis and having regard, where appropriate, to other legitimate factors relevant to the health of consumers, biosecurity, and the promotion of fair practices in the food and agricultural products trade:.

6.41 The list of Indian Standards formulated by FAD 23 is as follows:

- (1) IS 15887:2010 Principles for the risk analysis of food derived from modern biotechnology
- (2) IS 1588:2010 Guideline for the conduct of food safety assessment of food derived from recombinant – DNA plants.
- (3) IS 15889:2010 Guidelines for the conduct of food safety assessment of foods produced using recombinant – DNA microorganisms
- (4) IS/ISO 15955:2010 Foodstuffs – Nucleic acid based methods of analysis of genetically modified organisms & derived products

- Information to be supplied and procedure for addition of methods to ISO 21569, ISO 21570 or ISO 21571
- (5) IS/ISO 21569:2005 Foodstuffs – Methods of analysis for detection of genetically modified organisms & derived products – Qualitative nucleic acid based methods
- (6) IS/ISO 21570:2005 Foodstuffs – Methods of analysis for the detection of genetically modified organisms & derived products – Qualitative nucleic acid based methods
- (7) IS/ISO 21571:2005 Foodstuffs – Methods of analysis for the detection of genetically modified organisms & derived products – Nucleic acid extraction
- (8) 8) IS/ISO 21572:2005 Foodstuffs – Methods of analysis for the detection of genetically modified organisms & derived products – Protein based methods
- (9) 9) IS/ISO 22276:2006 Foodstuffs – Methods of analysis for the detection of genetically modified organisms & derived products – General requirements and definitions.

6.42 It may be seen that BIS has formulated or adopted international standards in the field of Bio technology which are mostly test methods and Guidelines. Moreover, these standards are voluntary in nature for producers to adopt.

(iv) Department of AYUSH

6.43 Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) as per Allocation of Business Rules, 1961 is mandated with the formulation of policy issues for development and propagation of Indian Systems of Medicine.

6.44 The Department have set-up National Medicinal Plants Board in November, 2000 for policy formulation coordination with Ministries/Departments ensuring sustained availability of medicinal plants and to coordinate all matters relating to their development and sustainable use. The Department of AYUSH are also functioning for last 16 years.

6.45 Considering the sensitivity of GMO products, their possible effects on the medicinal properties of agriculture crops which have medicinal value and other medicinal plants and the controversy surrounding the subject the Department were asked about the action taken by them and the National Medicinal Plants Board as a part of the responsibilities entrusted to them in the matter over the years.

6.46 When queried about the concerns being expressed by various quarters regarding the safety, etc. of Bt. Brinjal and other transgenic crops, the Secretary, Department of AYUSH informed the Committee during his Oral Evidence on 10 February, 2011:

“Sir, you are absolutely correct in what you are saying, and we agree fully with what you are saying. Your apprehensions are what we also have. That is why we are seeking the Committee’s support that at least, in future, for the other plants, we must come on to all committees at the initial stage itself so that when the research is carried on, all these issues including impact on human health, including impact on medicinal values, all of these, the departments’ in-charge of that must know so that whatever corrective measures are required can be taken at the beginning itself, not at the end which is why we are seeking the Committee’s support. In the last slide I have mentioned that we wish to come on to these committees. We would now be taking up with the departments. We would request for your support.”

6.47 Elaborating further he stated:

“Sir, could I just add to this? The number of medicinal plants in the country is now estimated at roughly 7,200. Out of these, 960 are traded; out of these, almost 180 are traded in high volume which means more than a 100 tonnes per year. The task is gigantic. That is why there is need for care at every stage. If people just pick up a plant and take it up for research without looking at this aspect, with such a large variety of plants, 7,000 plus, it is not very easy for someone who is not involved in it to keep track and he may not even be concerned with that aspect. Once again, we need your support for coming on to these committees.”

6.48 It was stated that the Department of AYUSH had last year, vide its letter dated 1 June, 2010 from the Secretary, AYUSH to the Secretary, Ministry of Environment & Forests conveyed their concerns that genetically modified Brinjal (Bt. Brinjal) may have implications on AYUSH sector. This Department had also requested that permission for open trials or commercial cultivation of Bt. Brinjal or other medicinal plants should not be given until a detailed analysis of their impact on Indian Systems of Medicines is done by a Group of Experts. A copy of the letter had been endorsed to the Secretary, Department of Bio-technology. Further, the Department of AYUSH had requested Ministry of Environment and Forests to co-opt Chief Executive Officer, National Medicinal Plants Board, Adviser (Ayurveda), Department of AYUSH and Director General, Central Council for Research in Unani Medicine (CCRUM) in GEAC or at least give them a hearing about the concerns of the Department of AYUSH.

6.49 Chairman, GEAC, MoEF sent a D.O. No. 13/7/2007-CS.III dated 25.8.2010 for seeking the comments on the background document prepared by MoEF/GEAC on Bt. Brinjal. In the letter it was mentioned that GEAC has examined the document received during public consultation and a background paper highlighting the suggestion for additional studies to address the concerns that have emerged from public consultation vis-à-vis data available from the studies that have been completed by technology providers have been prepared. The comments of Department of AYUSH were sent through a D.O. dated 22.9.2010. As the said background document itself had focus on safety study and concerns on introduction of Bt. Brinjal, this Department suggested for detailed and comprehensive safety studies to address the concerns. It was also stated that the plants material are highly sensitive to phyto-chemical/agro-climatic/environmental factors.

6.50 It was further stated that since the Department of AYUSH would be impacted in a major way in connection with genetic modification of the plants/crops having medicinal value, it would be essential that the representatives of this Department are associated at all stages of the approval process regarding genetic modification. The Department is presently not associated or represented in the Committees giving approval

for genetic modification of various crops including medicinal plants. Therefore, Department of AYUSH have taken up the matter with the Ministry of Environment & Forests and Department of Biotechnology so that Department of AYUSH get represented on various committees set up in connection with the approval process for genetic modification.

6.51 MoEF vide their D.O. letter dated 7th February, 2011 informed that GEAC have decided to constitute an Expert Committee to review the safety of Bt. Brinjal based on the outcome of public consultations. The Chief Executive Officer, National Medicinal Plants Board; Adviser (Ayurveda), Department of AYUSH and Director General, Central Council of Research in Unani Medicine have been included as a Member of the Expert Committee. Further, they informed that so far no transgenic medicinal plants have been developed and none are under field trials. The research being conducted is of a preliminary nature where the research institutions are developing transformation protocols for integration of the new gene. As the whole process will take several years, the request for co-opting representatives of AYUSH/Unani and National Medicinal Plants Board to the GEAC will be considered at the appropriate stage.

6.52 The Committee were also keen to know as to how co-opting of AYUSH/Unani and NMPB on GEAC serve the requisite purpose years later when researches are completed and the stand taken by the Department on the instant communication of Ministry of Environment and Forests. They were informed that the Department of AYUSH is of the view that there is a need for its involvement at the research stage itself, so that the impact on medicinal properties of the GM crops is specifically studied from the very beginning itself. A number of Committees involved in the approval process for GM crops have been constituted under the relevant Rules, such as (1) Review Committee on Genetic Manipulation (RCGM); (2) Institutional Biosafety Committees (IBSC); (3) Genetic Engineering Appraisal Committee (4) State Biotechnology Co-ordination Committee (SBCC) and (5) District Level Committee (DLC) under "The Rules for the Manufacture Use/Import/Export and Storage of Hazardous Micro Organism/Genetically Engineered Organisms or Cells, 1989" framed under Environment (Protection) Act 1986. The Biotechnology Regulatory Authority of India

(BRAI) Bill, 2010 is also under active consideration by the Department of Biotechnology. Now Department of AYUSH have taken up the matter with the Ministry of Environment & Forests and Department of Biotechnology so that Department of AYUSH get represented on various committees set up in connection with the approval process for genetic modification. Further, the Department of AYUSH would pursue the matter with both Ministry of Environment & Forests and Department of Bio-technology to get due representation in these Committees.

6.53 Noting from the same communication of the Ministry of Environment and Forests that in the meantime CEO, NMPB, Advisor (Ayurveda), Department of AYUSH and Director General, Central Council for Research in Unani Medicine have been included in the Expert Committee to review the safety of Bt. Brinjal. Some background documents have been circulated to them. And their comments on the background note have also been sent to the Ministry of Environment and Forests. But no meeting of the said Expert Committee has been held so far, the Committee sought a detailed clarification on the entire matter. They were apprised by Department of AYUSH that the Ministry of Environment & Forests vide their O.M. F.No. C-12013/4/2011/CS.III dated 28.02.2011 have now informed as follows:

“Subsequent to the moratorium on Bt. Brinjal Event EE-1, on February 9, 2010, the Genetic Engineering Appraisal Committee initiated the exercise of reviewing the outcome of the public consultation. Review of the 530 page document took some time. Subsequently a background paper highlighting the additional studies recommended by scientists/experts to address the concerns that have emerged from the public consultations as well as studies that have been completed so far was prepared and circulated to 18 scientists and experts including Department of AYUSH/Unani and NMPB. As the matter is of a highly technical in nature, it was felt that adequate time should be given to the experts. Comments from some experts have now been received. Further all experts being very senior members, there was some time constraints in scheduling the meeting on a convenient date. It is now proposed to hold the meeting of the Expert Committee during April 2011.”

6.54 From the documents submitted to them, the Committee also learnt that the Department of AYUSH came to know only on 7.2.2011 that CEO, NMPB; Adviser (Ayurveda) and DG, CCRUM have been included as the members of the expert committee, constituted by GEAC to review the safety of Bt. Brinjal. This slip was attributed by GEAC to oversight.

6.55 On the aspect of the effect on the exports of medicines prepared under various Systems of Indian Systems in case they are extracted/ prepared from Genetically Modified Agricultural Crops, medicinal plants and other Genetically Modified commodities. The Department informed the Committee that Only after the comparative analysis of chemical composition and bioactivity of genetically modified medicinal plants and conventionally cultivated medicinal plants the effect of medicinal values in Genetically Modified produce may be ascertained. In Indian systems of medicine, medicinal plants are largely used for preparation of medicine because of their medicinal values. Ministry of Environment and Forests & Department of Bio-Technology have informed that so far no genetically modified medicinal plants are under field trials. As no field trial of genetically modified medicinal plants has been undertaken, it is difficult to comment on the medicinal values of genetically modified medicinal plants. Therefore, the effect on the exports of medicines prepared under various Indian system of medicine in case they are extracted/prepared from genetically modified medicinal plants may not be properly estimated in the absence of actual data.

6.56 The National Medicinal Plants Board is also entrusted with the development of protocols for cultivation and quality control and for encouraging the protection of Patent Rights and IPR. About the efforts made by NMPB with a view to development of protocols for cultivation and quality control and for encouraging the protection of Patent Rights and IPR in the context of and with a view to monitor and regulate the transgenic research and development in food crops/medicinal plants, etc. during all these years, the Committee were told that the National Medicinal Plants Board has finalized agro-techniques of 82 medicinal plants and first volume of "Agro-techniques of Selected Medicinal Plants" covering 50 medicinal plants has already been published.

6.57 The quality of AYUSH products is critically dependant upon the quality of raw material used for their manufacturing. For the purpose of ensuring the quality of the medicinal plants, the National Medicinal Plants Board, Department of AYUSH has developed Good Agricultural Practices for Medicinal Plants and Guidelines on Good Field Collection Practices for Indian medicinal plants.

6.58 Through Quality Council of India the NMPB has also finalized the "Voluntary Certification Scheme for Medicinal Plants Produce" based on Good Agricultural and Good Collection Practices to enhance confidence in the quality of India's medicinal plant produce and make available good quality raw material to the AYUSH industry.

6.59 India has unique repositories of Traditional Knowledge (TK), associated with medicinal plants. The TK is very important for bio-prospecting and development of new drugs. TK needs to be preserved for perpetuity and posterity. In due appreciation of the needs for preservation of TK, the NMPB has supported a project of National Innovation Foundation to "develop database of less common medicinal plants by way of compilation of associated traditional knowledge". The project would encourage the protection of Patent Rights and IPR.

6.60 In response to all questions passed by the Committee regarding human health the Department of AYUSH passed on the responsibility to respond on the Department of Health Research.

6.61 When asked as to whether this implied that the knowledge and expertise available within the various Indian Systems of Medicine is not comprehensive enough to analyse the effects of GM Crops/commodities on human health though almost all medicines are derived from plants. It was stated that in response to the questions related to human health research, Department of Health Research was requested to submit response because the subject matter comes under the purview of that Department and they have been associated with the approval process with reference to genetically modified crops as the representative of Indian Council of Medical Research (ICMR) is member of Review Committee on Genetic Manipulation (RCGM) and Genetic Engineering Appraisal Committee (GEAC). The intention behind

requesting Department of Health Research to respond these questions was to provide appropriate and accurate inputs to the Committee. As far as knowledge and expertise available with the various Indian Systems of Medicines for analyzing the effects of Genetically Modified Crops/Edible Commodities on human health are concerned, they have the competence in conceptual perspective; however, there is need to develop the infrastructure and competence in terms of experience and practical skill.

(v) Department of Commerce

6.62 As per the Government of India (allocation of Business) Rules, 1961, the Department of Commerce is entrusted with the responsibility of the policy matter 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 & cotton.

6.63 The Committee, therefore, sought details of the countries importing food grains and commodities derived/produced from food crops during each of the last ten years from India. The data for country wise exports in last ten years is given in **Annexure - V**.

6.64 Based on the inputs received from traders and exporters, analysis of international market trends, consumer preferences, the Department were asked by the Committee about the international trading and exports potential of genetically modified agricultural produce including food grains and commodities derived/produced from food crops. The Department informed the Committee that genetically modified crops are not cultivated in India in a big way. Presently only Bt cotton is commercialized in India. Around 90% of the cotton grown is Bt cotton and only 10% of the area grows organic cotton. GEAC has approved the trials of transgenic mustard, corn, brinjal and tomato which are under various stages of testing and trials in the country.

6.65 The major exporters of GM crops/products which include soya bean, rapeseeds, wheat, maize etc. are USA, Argentina and Brazil. Whereas, the major importers include China (mostly for feed soya for edible oil), Indonesia, Philippines, Cambodia. The EU in general has a strict regime for

not permitting import of genetically modified crops. The global trade in GM food and food products is estimated to be around USD 4 billion.

6.66 Since the Department, amongst other things, are responsible for International Commodity Agreements (other than relating to wheat, sugar, jute and Cotton), they were asked that based on their experience of the existing legal provisions of various bilateral or multilateral International Commodity Agreements what would be the prospects of international trading and exports of genetically modified food crops and commodities derived/produced from such food crops.

6.67 It was stated that the Department of Commerce favours a stable and long term export policy for the exports of agricultural produce. The surplus available after accounting for domestic requirement, food security issues, etc. should be allowed to be exported out of the country. To the extent that Genetically Modified 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, international trade in such products can take place. This will also depend upon international acceptance to the Genetically Modified food and food products. Speaking on this aspect Director of the National Institute of Plant Genome Research informed the Committee during the Oral Evidence held on 28 September, 2010:

“Finally, I come to trade. I have noted that one also. It is true that there are some sensitive points. I agree to this thing. Today, if we have the basmati transgenic, our trade with Europe would be affected. Therefore, we should be careful at it. The academy has also recommended that there should be a strategic planning and some prioritisation of research where the GM technology needs to be applied. It need not be applied blindly everywhere. So, there should be a group for that.”

6.68 In accordance with the Government of India (Allocation of Business) Rules, 1961, the Department are also responsible for production, distribution (for domestic consumption and exports) and development of plantation crops, tea, coffee, rubber, spices, tobacco and cashew. From this point of

view, the Department were asked as to whether they have pondered over the prospects of exports as also international acceptance of some of the above mentioned crops or their produce in case they are genetically modified. They replied that there is no such proposal of international trade in GM Food Crops. Rubber Board of India has received permission from the GEAC to take up field trials in 0.5 ha each in the research farms of RRII in Kerala and Maharashtra. However, Rubber Research Institute of India has not done any field trials with genetically modified rubber so far.

6.69 There are no other proposals for genetic modification of plantation crops used for human consumption. It is felt that there may be no real demand for such GM crops when the emphasis is on organic production.

6.70 As per the Government of India (Allocation of Business) Rules, 1961 the Department are also mandated with the task of development and expansion of export production in relation to all commodities, products, manufacturers, semi-manufacturers including agriculture produce within the meaning of the Agriculture Produce (Grading and Marketing) Act, 1937. Querried as to whether the Department have a well laid roadmap to be followed to ensure that quality and standards wise , these products are totally in sync with and in conformity with the requirements of the international markets and our exports continue to maintain an upward trend, it was stated that this Department has many agencies/EPCs functioning under its aegis for the development of infrastructure and market abroad for various indigenous products including agriculture.

6.71 The Department, in consultation with other Ministries/Departments, lay down the policies/guidelines for the exporters for regulating the export of the commodities in sync with the requirement of International Trade. The Department are regularly monitoring any untoward development reported by our Mission abroad and the same are brought to the notice of all agencies involved in export promotion. They, in turn, sensitise their stakeholders on these developments and suggest corrective measures/compliance etc.

(vi) Department of Health Research

6.72 On the vital aspect of safety, Secretary, Department of Health Research and Director-General, Indian Council for Medical Research informed the Committee during his Oral Evidence on 18 January, 2011:

“So far the apprehensions have actually been from two angles. As far as the biologists and the agricultural people are concerned, it is the bio-diversity. That is the issue that they can address whether it is going to have a negative impact on the other crops or the similar crops. But from the medical angle, the apprehension is in terms of any unknown changes. First is the allergy which they could not find, but then they said that they should have carried out another test, the IGE Test. The second is on the terms of any systemic damages in the body. Now in the 14 days and in the 90 days test reports which were produced from the INTOX that does not tell of any effect on any system. But the long term, as I said, those two reports from abroad published in 2008 and 2009, they tell that if the long term exposure is there then there is a mild hepatic and renal derangement. Also, there is also a litter size of the second generation and third generation becomes less. I think, in my view, to lay the apprehensions to rest, the best way is to test it. I have seen the debate. It has been one argument versus another argument, one finding a fault with another’s data. I suggested last year also and we have also started doing those experiments in our centre at FDRTC in Hyderabad. We advise our scientists also saying that they may go ahead with their research but we should have our own independent investigation which are not funded by the company but our own funds. So, we have begun those experiments already. After this controversy the people failed to resolve them. I feel that in the long run the Department of Health Research has to lay the standards as far as health is concerned. In my view we cannot depend on somebody prescribing from saying you go ahead with this and do not go ahead with that. So, we should have our own standard manuals, though the Department of Bio-technology and ICMR long back published the guidelines. But I think that we should have our own data generated from India also and that it will take little more time but it ought not to be an indefinite delay, both ways, if the

interest of the farmers have to be protected and the agriculture sector has to be protected. Food security is an issue and we cannot ignore. In the terms of a conservative nature if we keep on blocking a progress, that is impossible. But we must prove it. We have taken steps already and we have moved.”

6.73 Queried about the existence of any post-release surveillance in view of media reports about Bt. cotton causing skin problems to those in contact, he admitted:

“We have not really looked at that data. That data sporadically poured in. There is no documentation of the entire population being exposed to that. I think, that surveillance has to be put in place. But so far these are just sporadic reports. Based on that it is impossible to draw a conclusion. I have looked at those reports. We have discussed them in our meetings.”

6.74 On the question of the probability of Gene Transfer and the need for cooperation between various agencies mandated with different responsibilities in the system he clarified:

“Then about the introduction of the gene in our crops, whether it will disturb the eco system around and whether the same will get transferred to other plants and animals, can it get incorporated into the animal genes, etc., people have not found any evidence so far. People have tried those experiments but we cannot say that it does not happen and it cannot happen. I am not the person to say it. Or as a scientist, I am not supposed to say so. From bacteria to plants, genes can go. Agro bacterium is one species through which the genes can go to the plants. Otherwise, going back into the bacteria has not been seen so far. But we should not ignore something happening in biology. We take your suggestion that we must do that. But the point which I was going to make as one of my submissions is that in a country where food security will be an issue in future, we are considering it seriously. There, ICMR, ICAR and may be the Department of Health Research and the Department of Agriculture, Education and Research and the Ministry of Environment and Forests have to create a group actually. There should be a statutory

committee formed by these Departments. As regards the animal side, they have to do research from their side and already, people are testing on avian species and others. That data should be seen by each other and jointly investigated because in India, it will be experimental so far. Nothing is natural and whatever reports are there, they are from abroad. But we must analyse them jointly. When we look at the problem more and more, we feel the need of a joint committee because GM crops and other things are going to be there for a long time. There is a felt need and there is a strong feeling by some people that to meet food security, we should do that.”

6.75 About the regulatory mechanism and evaluation and assessment procedures, the witness informed the Committee:

“My immediate reaction is that we have thought of this subject. We have discussed about it. There should be regulations and there should be regulatory control. I have another opinion which we discussed in those Committees. I am conveying that when we say any testing, it should be independent. So far, we trust on the companies themselves sponsoring their toxicology testing, their this evaluation and that evaluation. Our own institutions have their own responsibilities that we should take up our own testing mechanisms and we should have our own testing. For the surveillance later on, it should be a regulatory control and preferably through the Government which we can control. That was the view point.”

6.76 On the question of reliability of data being assessed and evaluated for approval of transgenic agricultural crops, he stated:

“Our institutions in Hyderabad, the NIN and the Food Toxicology Research Centre, work on the food and drug toxicology from the human safety point of view. When this entire thing was building up, they were only given the responsibility to look at the data work which was generated from somewhere else. We have not set up any protocol for testing the products of company A or company B because the companies in India get it tested from a number of accredited institutions. Drug Controller General accept them for the drugs. Now from food point of view, they went to one of the INTOX companies in

Pune. So, they had generated the data.----- Initially we were given only the responsibility of only to look at what has been done elsewhere. As experts, we are members of the Committee on RCGM and the Genetic Engineering Appraisal Committee. Actually, during the last one-and-a-half years when this debate started building up, then we instructed our own institution in Hyderabad. We said that we should have our own data. We should start testing of our own, whether somebody asks or somebody does not ask us. This is a question for a public good. We have to generate data. They have started working on that. They have started working on the animal which is also shown here. There are a number of things like bt. maize, bt. brinjal. They have started testing of their own. We have taken up these initiatives as a scientific body. The ICMR collects the data which I again head as the Director General. Then, the Government will take a view. So, creating other forum, we propose to do it with the ICAR and DHR because it should be a joint-one looking at the animal data so that the country gets one opinion which is well-debated. We will get back to you. We are already working on it. We would not fail the country's confidence. We will do that."

6.77 When the Committee broached the matter of adequacy or otherwise of the tests being conducted to evaluate safety of these products, he stated:

"When I have been saying that it is 'my view', it is not my personal view. These are the views of the Department because I would not have any identity till I would be in the Chair. Secondly, when I am thinking about the minimum exposure, I totally agree with you. We must totally go on the higher side. That suggestion of yours is appropriate. At least 90 per cent of the average life span of the animal should be exposed and this applies for whichever species we test. Rats are the normal animals which are tested as recommended by the international guidelines. But we can go for the rabbits and try others also because in a developing area, we should be overdoing it and not less of it. I totally agree with your point of view."

6.78 The Committee also sought the views of Secretary, Department of Health Research and Director-General, Indian Council of Medical Research on

the reported violations of protocols during the evaluation and assessment done by the regulatory mechanism. He initially stated:

“Sir regarding the violation of the protocols, we do not have data to comment on the issue.”

6.79 When told that the Committee could not agree with this explanation that he did not have data on violation of the protocols as he happened to be the member of these two Committees which were meant for ensuring all these things and that even if he had not been informed he could have raised this issue on the basis of media reports in the Committee itself. The witness further stated:

“I think we will get back to you with this type of detail. Offhand, I cannot answer this. I apologize. I do not have that data. I was talking about the present testing of the bt. brinjal.”

6.80 The witness was, thereafter, directed to furnish a detailed report in the matter to the Committee within 15 days. This Report was, however, not submitted.

(vii) National Biodiversity Authority

6.81 The aims and objectives of National Biodiversity Authority which administers the Biological Diversity Act, 2002 are as follows:

- Reaffirming the sovereign rights over its biological resources of India
- To prevent misappropriation of bioresources and/or associated knowledge.
- To protect biodiversity in general in an holistic manner
- To regulate use of biological resources
- To ensure sustainable utilization and equitable benefit sharing
- To provide legal recognition and support to the bioresources and associated traditional knowledge.

6.82 To achieve its mandate NBA as per Sub - Section 1, 2, 3 & 4 of Section 18 of Biological Diversity Act, 2002 is vested with powers to:-

- Advise the Government of India on matters relating to conservation of biodiversity, sustainable use of its components and equitable sharing of benefits arising out of utilization of biological resources.

- Regulate activities and issue guidelines for access to biological resources and for fair and equitable benefit sharing in accordance with the sections 3, 4 and 6 of the Biological Diversity Act, 2002. Certain individuals/ nationals/organizations require prior approval of NBA for obtaining biological resources and/or associated knowledge for use.
- Take necessary measures to oppose the grant of intellectual property rights in any country outside India on any biological resource obtained from India or knowledge associated with such biological resource derived from India.
- Advise the State Governments in the selection of areas of biodiversity importance to be notified as heritage sites and suggest measures for their management.
- NBA and SBB provide guidance and technical support to Biodiversity Management Committees (BMC) for preparing People's Biodiversity Registers (PBR).
- Perform such other functions as may be necessary to carry out the provisions of this Act.

6.83 The Regulatory powers of the Authority are as follows:

- National Biodiversity Authority regulates the activities referred to under sections 3, 4 and 6 of the Act as under:
- Any natural/legal person other than from Indian territory as defined under section 3(2) should necessarily obtain prior approval for accessing the biological resources and /or associated knowledge thereto obtained in India for research or for commercial utilization or for bio-survey and bio-utilization.
- Likewise results of research relating to any biological resource occurring or obtained from India should not be transferred to certain persons without approval of the NBA for monetary consideration or otherwise to any person who is not a natural/legal person of India (Section 4).

- Applications for Intellectual Property Rights by whatever name called in or outside India for any invention based on any research or information on a biological resource obtained from India by any person should necessarily go with the approval of NBA (section 6).
- NBA while granting approval for the said purposes will impose benefit sharing fee or royalty or both or impose conditions including the sharing of financial benefits arising out of the commercial utilization (Sec.6 r/w Sec.19 & 21).
- NBA is empowered to issue guidelines for access to biological resources and for fair and equitable benefit sharing by virtue of the sections 3,4 and 6.
- NBA may advise the Central Government on matters relating to the conservation of biodiversity, sustainable use of its components and equitable sharing of benefits arising out of the utilization of biological resources.
- NBA may advise the State Governments in the selection of areas of biodiversity importance to be notified under sub-section (1) of section 37 of the Biological Diversity Act, 2002 as heritage sites and measures for management of such heritage sites.
- NBA shall perform such other functions as may be necessary to carry out the provisions of the Biological Diversity Act, 2002.
- NBA may, on behalf of the Central Government, take any measures necessary to oppose the grant of intellectual property rights in any country outside India on any biological resources obtained from India or knowledge associated with such biological resource which is derived from India (Sec.18(4)).

6.84 The Authority is also vested with Quasijudicial Powers which are as follows:

By virtue of section 50 (4) of the Biological Diversity Act, 2002 the NBA is vested with quasi-judicial powers (vide section 50 (5)) to adjudicate any dispute arises between the State Biodiversity

Boards once Central Government refer such disputes to the NBA. For this the NBA shall have the same powers as are vested in a civil court under the Code of Civil Procedure, 1908.

6.85 Constitution of the NBA is as under:

- (i) a Chairperson, who shall be an eminent person having adequate knowledge and experience in the conservation and sustainable use of biological diversity and in matters relating to equitable sharing of benefits, to be appointed by the Central Government;
- (ii) three ex officio members to be appointed by the Central Government, one representing the Ministry dealing with Tribal Affairs and two representing the Ministry dealing with Environment and Forests of whom one shall be the Additional Director General of Forests or the Director General of Forests;
- (iii) Seven ex officio members to be appointed by the Central Government to represent respectively the Ministries of the Central Government dealing with—
 - (a) Agricultural Research and Education;
 - (b) Biotechnology;
 - (c) Ocean Development;
 - (d) Agriculture and Cooperation;
 - (e) Indian Systems of Medicine and Homeopathy;
 - (f) Science and Technology;
 - (g) Scientific and Industrial Research;
 - (h) five non-official members to be appointed from amongst specialists and scientists having special knowledge of, or experience in, matters relating to conservation of biological diversity, sustainable use of biological resources and equitable sharing of benefits arising out of the use of biological resources, representatives of industry, conservers, creators and knowledge-holders of biological resources.

6.86 About the infrastructure and manpower at the disposal of the Authority the Committee were informed that the Office of NBA is now located in a rented accommodation at M/s TICEL BioPark, a Government of Tamil Nadu undertaking. Total area hired is 8600 sq.ft. (super built area). Action has been initiated to obtain land for construction of own building to house the office of the NBA from Government of Tamil Nadu for which requisition has been made for allotment of 5 acres of land.

6.87 Furthermore, the staff position as on date is as follows:

Name of the post	Sanctioned strength	Men-in-position	Vacancy
Chairman	1	1	-
Secretary	1	1	-
PS to Chairperson	1	1	-
PS to Member Secretary	1	1	-
Administrative Officer	1	1	-
Accounts Officer	1	1	-
Technical Officer - IPR1 - Benefit sharing..1	2	1	1
Advisor (Law)	1	1	-
Office/Computer Assists	2	2	-
Technical Assistants	2	2	-
Stenographer "C"	1	1	-
Stenographer "D"	1	-	1
Peon	1 (1 post surrendered & 2 to be filled by outsourcing)	1	-
Total	16	14	2

6.88 The qualification for the post of Technical Officer (IPR) is under revision and hence the post has not been filled up. Efforts to fill up the post of Stenographer D through deputation are not fruitful in spite of several

attempts and now action is being taken to fill up the post through direct recruitment.

6.89 About the adequacy of the manpower the authority informed the Committee that there is shortage of personnel in NBA with requisite technical and scientific knowledge to meet the growing work load. The posts sanctioned to NBA are solitary posts and hence persons recruited against such posts do not have promotional opportunities due to lack of promotion policy in NBA. To avoid trained personnel leaving NBA for want of promotional opportunities, a consultant viz. National Productivity Council under Ministry of Commerce, Government of India has been engaged for job study, devising the promotion policy, appropriate incentive scheme and suggesting creation of additional posts. The work is in progress.

6.90 Section 8(4)(a) of Biological Diversity Act stipulates as follows:

A Chairperson, who shall be an eminent person having adequate knowledge and experience in the conservation and sustainable use of biological diversity and in matters relating to equitable sharing of benefits, to be appointed by the Central Government

6.91 The following have been appointed as Chairpersons since the establishment of the Authority.

Sl. No.	Name of the Chairman	Tenure
1	Dr. Balakrishna Pisupati	From 12th August 2011 onwards
2	Shri M.F. Farooqui, IAS	11th Nov 2010 to 11th Aug 2011
3	Dr. P.L. Gautam	31st Dec 2008 to 3rd Nov 2010
4	Shri P.R. Mohanty, IFS	01st Oct 2008 to 31st Dec 2008
5	Shri G.K. Prasad, IFS	20th May 2008 to 30th Sep 2008
6	Dr. S. Kannaiyan	20th May 2005 to 19th May 2008
7	Shri Viswanath Anand, IAS	01st Oct 2003 to 14th July 2004

The Sl. No. 1, 3 and 6 were appointed as regular/full time Chairman. The rest held the charge of Chairman additionally.

6.92 Queried as to whether Section 8(4)(a) was adhered to while finalizing each of these appointments, it was replied that the Section 8(4) (a) was

adhered to in finalizing the appointments. There were no deviations from Section 8(4) (a) while finalizing the appointments of Chairmen.

6.93 The Committee also found that Section 13(1) of the Act stipulates as follows:

13(1). The National Biodiversity Authority may constitute a committee to deal with agrobiodiversity.

Explanation – For the purposes of this sub-section, “agro-biodiversity” means biological diversity of agriculture related species and their wild relatives.

6.94 Asked as to on how many occasions has the committee to deal with agro-biodiversity constituted by the Authority in terms of Section 13 of the Act since the establishment of the Authority, it was stated that NBA has constituted an expert committee to deal with agro-biodiversity matters in December 2005. Further the committee has been re-constituted on 27th October, 2009 and the term was extended.

6.95 About the composition of the said committee and its tenure on each occasion, it was stated that in 2005, the first committee was constituted with a chairperson and 15 members. (3 years)and in 2009, the committee was re-constituted with a chairperson and 18 members. (Renewed after every 6 months)

6.96 Asked further about the number of times the said committee met during each of its term, it was stated that during the first and second term the committee has met one time each.

The Section 18(1) of the Biological Diversity Act states as follows:

18(1) It shall be the duty of the National Biodiversity Authority to regulate activities referred to in sections 3, 4 and 6 and by regulations issue guidelines for access to biological resources and for fair and equitable benefit sharing.

6.97 When asked to furnish copies of guidelines issues in terms of obligation laid down on the Authority in Section 18(1), the Authority informed the Committee that the guidelines are under finalization. In this connection, a draft template on ABS was prepared by the Expert committee and discussed

at length in the Authority meeting and it was decided that it needs further fine tuning and improvement. The Authority desired that after fine tuning and improvement the same may be placed in the NBA website for inviting comments from different quarters. It was also decided to hold a special workshop inviting stakeholders, institutions concerned to discuss about draft ABS guidelines including template for finalization. It is taking considerable time as it is a new subject area and there are no previous templates that exist in our country to decide the appropriateness of benefit sharing when bioresources/genetic resources form a part of the product.

6.98 As of now the access applications are being processed and benefit sharing components are determined on a case-by-case basis under the broad framework of the Biological Diversity Rules, 2004.

(vii) Food Safety and Standards Authority of India

6.99 The Committee were informed that in India multiple regulations for food have been enacted at different points of time. There are different laws which deal with food products and standards. Some of these are Prevention of Food Adulteration Act, 1954; Fruit Products Order, 1955; Meat Food Products Order, 1973; Vegetable Oil Products (Control) Order, 1947; Edible Oils Packaging (Regulation) Order, 1947; Solvent Extracted Oil, De-oiled Meal and Edible Flour (Control) Order, 1967; Milk and Milk Products Order, 1992; and various provisions of the Essential Commodities Act, 1956. Multiplicity of laws creates confusion in the minds of consumers, traders, manufacturers and investors and prevents a coordinated approach to food safety issues. A number of committees, including the Standing Committee of Parliament on Agriculture in their Twelfth (Fourteenth Lok Sabha) Report presented to the Parliament on 20 April 2005, have emphasized the need for a single regulatory body and an integrated food law. The Food Safety and Standards Act, 2006 consolidates eight laws governing the food sector and established the Food Safety and Standards Authority (FSSA) to regulate the sector. The Act was passed in 2006 and the Food Safety and Standards Authority established in 2008.

6.100 The Food Safety and Standards Act, 2006 (the Act) has 12 chapters containing 101 sections and two schedules. The Act incorporates the salient

provisions of the Prevention of Food Adulteration Act 1954, and is based on international best practice in the application of science to food safety issues. This Act with its three tier structure (an apex Food Safety and Standards Authority, a Central Advisory Committee and various Scientific Panels and Committees) is expected to lay more emphasis on science based and transparency decisions in both standard setting and implementation. The new law recognizes the fact that hazards to food can arise from any link in the food supply chain and a risk based approach is required to minimize the hazards and ensure public safety.

6.101 Objectives of the Integrated Food Law are to:

- Consolidate the laws relating to food and establish a single reference point for all matters relating to food safety and standards, by moving from multi-level, multi-departmental control to a single line of command.
- Establish the Food Safety and Standards Authority of India (FSSAI) as an apex regulatory authority for laying down science based standards for articles of food.
- Regulate manufacture, storage, distribution and sale and import of articles of food to ensure availability of safe and wholesome food for human consumption.
- Pool infrastructure, manpower and testing facilities for better standard fixation and enforcement through their proper redeployment and consideration.

New provisions of FSS Act

- Covering Functional Foods, supplements, Nutraceuticals
- Issue of Licenses within 2 months of application.
- Provision of Improvement Notice by Designated Officers
- Prosecution, should be within 1 year of offence.
- Special Courts for summary trials
- Compensation to Victims (for any case of Injury/ Grievous injury/ Death)
- Rewards to informers (informing about the violators – adulteration etc.) by State Govt.

- One composite license for unit(s) falling in one area
- Encouraging Self regulation and adherence to specified food safety management systems.
- No License for petty food business operators; only registration is mandatory
- Central licensing from Authority for high risk items.
- Food Safety Officer with a wider mandate will replace food Inspector.
- Decriminalization of law and expeditious disposal of cases
- Financial penalties for less serious cases.
- Right to contest laboratory results by opting to send sample to accredited laboratory.

6.102 About the mandate, role and responsibility and the powers of the Authority the Committee were informed that Food Authority has the mandate of laying down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import to ensure availability of safe and wholesome food for human consumption. The responsibilities are as follows:

- (a) Developing the standards and guidelines in relation to articles of food and specifying an appropriate system for enforcing various standards notified under this Act;
- (b) fixation of the limits for use of food additives, crop contaminants, pesticide residues, residues of veterinary drugs, heavy metals, processing aids, myco-toxins, antibiotics and pharmacological active substances and irradiation of food;
- (c) notifying the mechanisms and guidelines for accreditation of certification bodies engaged in certification of food safety management systems for food businesses;
- (d) developing the procedure and the enforcement of quality control in relation to any article of food imported into India;
- (e) developing the procedure and guidelines for accreditation of laboratories and notification of the accredited laboratories;

- (f) notifying the method of sampling, analysis and exchange of information among enforcement authorities;
- (g) conduct survey of enforcement and administration of this Act in the country;
- (h) lay down food labelling standards including claims on health, nutrition, special dietary uses and food category systems for foods; and
- (i) the manner in which and the procedure subject to which risk analysis, risk assessment, risk communication and risk management shall be undertaken.
- (j) provide scientific advice and technical support to the Central Government and the State Governments in matters of framing the policy and rules in areas which have a direct or indirect bearing on food safety and nutrition;
- (k) search, collect, collate, analyse and summarise relevant scientific and technical data particularly relating to –
 - (i) food consumption and the exposure of individuals to risks related to the consumption of food;
 - (ii) incidence and prevalence of biological risk;
 - (iii) contaminants in food;
 - (iv) residues of various contaminants;
 - (v) identification of emerging risks; and
 - (vi) introduction of rapid alert system;
- (l) promote, co-ordinate and issue guidelines for the development of risk assessment methodologies and monitor and conduct and forward messages on the health and nutritional risks of food to the Central Government, State Governments and Commissioners of Food Safety;
- (m) provide scientific and technical advice and assistance to the Central Government and the State Governments in

implementation of crisis management procedures with regard to food safety and to draw up a general plan for crisis management and work in close co-operation with the crisis unit set up by the Central Government in this regard;

- (n) establish a system of network of organisations with the aim to facilitate a scientific co-operation framework by the co-ordination of activities, the exchange of information, the development and implementation of joint projects, the exchange of expertise and best practices in the fields within the Food Authority's responsibility;
- (o) provide scientific and technical assistance to the Central Government and the State Governments for improving co-operation with international organisations;
- (p) take all such steps to ensure that the public, consumers, interested parties and all levels of panchayats receive rapid, reliable, objective and comprehensive information through appropriate methods and means;
- (q) provide, whether within or outside their area, training programmes in food safety and standards for persons who are or intend to become involved in food businesses, whether as food business operators or employees or otherwise;
- (r) undertake any other task assigned to it by the Central Government to carry out the objects of this Act;
- (s) contribute to the development of international technical standards for food, sanitary and phyto-sanitary standards;
- (t) contribute, where relevant and appropriate to the development of agreement on recognition of the equivalence of specific food related measures;
- (u) promote co-ordination of work on food standards undertaken by international governmental and nongovernmental organisations;

- (v) promote consistency between international technical standards and domestic food standards while ensuring that the level of protection adopted in the country is not reduced; and
- (w) promote general awareness as to food safety and food standards.

6.103 When asked about the adequacy of infrastructure, manpower, facilities, etc. available with the Authority *vis-a-vis* task at hand and the steps being taken to remove shortfalls, if any along with their time-lines the Authority replied that The Food Safety and Standards Act, 2006 seeks to replace the multiple food laws, standard setting bodies and enforcement agencies prevalent in the country with one integrated food law. Hitherto, food was being regulated in the country through various agencies under different Ministries/Departments. The States/UTs are responsible for implementation of Prevention of Food Adulteration Act, 1954, while there are other central agencies under various Acts and Orders viz., the Fruit Products Order, 1955, the Meat Food Products Order, 1973, the Milk and Milk Products Order, 1992, the Vegetable Oil Products (Control) Order, 1947, the Edible Oils Packaging (Regulation) Order, 1998, the Solvent Extracted Oil, De oiled Meal, and Edible Flour (Control) Order, 1967 and any other order issued under the Essential Commodities Act, 1955 for licensing of manufactures. The food regulatory mechanism had several bottlenecks in implementation as follows:

- (a) Multiplicity of food laws, standard setting and enforcement agencies for different sectors of food
- (b) Varied Quality/Safety standards and poor harmonization
- (c) Thin spread of manpower, poor laboratories infrastructure and other resources
- (d) Standards rigid and non-responsive to scientific advancements and modern technologies
- (e) Poor information dissemination to consumers.

6.104 The key features of the Food Safety and Standards Act, 2006 to

address the challenges in food safety are:

- (a) Movement from multi-level and multi-department control to a single line of command
- (b) FSSAI as a single reference point for all matters relating to Food Safety and Standards, Regulations and Enforcement
- (c) Unified licensing system and provision for registration of small food business operators
- (d) Achieve high degree of consumer confidence in quality and safety of food
- (e) Effective, transparent and accountable regulatory framework
- (f) Emphasis on gradual shift from regulatory regime to self compliance
- (g) Adequate information dissemination on food to enable consumer to make informed choices.
- (h) Mechanism for speedy disposal of cases and provision for graded penalties based on gravity of offense
- (i) Food laboratories accredited by NABL or other suitable agency.
- (j) Focus on food safety throughout the entire food chain.
- (k) Preventive approach based on food safety system rather than end product approach.
- (l) Emphasis on training and capacity building of all stakeholders
- (m) Consistency between domestic and international food standards without reducing safeguards to public health and consumer protection

6.105 The following activities have been done so far toward the implementation of FSS Act, 2006:

- (a) Food Authority/ Central Advisory Committee, 8 Scientific Panels, and Scientific Committee established.
- (b) Integration of Staff under section 90 from various Ministries/Departments
- (c) Gap analysis study of 50 State Food Testing Laboratories completed
- (d) Food Import regulation mechanism started at major ports of entries.

- (e) Regular interactions with State/ UTs to ensure preparation toward implementation
- (f) Awareness Generation, Training of State regulators (more than 400 personnel trained including trainers),
- (g) More than 20 National consultations/ Regional Conferences including one International workshop conducted
- (h) Framework for accreditation of the food laboratories, Certification/Inspection bodies to audit compliance to food safety system, Food safety Plan.
- (i) Rules for various provisions under FSS Act, 2006 notified on 5-5-2011.
- (j) Regulations for various provisions under FSS Act, 2006 are under approval and likely to be notified shortly

6.106 Although, the Act was notified on 24th August, 2006, the Food Safety and Standards Authority of India was notified only on 5th September, 2008. The Authority could start functioning from January/ February, 2009 with the transfer of staff from various Ministries/ Departments and the appointment of a full time Chief Executive Officer.

6.107 The Food Safety and Standards Act, 2006 will come into force three months after the notification of the Rules, i.e. from 5th August, 2011. The next 5 years are therefore, very crucial as several new activities and initiatives will take off, for which adequate infrastructure, including increased manpower, is absolutely essential for successful enforcement of the Act. The enforcement of the Act is through the State Government machinery and State Governments need to be appropriately and quickly strengthened to ensure effective enforcement. In the first three years of its existence, the FSSAI has been allotted Rs.8.00cr in 2008-09, Rs.21.00cr. in 2009-10 and Rs. 32.37 crore in 2010-11 mainly for salaries and miscellaneous administrative expenses. This level of fund allotment cannot obviously meet the requirements of FSSAI in the subsequent years and will be grossly inadequate for carrying out its mandate. Therefore, FSSAI requires substantial funding for the next 5 years both for Central level and State level infrastructure and manpower.

6.108 The following was submitted by the Authority about the problems to be addressed:

- (a) Inadequate infrastructure, manpower and other resources at the Central and State levels for enforcement of the FSS Act.
- (b) Inadequate laboratory infrastructure at Central and State levels for testing of food articles.
- (c) Lack of awareness of consumers and other stakeholders about food safety issues.
- (d) Existing licensing mechanism under multiple agencies which needs to be replaced with a unified licensing/ registration mechanism under the FSS Act.
- (e) Lack of any integrated food safety surveillance system, including surveillance of imported food.
- (f) Need for establishment of e- governance system from panchayat level upwards for food safety matters.
- (g) Absence of any national level state of the art institution for carrying out research on food science and risk assessment.
- (h) Lack of trained personnel and absence of any central training institute to cater to the requirements of FSSAI for implementation of the FSS Act.

6.109 About the steps proposed to Address the above Problems, it was submitted that the following activities are proposed for addressing the above issues:

A. At Central level

- (a) Strengthening of FSSAI's headquarters
 - Staffing with adequate number of appropriately qualified personnel
 - Construction of new office building for FSSAI headquarter
 - Construction of residential accommodation for FSSAI staff
- (b) Development of science based standards
 - Recruiting personnel with qualifications and expertise in relevant field

- Establishment of a National Food Science and Risk Assessment Centre

(c) Food testing facilities

- Upgradation of existing Central Food Laboratory at Kolkata and establishment of new CFL at Mumbai.
- Establishment of testing facilities for genetically modified food.

(d) Surveillance mechanism

- Development of a food safety surveillance framework and establishing a mechanism for surveillance, both active and passive, which will be implemented through a competent agency selected through a competitive process.
- Safety of imported food for which adequate number of personnel, and infrastructure for new offices are required.

(e) Enforcement of the Act

- Staff requirement for central licensing
- Awareness generation and educational programmes
- Communication through media
- Development of training material and special courses in association with professional institutions and universities
- Establishment of National Food Safety Training Institute (NFSTI)
- Training of stakeholders at NFSTI

(f) Reward scheme for information on adulterated/ unsafe food

(g) Establishment of a national helpline

B. At State level

(a) Strengthening of district level food safety office

- Construction of building
- Provision of office equipment, vehicle etc.

(b) Food testing facilities

- Upgradation of 62 public food laboratories
 - Upgradation of 10 public food laboratories to referral laboratories
 - Providing one mobile food laboratory each to every State and U.T.
 - Providing one food laboratory each to 150 districts.
- (c) Establishment of emergency response centre in each State
- (d) Training programmes by the States/ UTs
- (e) Information, education and communication activities of the State Governments
- (f) E- governance from panchayat level upwards
- Existing networks of other Ministries will be utilised.

6.110 When queried about the ongoing initiatives the following information was submitted to the Committee:

- (a) 355 posts have been sanctioned for FSSAI in September, 2010, most of the Service Rules have been approved by the Government and Recruitment Rules are being finalised for filling up the posts. Besides the Authority has further made a tentative assessment of manpower requirement for catering to various responsibilities assigned to the Authority as per FSS Act, 2006 over next plan period for its effective and smooth implementation.
- (b) Gap analysis of 50 food testing laboratories has been carried out.
- (c) Imported food clearance process has been taken over at 5 ports, 4 airports and ICDs at Delhi and operationalisation of activities at 7 additional ports planned for 2011-12.
- (d) FSSAI Regional Offices have been established in Delhi and Mumbai.
- (e) Process of standard setting for some new items as, for example probiotics, food for special purpose and nutritional uses, alcoholic drinks, trans fatty acids, GM food labelling, caffeinated beverages etc. have been initiated.

- (f) Training programmes have been organised for Food Safety Commissioners, Food Safety Officers (ToT), Designated Officers and Authorized Officers (for imported food safety). Several States have conducted further training programmes for their Food Safety Officers.
- (g) For awareness generation, print advertisements on food safety, feature programme on Doordarshan, Kalyani and radio jingles on AIR have already been initiated. Pamphlets, brochures etc. on FSSAI have been widely distributed. FSSAI also has a very informative website which is daily updated.
- (h) Advisories have been issued by FSSAI whenever warranted, as for example in the case of melamine in imported milk, possibility of radioactive contamination in imported foods from Japan, antibiotics in honey etc.
- (i) FSSAI has established linkages with relevant institutes for development of training material or conducting studies/ surveys or advising FSSAI in technical matters. Such institutes are IIPA, IGNOU, NIN, IIMB, EIC, NISG, APEDA, NDDB, QCI, IVRI and CFTRI.

6.111 As regards timelines for the purpose it was stated that the activities of FSSAI are ongoing. However, the first 5 years after the Act comes into force are the most crucial years as the success of the Act and the fulfilment of its mandate will totally depend on the availability of funds for initiating all the activities included in the scheme. Therefore, budget requirement has been projected for the first 5 years, which coincides with the Twelfth Five Year Plan period.

6.112 Asked to spell out the quantum of fund required for the activities proposed the following estimates were furnished to the Committee:

Broad Head of Activity/ Initiative	Fund Required in 12th Plan Period(Rs.in crore)	
	Central Level	State/UT level
Strengthening of Food Safety Infrastructure both at Central and State level	630.00	410.00

Strengthening of Food Laboratory Infrastructure (Including Up-gradation of 72 Public Labs, Mobile Labs, Food Lab at each District, National Food Science & Risk Assessment Centre and Up-gradation of CFLs)	195.00	1021.00
Training & Capacity Building of Stakeholders including National Food Safety Training Institute	15.00	30.00
E-Governance system for Food Safety from Panchayat upwards and Food Safety Surveillance	506.00	50.00
Communication, Awareness & Educational Programmes	900.00	350.00
New Building for FSSAI Headquarter & Housing facility for staff	450.00	-
SUB- TOTAL	2696.00	1861.00
GRAND TOTAL	4557.00	

Note: Financial outlay of Rs. 2,530 crore required by State/UT Governments in terms of only salary of manpower for Enforcement System during the 12th Five Year Plan is not included in the above.

Regulating and Monitoring of Imported food

As per Clause 16 of the Act:

(1) 'it shall be the duty of the Food Authority to regulate and monitor the manufacture, processing, distribution, sale and import of food so as to ensure safe and wholesome food.

(2) Without prejudice to the provisions of sub-section (1), the Food Authority may by regulations specify -

- (a) The standards and guidelines in relation to articles of food and specifying an appropriate system for enforcing various standards notified under this Act
- (b) the limits for use of food additives, crop contaminants, pesticide residues, residues of veterinary drugs, heavy metals, processing aids, myco-toxinz, antibiotics and pharmacological active substances and irradiation of food;
- (c) the mechanisms and guidelines for accreditation of certification bodies engaged in certification of food safety management systems for food businesses;
- (d) the procedure and the enforcement of quality control in relation to any article of food imported into India;
- (e) the procedure and guidelines for accreditation of laboratories and notification of the accredited laboratories;
- (f) the method of sampling, analysis and exchange of information among enforcement authorities;

- (g) conduct survey of enforcement and administration of this Act in the Country;
- (h) food labeling standards including claims on health, nutrition, special dietary uses and food category systems for foods; and
- (i) the manner in which and the procedure subject to which risk analysis, risk assessment, risk communication and risk management shall be undertaken.

6.113 As reportedly food products/commodities derived from transgenic sources are being sold in the Country, the Committee desired to know about the action taken by the Authority with a view to regulate the distribution, sale and import of such items. In response they were informed that at present all matters pertaining to GM Organisms including GM food is regulated by Genetic Engineering Approval Committee of the Ministry of Environment & Forest in the Country.

6.114 Asked further if the Authority by means of a specified regulation defined limits for use of food additives, crops contaminants, pesticide residues, residues of veterinary drugs, heavy metals, processing aids, myco-toxinz, antibiotics and pharmacological active substances and irradiation of food, it was submitted that the draft Food Safety and Standards Regulations, 2010 were published vide Notification dated 20-10-2010 for inviting public comments. Based on the comments received, the Regulations are under process of finalization.

(1) The use of food additives and their limits and irradiation of foods are covered under Food Safety and Standards (Food Products standards and Food Additive) Regulations, 2011.

(2) The definitions and limits etc. of heavy metals, crop contaminants, myco-toxinz, pesticide residues and residue of veterinary drugs, antibiotics are covered under separate regulation namely Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011.

(3) The labelling of Irradiated Foods is given under Food Safety and Standards (Packaging and Labelling) Regulations, 2011.

6.115 It was further submitted that the above Regulations are in line with existing Prevention of Food Adulteration Rules, 1955 which will be repealed

after the new regulations are notified shortly. The Chapter on Processing Aids has not been prescribed presently and this will be considered by Scientific Panel on Food Additives, Flavouring, Processing Aids and Material in Contact with Food before the draft Regulations in this regard are published for public comments.

6.116 About the Authority having specified mechanisms and guidelines for accreditation of certification bodies engaged in certification of food safety management systems for food businesses, the Committee were told that the number and capabilities of regulatory agencies in the states, municipalities and panchayats are currently inadequate and it will take some time for building up a strong cadre of food safety officers across the country. Keeping in view the emphasis placed by the Act on self compliance, it is necessary for the Food Authority to put in place detailed guidance documents on food safety requirements to be followed by food business operators. This will enable FBOs to assess themselves against these requirements and retain evidence of their due diligence in this regard.

6.117 The Act specifies that the primary responsibility for safety is on the food business operators and for this, implementation of appropriate food safety management systems is essential for which the FBO can be held accountable. The FSSAI as a part of its regulations has developed reference documents which prescribe and provide levels of safety and provide guidelines and norms which can at the same time, be evaluated. FBOs are required to comply with these requirements with whatever resources available and gradually achieve acceptable levels of safety. In a sector which is characterised by complex technology, unorganised operations and large number of small players, only a flexible system of self compliance, to be periodically audited by the regulator, will be feasible. The degree of compliance can then be checked by periodic regulatory inspection. It will also incentivise better safety practices in industry, thereby reducing the need for frequent inspections.

6.118 The following draft documents have been developed to support the framework through competent implementation agency:

- Requirements for certification bodies / Inspection Bodies

- Procedure for Recognition of Certification / Inspection Bodies by FSSAI and application form
- India HACCP standards requirements
- Agreement to be signed between recognized CBs/IBs and FSSAI
- Agreement between FSSAI and NABCB
- Certification criteria for Food Safety Professional along with competence requirements.
- Certification Process of Food Safety Professionals

6.119 To a query of the Committee as to whether the procedure and the enforcement of quality control in relation to any article of food imported into India in general and of commodities/food products derived from transgenic sources has been specified by the Authority, it was stated that the following Framework for Safety of Imported Food has been laid down by FSSAI:

- Demand for imported food items has increased considerably in India coinciding with the impressive economic growth achieved by the Country and concurrent changes in the import regulations since last few years. Imports into India are permitted to be made through 255 entry points. These include 82 customs ports, 32 customs airports, 132 land customs stations and 9 foreign post offices/sub-foreign post offices. According to Directorate General of Commercial Intelligence & Statistics (DGCI&S), Ministry of Commerce, data India imported more than 76 lakh MTs of food items during 2007-08 and 2008-09.
- Under the Food Safety and Standards Act, 2006, the Food Authority has also the mandate of ensuring safety of food items imported into the country.
- Port Health Officers (PHOs) of Directorate General of Health Services (DGHS) who were performing the duty of taking samples of imported food items under section 6 of PFA Act and getting tested in Central Food Laboratories (CFLs) or PFA labs in States had withdrawn from the services related imported food safety at some of the ports.
- Keeping in view the mandate under FSS Act and based on the discussion & deliberations, it was realized that the FSSAI should get

into the process of imported food clearance through appointment of Authorised Officers in pursuance of section 47(5) of FSS Act, 2006 and take over the functions of PHOs where services had been withdrawn by DGHS.

- The FSSAI has operationalized the Food Import Clearance Process since August-September, 2010 in a phased manner through appointment of Authorized Officers in terms of section 47(5) of the FSS Act, 2006, at Chennai, Kolkata, Haldia, Mumbai and JNPT seaports, Chennai International Airport, Mumbai International Airport, Kolkata International Airport, Indira Gandhi International Airport, New Delhi, CONCOR-ICD Tughlakabad, CWC-ICD Patparganj, ICD Faridabad/Ballabgarh, ICD Dadri and ICD Loni in the NCR region.
- The functions of the FSSAI's Authorized Officer inter alia include the existing functions of the Port Health Officer under the PFA Act, 1954 with respect to imported food clearance process, in co-ordination with the Customs authorities.
- Adequate numbers of NABL accredited laboratories have been authorized at these locations for analysis of samples of imported food items.
- MIS system to put import activities online has already been developed and pilot run has been started at Chennai w.e.f. 1st June, 2011.
- Draft Food Import Regulations have also been developed.
- Total 29,756 Samples (till 31st May, 2011) tested so far out of which 152 were non-conforming.

6.120 The FSSAI will also develop data base for risk based food clearance system in due course.

6.121 With regard to the import of foods derived from transgenic sources, the relevant provisions of Section 22 of Food Safety & Standards Act, 2006, which mandates Food Safety & Standards Authority (FSSAI) to regulate genetically modified food, have not been notified by the Government. However, on 7th April 2006, the Ministry of Commerce and Industry through Director General of Foreign Trade (DGFT) has notified new regulation for

import of GM products by amending Schedule - I (Imports) of the ITC (HS) Classifications of Export and Import Items, 2004-09 under the Foreign Trade Policy (2004-09) to be effective from 1st April 2006. As a result of the new import policy, (i) all applications for import of GMOs/LMOs for research, bulk import of GM food, feed, raw or processed or any ingredient of food, food additives or any food product that contains GM materials will require prior approval by GEAC; (ii) At the time of import, all consignments containing products which have been subjected to genetic modification will carry a declaration stating that the product is 'Genetically Modified'. (iii) In case such a consignment does not carry this declaration and is later found to contain genetically modified material, the importer is liable to penal action under the Foreign Trade (Development and Regulation) Act, 1992.

6.122 About the Authority having laid down the procedure and issued guidelines for accreditation of laboratories and notified accredited laboratories, the Committee were informed that under sections 16(2) and 43 of the Food Safety and Standards Act, 2006, the Food Authority is mandated to lay down the procedure and guidelines for accreditation of laboratories and notification of the accredited laboratories. FSSAI may notify laboratories and research institutions accredited by NABL or any other accreditation agency.

6.123 Food testing laboratories (under Central and State Govt.) are currently either deficient in equipments and infrastructure or lack adequately trained technical staff. It will take some time for building up a strong cadre of food analysts and food microbiologists across the country. Keeping in view the emphasis placed by the Act on the role of the food analyst and the standard of food testing laboratories, it is imperative for the Food Authority to put in place a reliable laboratory upgradation and accreditation system. This will enable harmonisation of standards across the country with reliability, enabling food safety surveillance and monitoring, by incentivising laboratories both in the public and private sector to upgrade their technical skills, testing arrangements and infrastructure.

6.124 Authority has undertaken a gap study of Central and State Food Testing Laboratories so as to formulate a strategy to operate them at acceptable levels of reliability and competence. The study has indicated the

urgent need to upgrade infrastructure, strengthen staffing and training inputs and put in place more reliable laboratory management and operation procedures. Currently there are also no reliable mechanisms to evaluate and benchmark the performance of the laboratories through periodic inter laboratory comparisons. The food testing system should promote good laboratory management techniques, improvement in test competencies and encouragement of best practices in food testing.

6.125 FSSAI has adopted the following framework for upgradation of food testing laboratories in the Country:

1. An entry level/Preliminary standard is being laid down for existing food testing laboratories in the public (Centre and State Government) sector which will be given a period of one year to come up to acceptable levels of food testing to meet the requirements of Food Safety and Standards Act, 2006. Till then they will continue to perform the current functions so that there is no disruption of testing services.
2. Guidance documents, operational protocols and reporting formats to be adhered to by food testing laboratories are being prepared. Food testing laboratories would also be required to report essential information regarding food hazards to the Food Safety and Standards Authority without violating confidentiality requirements. Food testing laboratories in the public sector will be given a period of 3 years for achieving NABL levels of reliability.
3. Since FSSAI has taken over testing of food samples at selected ports of entry, it is necessary to put in place an effective system for sample testing by expanding the number of laboratories capable of undertaking such testing at high levels of reliability. The existing list of laboratories which are competent to test imported food will be expanded to make food testing at ports of entry more efficient and effective. Private laboratories would need to achieve and retain NABL level for them to perform these functions.

4. FSSAI is in the process of laying down the procedure for accreditation of referral laboratories. Referral labs will have to adhere to the specified NABL standards suitably modified and accepted by FSSAI. The requirements of referral laboratories will be expanded to include capacity building, hand holding, training etc. in addition to those which are laid down in the NABL standards. A mechanism for evaluating and benchmarking the competence of laboratories in these areas will also be laid down.
5. Upgradation of State Food Testing Laboratories to NABL standards will be taken up on the basis of gap studies carried out, in association with the State Governments. States can also undertake projects to upgrade their labs to approved referral standards.
6. The minimum requirements of food testing to be performed by laboratories will be developed by FSSAI and notified. Since upgradation of food testing laboratories in the States will require considerable investment, additional staffing and training, it is necessary for capable organisations to be entrusted the task of coordination and turnkey delivery as Programme Implementing Agencies. Programme Implementing Agencies will be identified through an open competition. The deliverables from implementing agencies are being finalised and competent consultants will be associated with the exercise to support the Programme Implementing Agencies. The resources required for laboratory upgradation would be accessed from the schemes of the Government of India and also from the budget of Food Authority.
7. Since the Food Business Operator will be now required under the FSSAI Licensing Regulations to undertake larger and more frequent number of sample testing to demonstrate due diligence of Good Manufacturing Practices, a large number of laboratories both in the public and private sectors are required to be notified for food testing.

8. A Steering Committee under the chairmanship of Chairperson, FSSAI will be constituted in FSSAI to oversee the implementation of the Food Testing Laboratory Upgradation Strategy.

6.126 The gap studies have clearly established the need for supporting Government Laboratories in their upgradation efforts. On their own they may not be able to coordinate and execute the complex steps involved in procurement of equipments, training, staffing, putting in place protocols and inter laboratory comparisons. Resources also would need to be mobilised. FSSAI will coordinate with the State Governments to help in the upgradation of these food testing laboratories in a defined time frame.

6.127 When asked as to whether the Authority has worked out some system of sampling, analysis and exchange of information among enforcement authorities and the efficacy of the system put in place for the purpose it was submitted to the Committee that after the notification of the Food Safety and Standards Rules, 2011, the procedure for undertaking samples and the methods of testing will undergo a change. Rules 2.4.2 (7) of FSSA Rules provide details of the new procedure for sampling. Under the new procedure for sampling, instead of 3 samples, 4 samples will now be taken and the Food Business Operator will be given an opportunity to send one of the samples to an accredited laboratory for testing, in addition to the public laboratory to which the sample is sent. In case there is difference in the results of the two labs, prosecution can only be launched if a referral laboratory confirms the presence of the contaminant and the violation of law.

6.128 FSSAI has carried out a detailed review of the current methods of sampling practices being followed by the regulatory personnel in various parts of the country. The general finding is that a large number of cases which have been filed in Courts have been contested on account of the faulty sampling procedures and testing protocols. This is mainly due to the lack of adherence to laid down procedures, inability of public laboratories to carry out food testing at the required levels of reliability and convince the Courts of the violation of law. Under the FSS Act 2006, FSSAI is mandated to accredit laboratories both in the public and private sector with the required capabilities for food testing. FSSAI has already enrolled the services of

competent laboratories of NABL standards for doing testing of imported food products. The accreditation system for laboratories is also being finalised which will enable a much larger number of laboratories which will achieve NABL standards to enter the area of food testing.

6.129 Separately, FSSAI also proposes to set up an expert committee to go into the current sampling practices and testing protocols to ensure that prosecution is carried out only on the basis of reliable sampling methodology and scientific testing protocols.

6.130 About the regulations issued by the Authority in context of food safety and standards including claims of health, nutrition, special dietary uses and food categories systems for food including commodities/products derived from transgenic sources, the Committee, were informed that the draft Food Safety and Standards Authority of India Regulations, 2010 have been notified in the Gazette of India (the Gazette No. 2-15015/30/2010-FSSAI) on 20th October, 2010 inviting comments till 20th November, 2010. The Food Safety and Standards Authority of India Regulations, 2010 have been sent for approval of the Central Government before final notification by the Food Authority.

6.131 The Food Safety and Standards Authority of India is in the process of formulation of Draft Regulation on Foods for Special Nutritional or Dietary Uses, labelling claims & food categories systems of food additives. However, the commodities/products derived from transgenic sources is not under the purview of Food Authority. These draft Regulations is being considered by the Scientific Panels of the Food Authority. These draft regulations will then be considered by the Scientific Committee, Food Authority and sent for Gazette Notification after the previous approval of Central Government.

6.132 The Committee also desired to know the procedure laid down by the Authority subject to which risk analysis, risk assessment, risk communication and risk management shall be undertaken in general and in the context of food commodities/products in transgenic sources in particular they were told that FSSAI has a significant role to play in ensuring a safe food supply by maintaining robust evidence based processes for developing food standards and responding to food safety issues which enables

consumers to make informed choices and maintain public confidence in safety of foods.

6.133 FSSAI's general framework for risk analysis incorporating the key components of risk assessment, risk management and risk communication provides a systematic and disciplined approach. This framework provides with information and evidence required for effective decision making to support the development of standards, manage emerging issues and to provide consumers with adequate information leading to effective food safety outcomes and improvement in public health. This overarching general framework for risk analysis is further supplemented by the risk analysis policy and procedures of individual scientific panels to deal with specific issues in their areas of concern.

6.134 The Act stipulates that the Food Authority shall also -

- (a) *provide scientific advice and technical support to the Central Government and the State Governments in matter of framing the policy and rules in areas which have a direct or indirect bearing on food safety and nutrition;*
- (b) *search, collect, collate, analyse and summarise relevant scientific and technical data particularly relating to -*
 - (i) *food consumption and the exposure of individuals to risks related to the consumption of food;*
 - (ii) *contaminants in food;*
 - (iii) *residues of various contaminants;*
 - (iv) *identification of emerging risks*

6.135 About the the activities of the Authority undertaken with a view to search, collect, collate, analyse and summaries relevant scientific and technical data as per their mandate in general and with particular reference to commodities/food product derived from transgenic origins it was stated that The Food Safety and Standard Authority of India (FSSAI) has been established with mandate of laying down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import, to ensure availability of safe and wholesome food for human consumption. Under Section 16 (3) (b) & (e) of the Food Safety and Standards Act,2006, the Food Authority shall search, collate, analyse and

summarise relevant scientific and technical data particularly relating to identification of emerging risks, incidence and prevalence of biological risk, introduction of a rapid alert system etc and establish a system of network of organizations with the aim to facilitate a scientific co-operation framework by the co-ordination of activities, the exchange of information, the development and implementation of joint projects, the exchange of expertise and best practices in the fields within the Food Authority's responsibility. The Authority is also expected to track food safety trends and advise the Government suitably.

6.136 Thus establishment of a network of organizations with the aim of facilitating scientific co-operation and research & development on identified food safety issues by the co-ordination of such research activities is a critical mandate of the Authority. The Food Authority has to put in place a reliable system of identifying food safety threats and to undertake the necessary research on these issues in a focussed manner. The objective is to formulate an appropriate scientific remedy in-line with the Act that will be comprehensive, science based and implementable in Indian conditions.

6.137 The FSSAI has floated an Expression of interest inviting proposals from experienced agencies to develop and implement a scheme for undertaking (I) Research & Development, (II) establishment of Food Safety Centres and (III) Centers of Excellence in India.

6.138 Amongst others, FSSAI is currently Working with the following institutions on different issues related to Food Safety:

Central Food Technological Research Institute (CFTRI)

Testing of imported food, scientific issues related to novel food products and nutraceuticals.

Indian Institute of Toxicological Research, Lucknow.

Issues related to Food Toxicology and food standards.

6.139 FSSAI since inception is making efforts to establish interface and working relationships with its various stakeholders at all levels as mandated under section 16(3) (c), 16(3) (g), 16(3) (n) and 29(3) of FSS Act 2006. The basic aim of Food Safety and Standards Act 2006 is to make food safety a

national movement. The shift is to be achieved from controls to self regulation, self compliance and motivation through focused communication and participation. The involvement and participation of all the stake holders is to be ensured by making consumers, industry and all other stake holders partner in the food safety.

6.140 The biggest stake holder is consumer himself. He is the one who takes the final decision on what to eat, and this establishes the requirement of food safety. Nutrition, health and hygiene are other considerations for stake holders.

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 a 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.

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.

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.

6.144 In view of the Committee, Department of Agriculture and Cooperation has not discharged its mandated responsibility in a professional manner, in so far as, the introduction of transgenic agricultural crops in India as a policy matter is concerned. At that point of time it was a technology that was being applied in hardly a few countries whose agricultural practices, farmers profile, populations dependence on agriculture and allied sectors was totally different from the situation obtaining in India. Department of Agriculture and Cooperation failed to appreciate the fact that India has 70% population surviving on agriculture and allied activities against 2% or so farming community in USA, Canada, etc. It also failed to appreciate the huge difference in size of land holdings in India where 70% of farmers are small and marginal ones with

average land holding of about 1.25 acre against hundreds of hectares of land owned by individual farmers in USA. The huge differences in farmers' incomes, levels of mechanization, availability of irrigation facilities, etc. were also not properly analysed. The ineffectiveness of PPV&FRA Authority and National Biodiversity Authority which are virtually non-existence even now was also ignored.

6.145 Another aspect on which Department of Agriculture and Cooperation failed miserably was the cost of seed and other inputs that the introduction of transgenics in agricultural crops would entail. The cost benefit analysis was clearly in favour of industry and not the farmers. Resultantly, Bt. cotton seed was sold at a whopping Rs. 2200 per kg. when local seed cost hardly a fraction of it. The difference was so outrageously high that a judicial intervention was required to force the company in question to lower the price of seed. Even now at Rs. 1500 per kg. or so the cost of seed in the opinion of the Committee is still very high considering that for a majority of farmers in India for whom even a single rupee matters in these several distressful years of agrarian crisis this amount is a tall order. The decline in yield after initial two three years of increase due to reduction in yield loss caused by pests caused additional distress to the farmers. Furthermore, the exorbitantly high input costs, as one of the witnesses, who has been closely monitoring Vidharbha region for years together, apprised the Committee that from an average Rs. 8000 to Rs. 12000 per acre investment in cultivating traditional varieties of cotton the farmer

had to invest a massive Rs. 48000 to Rs. 54000 per acre for Bt. cotton cultivation. Thus the input cost escalated almost five times the yield did not increase in commensurate measures and even fell after the initial years. Bt. cotton has also not been a sustainable agriculture technology. The Committee have been informed by farmers that it uses massive quantities of water and other outputs. Though farmers in Gujarat, where availability of water is better than Vidharbha, were benefitted to some extent, in Vidharbha, however, Bt. cotton has only contributed towards agrarian crisis. The better productivity of Bt. cotton also has not stood the test of time as in the latest estimates productivity figures have gone considerably down. In fact, Secretary of Department of Agriculture and Cooperation admitted before the Committee that several traditional varieties of cotton grown in Brazil had three times more yield than Bt. cotton yield in India and Brazil was not encouraging cultivation of Bt. cotton now. A team of Government was going to Brazil to study these developments for being gainfully utilized in India.

6.146 Another very important question that needs to be answered by DAC is about the approval for commercialization of Bt. cotton in India. Bt. cotton is a cash crop which in no way would have contributed to the food security of the Country. The lacs and lacs of hectares of land that have got diverted to Bt. cotton cultivation because of misconception about its potential have obviously reduced the area of cultivation of several food crops during all these years thus jeopardizing the Country's food security to that extent. That the Department of Agriculture and Cooperation did not discharge its

responsibility in terms of NPF 2007 even when commercialisation of Bt. brinjal was approved is apparent from the fact that brinjal though a staple food in many States of the Country has never been in short supply inspite of losses caused by pests, etc.. Its cultivation is restricted to very small patches of farmers' fields and in the cost benefit terms brinjal was not going to make any noticeable difference in the fortunes of the vast majority of cultivators in the Country. DAC also failed to appreciate that both in case of cotton and brinjal the Country has countless number of traditional varieties. Most of them have been wiped out in their natural form in case of Bt. cotton, and had the moratorium not been placed on the commercialisation of Bt. brinjal, the same fate would have been fallen on the traditional brinjal varieties. The Committee feel that this is a very serious matter and, therefore, recommend that an indepth probe may be carried out to track the decision making involved in commercial release of Bt. cotton right from the initial stage. It has to be found out how Bt. cotton became priority when the avowed goal for introduction of transgenics in agricultural crops was with a view to ensure and maintain food security.

Department of Food and Public Distribution

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

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

Department of Consumer Affairs

6.148 The examination of Department of Consumer Affairs which are the guardian of consumer rights in the Country also revealed the

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

been mentioned elsewhere in this Report copious amounts of cotton seed oil has been produced in the Country from Bt. cotton seeds during last decade since Bt. cotton cultivation started in India. The Committee would like to have the considered views of the Department on this issue from the point of view of Consumer Protection Act, consumer rights, informed consumer choice, etc. without any delay.

Department of AYUSH

6.149 As is common knowledge, several food crops have substantial medicinal value and they are extensively used in the Indian System of Medicines viz. Ayurveda, Unani, Siddha. Agricultural food crops are also used in Naturopathy and Homeopathy. The Committee, therefore, examined the Department of AYUSH which are mandated with the formulation of policy issues for development and propagation of India System of Medicines. It came as a huge surprise to the Committee when the principal witness admitted during the his oral evidence before the Committee on 10 February, 2011 that the Department became aware of the various implications of transgenic food crops on the Indian System of Medicines only after they received the questionnaire of the Committee for eliciting written information from the Department. The Committee also note that the Department of AYUSH had on 1 June, 2010 through a communication to the Secretary, Ministry of Environment and Forests conveyed their concerns that Bt. brinjal may have implications on AYUSH sector. They had also asked them not to permit open trial or commercialization of Bt. brinjal or any other

medicinal plant until detailed analysis of their impact on India System of Medicines is done as plant materials are highly sensitive to phytochemical/agroclimatic/environmental factor. The Department of AYUSH had in view of all these developments requested Ministry of Environment and Forests to co-opt Chief Executive Office of National Medicines Plant Board, Adviser, Ayurveda, Director General, Central Council for Research in Unani Medicines in GEAC. Interestingly, the Ministry of Environment and Forests through their letter dated 7 February, 2011 informed the Department of AYUSH that so far 'no transgenic medicinal plant have been developed and none are under field trials. The research being conducted is of a preliminary nature, where the research institutions are developed a transformations protocol for integration of all the new genes as the whole process will take several years the request for inclusion of AYUSH/Unani and National Medicinal Plants Board to GEAC will be considered at the appropriate stage.'

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.

6.151 The Department of Commerce are entrusted with the responsibility of attending to policy matters relating to international trade in goods and services including agreements with other countries/various international trade body but excluding agreements relating to wheat, sugar, jute and cotton. The Committee note India exported agricultural products worth Rs. 89523 crore during the year 2009-10. From the data submitted by the Government to Committee it is observed that exports of agricultural products have shown a continuously rising trend in the last decade. A major chunk of our exports have been of rice mostly basmati. EU is one of the important importers alongwith several Middle East countries. The Department of Commerce admitted before the Committee that exports of transgenic crops will depend upon international acceptance to transgenic food and food products. The Department also stated that there may be no real demand for GM crops when the emphasis is on organic production. It needs to be pointed out that the Department of Commerce are also a member of GEAC. From the inputs provided by the Department, the Committee feel that cultivation of genetically modified food crops will have a debilitating effect on the export of agricultural products.

EU already has a strict regime for not permitting import of genetically modified crops. With the awareness about the safety and other concerns about transgenic crops taking centre stage now, there is a strong possibility of several other countries following suit. The volume of global trade in GM food and food products being of the order of a paltry US dollar 4 billion speaks volumes about the acceptability of GM products. The Committee, therefore, strongly feel that the negative impact of genetically modified crops on the country's agricultural exports is another important aspect that needs to be factored in while taking a decision in regard to introduction of genetically modified crops. The Committee desire the considered views of the Government in the matter.

National Biodiversity Authority of India

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.

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.

Food Safety and Standards Authority of India (FSSAI)

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, accreditation procedure for referral labs is not yet devised.

6.155 In the opinion of the Committee the Government should realize the magnitude of the task to be performed by FSSAI. Apart from regulating local food and food products, the Authority has to ensure food safety of food items imported into the Country. Imports in India are permitted through 255 entry points. These include 82

custom ports, 32 customs airports, 132 land customs stations and 9 foreign port offices, sub foreign post offices. During 2007-08 and 2008-09 76 lakh metric tonnes of food items were imported into the Country. For the Committee the most worrying aspect in the matter is the admission of the representative of Directorate General of Foreign Trade before the Committee during Oral-Evidence that there was absolutely no monitoring of the food items being imported into the Country.

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.

CHAPTER - VII

OTHER MAJOR ISSUES

7.1 Under Article 246 of Constitution of India the following is laid down in List-II i.e. the State List under the Seventh Schedule as the 14th entry:

Agriculture, including agricultural education and research, protection against pest and prevention of plant diseases

7.2 Several States are as yet undecided about transgenics crops or have denied permission for field trials of GM/transgenic food crops and other plants/crops. The Governments of Bihar and Rajasthan have in fact withdrawn permission for ongoing trials. When asked to clarify the position in the matter the Ministry of Environment and Forests informed the Committee that as per Clause 4 (4) under Rules 1989, the GEAC is the apex authority responsible for approval of proposals relating to GM crops into the environment including experimental field trials. As per Clause 4 (5 & 6) under Rules 1989, the role of the State Government through the State Biotechnology Coordination Committee (SBCC's) and District Level Committees is to monitor the compliance of the safety guidelines and conditions stipulated by the GEAC during the field trials. It also has powers to inspect, investigate and take punitive action in case of violations of statutory provisions. Therefore, prior approval of the State Government is not necessary. However, as the State Governments are involved in the monitoring of the field trials, GEAC taking into consideration the objections raised by some of the State Governments, has directed the applicant to obtain no objection from the respective States where the trials are proposed to be conducted.

7.3 As regards the views of the State Government/Union Territory regarding the GM crop field trials, details are as follows:

Bt cotton: There has been no request from the nine cotton growing states (Punjab, Haryana, Rajasthan, Madhya Pradesh, Gujarat, Maharashtra, Andhra Pradesh, Karnataka and Tamil Nadu) to revoke the approval granted for Bt cotton cultivation.

Bt brinjal event EE-1: The State Governments of Andhra Pradesh, Chhattisgarh, Karnataka, Bihar, West Bengal, Orissa, Uttarakhand and Madhya Pradesh have expressed apprehensions on the safety of Bt brinjal and have called for extreme caution as Bt brinjal is the first GM food crop to be introduced in the country. The Governments of Kerala and Uttarakhand have informed that they have taken a decision to prohibit environmental release of all GM seeds and keep the State totally GM free.

Field Trials: State Governments of Bihar, Kerala and Madhya Pradesh have informed that GM crop field trials will not be allowed in the State.

7.4 Queried further as to how many of the States have agreed for these activities, the Ministry stated that field trials have been allowed in the States of Maharashtra, Tamil Nadu, Karnataka, Andhra Pradesh, West Bengal, Punjab, Haryana and Rajasthan.

7.5 Queried further about the undecided ones, the Ministry stated that only Himachal Pradesh has informed that they will take a view on Bt brinjal after all trials have been completed and after the Government of India has decided.

7.6 During the course of the Committee's examination media reports appeared about Government of Bihar expressing their disapproval of field trials being conducted in Bihar. The Ministry of Environment and Forests and GEAC were asked to submit a factual report in the matter to the Committee. GEAC was also asked to submit alongwith its report in the matter all relevant correspondence, reports and submissions of all concerned. In response it was stated that in due compliance with the regulatory procedure under Rules 1989, this Ministry vide letter of even number dated December 24, 2010 had accorded approval to M/s. Monsanto India Ltd for conduct of BRL-II t with two transgenic corn hybrids namely Hishell & 900M Gold containing stacked cry2Ab2, cry1A.105 (Event MON 89034) & CP4EPSPS (Event NK603) genes at five locations during Rabi 2010 and nine locations during Kharif 2011 at the following locations subject to

stringent safety norms. As per Rules 1989, prior approval of the State Government is not necessary for allowing GM crop field trials.

S.No	Locations (Rabi 2011)	Kharif 2011
1.	Begusarai / Samastipur, Bihar;	Begusarai Bihar;
2.	Bhagalpur Bihar;	Bhagalpur Bihar;
3.	TNAU Coimbatore;	TNAU Coimbatore;
4.	UAS Dharwad;	UAS Dharwad;
5.	ANGRAU Karimnagar;	ANGRAU Karimnagar;
6.	-	BHU Varanasi,
7.	-	MPUAT Udaipur;
8.	-	AAU Vadodara
9.	-	DWSR Jabalpur

7.7 During Rabi, the field trials were initiated only in Samastipur in Bihar and University of Agriculture Science, Dharwad in Karnataka. No trials have been initiated during Kharif 2011 as the applicant has been directed to obtain 'No Objection' from the respective State Governments before initiating the trials.

7.8 The Chief Minister, Bihar informed the Minister for Environment and Forests (IC) on 5.3.2011 that he is opposed to the transgenic maize field trials in Bihar and permission given in this regard should be withdrawn.

7.9 On the basis of the request received from the Chief Minister, Bihar and decision taken in the GEAC meeting held on 09.03.2011, M/s. Monsanto was directed to terminate the BRL-II trials with transgenic maize in Bihar on 10.3.2011. Copy of the communication was sent to Chief Secretary, Secretary (Agriculture), Secretary (Environment), Commissioner (Agriculture) of the State Government of Bihar as well as to Director (Research) and Director (Extension) of the State Agriculture University at Samastipur. A separate communication was also sent to Secretary (Agriculture) along with a copy to Chief Secretary and Commissioner (Agriculture) informing them of the GEAC decision and direction issued to M/s. Monsanto.

7.10 Subsequently in the communication dated March 14, 2011, the Chief Minister of Bihar has raised the following points regarding the approval granted to M/s. Monsanto:

- (i) The approval letter issued by the GEAC to M/s. Monsanto to conduct BRL-II trials on 24.12.2010 which was marked to various officials of the State Government has not been received by the respective departments;
- (ii) M/s. Monsanto has informed the State Government of the trials only on 24.2.2011 even though the sowing was done on 21.2.2011. Therefore, it needs to be investigated whether the isolation distance and safeguards were followed or not.
- (iii) The farm at Regional Station of IARI at Pusa, Samastipur does not have the one km isolation distance from all the four directions.
- (iv) The trial was hurriedly uprooted in an unscientific manner and without the presence of any representative from the State Department of Agriculture.

7.11 The matter was examined and the following facts of the case were communicated to the Government of Bihar:

- (i) The approval letter dated 24.12.2010 has been issued through Speed Post to all the respective State Government Departments where trials were to be conducted. Scanned copy of the approval letter was also sent by e-mail to the State Government wherever email addresses were easily accessible. Email sent to Chief Secretary, Principal Secretary of the State Government of Bihar is placed on file. GEAC has also been following up with the State Governments to actively participate in the monitoring and evaluation of GM crops by appointing a nodal person who could interface with the GEAC and RCGM. However, in spite of follow up, we have not received any response.
- (ii) The GEAC had accorded approval for conduct of BRL-II trials at five locations during Rabi 2011 and nine locations during Kharif 2011. However, the applicant was able to initiate the trial at only two locations, namely, Begusarai in Samastipur, Bihar within the IARI Regional Research Station on 24.2.2011 and UAS, Dharwad, Karnataka within the State Agriculture University on 6.1.2011.
- (iii) As per the conditions stipulated in the approval letter, the applicant is required to inform the GEAC/State Government

details of BRL-II trials which include locations, area, site plans, protocols, name of the lead scientists responsible for all aspects of the trials within 15 days of issue of the clearance letter. The applicant has not complied with this requirement.

- (iv) As per the GEAC approval, BRL-II maize trials were to be conducted and monitored under the direct supervision of Director, Directorate of Maize. This aspect has been complied with.
- (v) As per the Indian Minimum Seed Certification Standards, the isolation distance for hybrid maize is maximum 300 m and for open pollinated varieties, the maximum distance is 1 km. The BRL-II trials were conducted with transgenic hybrid maize and therefore 300 m isolation distance is adequate. It may be further noted that the GEAC in its meeting held on 10.6.2009 had extensively deliberated on three protocols for conduct of field trials with transgenic maize. The GEAC had opted for the most stringent protocol (Protocol-III) which requires 300 m isolation distance plus sowing of 10-13 rows of African tall maize covering a distance of 6-7.8 m all around the experimental plot area. The protocols submitted by the applicant to Director, Directorate of Maize is in line with the protocol prescribed by the GEAC.
- (vi) As regards terminating the BRL-II trials, the applicant has informed vide their letter dated 14th March 2011, that the trial site was already ploughed by the local IARI research personnel when their representative visited the site on March 11, 2011 at 6.30 AM without any notice to the company or their involvement. However, the communication dated 14th March 2011 received from the Chief Minister indicates that the trial was hurriedly uprooted in an unscientific manner and without the presence of any State Department of Agriculture representative.
- (vii) The Director, Indian Agriculture Research Institute vide communication dated March 24, 2011 has submitted full details of the harvest and termination report in respect of GM maize trials within the IARI Regional Research Station at Samastipur,

As of now there are no GM crop trials in Bihar.

7.12 GEAC, however, did not submit the correspondence, reports and submissions of all concerned which were sought by the Committee.

7.13 As in the case of Bihar several reports about field trials, etc. have come in the context of Rajasthan, Karantaka, etc. There is, therefore, a view that rather than presenting a *fait accompli* to the State Governments and other stakeholders including the farmers and consumers, the entire process ought to have been worked out in reverse by evolving a consultative mode based on the requirements of the various agro-climatic zones, public opinion, ethical issues, etc.

7.14 The Department of Agriculture & Cooperation are the apex body for agriculture and cooperation at the Central Government level to coordinate with, amongst others, the State Governments. The Committee, therefore, sought their considered views about what could have been an ideal approach towards development of GM/Transgenic food crops on the one hand and their propagation on the other hand so that the States and other stakeholders were kept in loop from the beginning as per the Constitutional scheme of things and other requirements.

7.15 In response they stated that efforts are being made in India since the early eighties to develop transgenic crops in public research institutions. The Government of India has been very supportive of the efforts to develop transgenic crops and has invested liberally in this sector through the Department of Bio-technology, Department of Science and Technology and ICAR.

7.16 The development of bio-technology in agriculture in India has been fairly encouraging. Bt. Cotton has been successfully commercialized in India. The spectacular improvement in cotton acreage and production is evident by the success of Bt. Cotton. The area under Bt. Cotton increased from 29000 ha. in 2002, to 9.34 million ha (anticipated) in kharif -2010. The area and production increase due to Bt. Cotton from 2002 onwards is at **Annexures VI & VII**. The average yield increased from 309 kg. per ha. in 2001-02 to 560 kg. per ha. in 2007-08, turning India from an importer to a net exporter of cotton. This success story would not have been possible if the nine States namely Punjab, Haryana, Rajasthan, Madhya Pradesh, Gujarat, Maharashtra, Andhra Pradesh, Karnataka and Tamil Nadu had not participated in promotion of Bt. Cotton. The Department is of the view that the application

of biotechnology in agriculture should be in line with the NPF with aim to improve productivity and net income of farmers. Since agriculture is a State Subject and States are major stakeholders, hence involving them and seeking their opinion would be appropriate. However, DAC is of the view that there is a need to make the public aware of the benefits of biotechnology, provided it is implemented / applied after indepth scientific analysis of associated risks.

7.17 With the applicant now being directed by GEAC to obtain no objection from State Government a mechanism has been put in place to integrate public opinion and concerns of States in the decision making process, even though it is not mandatory under the Rules 1989. However, this aspect has been addressed in the new Biotechnology Regulatory Authority of India Bill where it is mandatory for the authority to consult the public.

7.18 The Committee take note of the fact that under the constitutional scheme of things agriculture is a State Subject. Article 246 of Constitution of India explicitly assigns 'agriculture, including agricultural education and research, protection against pest and prevention of plant diseases to the States of the Union. In such a situation, there is no scope for any misinterpretation of role and responsibility of the State Governments with matters concerning or having a bearing on agriculture. In case of field trials of transgenics crops the Committee find that a peculiar situation obtains. For a thing as crucial as field trials till recently the State Governments were not even consulted. The Ministry of Environment and Forests have without any appreciation of the constitutional positions defended their decision on the specious plea that as monitoring during the field trials is the responsibility of SBCCs and DLCs which are entities of State Governments prior approval of State

is not necessary. The Committee are not at all convinced by the flawed logic extended by Ministry of Environment and Forests. In view of the diverse opinions about transgenic crops and controversies surrounding their induction a mandatory consultation process with the State Governments culminating into seeking their permission for field trials, in the opinion of the Committee should have been inbuilt in the regulatory mechanism. This was inexplicably not done by Ministry of Environment and Forests leading to several States being compelled to voice their objections to the apparently flawed procedure being followed in a matter, which is in the domain of the State Governments. The Committee note that the Ministry have, thereafter, taken remedial action and from last year onwards the applicant is required to obtain a no objection certificate from the State where the trial is proposed to be conducted. The Committee also recommend that since States have a major role in agriculture sector and most of the responsibility at field level devolves on them, the Government should apportion appropriate responsibilities on the States in the Biosafety Law recommended by the Committee. This will not only be in consonance with the Constitution and the Government will be saved the embarrassment of a Bihar type incident, but would be a practical and pragmatic approach to deal with various developments in the agriculture sector where at the ground level the Central Government at best has a peripheral role.

7.19 Coming to the position obtaining in various States in regard to transgenics crops and field trials Andhra Pradesh, Chattishgarh,

Karnataka, Bihar, West Bengal, Orissa, Uttarakhand, and Madhya Pradesh have expressed their reservations about Bt. brinjal. Kerala and Uttarakhand have in fact decided to prohibit environmental release of all GM seeds to keep the State totally GM free. Bihar, Kerala, Madhya Pradesh and Rajasthan have also disallowed field trials in the State. Himachal Pradesh will take a view on Bt. brinjal once all trials are completed and Government of India have taken a decision in the matter.

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

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

(ii) Regulation and Labelling

7.22 The Food Safety and Standards Act, 2004 enjoins upon the Food Safety and Standards Authority of India the responsibility of matters like

safety regulation, labeling and related aspects of all food items covered under the Act genetically modified ones not excluded.

(a) Regulation

7.23 Section 22 of the FSSAI Act stipulates that 'no person shall manufacture, distribute, sell or import any novel food, genetically modified articles of food, irradiated food, organic foods, foods for special dietary uses, functional foods, nutraceuticals, health supplements, proprietary foods and such other articles of food which the Central Government may notify in this behalf'. During the last few years cultivation of transgenic cotton has increased manifold. As of now transgenic cotton is cultivated on about 9 million hectares in the Country. This was about 29000 hectares in 2002. Today almost 90% cotton cultivated in India is transgenic. The cotton seed oil production as per information available from industry sources has also gone up from about 400000 metric tonne in 2002 to 1210000 metric tonne in 2011. The Committee, therefore, also desired to know if the Authority had received any request for manufacture, distribution and sale of cottonseed oil during last five years and what action had it taken on each of such requests. In response FSSAI stated in a written submission to the Committee that no such request have been received by FSSAI so far since at present all matters pertaining to GM Organisms including GM food is regulated in the Country by Genetic Engineering Appraisal Committee of the Ministry of Environment & Forests.

7.24 The transgenic food crops and other products derived from them are being accorded high priority by the regulatory agencies the world over. The Committee, therefore, were keen to know as to what extent does the role of the Authority differs or is in conformity with similar entities functioning in the Countries where products/commodities derived from transgenic food crops are in existence or are being manufactured or are being introduced for human consumption.

7.25 In response they were informed that FSSAI has carried out a detailed review of GM Food regulations of other countries which has been summarised in the form of a resource document (**Annexure- VIII**). The resource document contains details of regulation of GM food in India and

other countries, similarities and differences in regulation of GM foods from other countries, regulatory options and way forward for India. The Authority also informed the Committee that Section 22 of FSS Act, 2006 which mandates Food Safety and Standards Authority of India to regulate GM Food in the country, has not been notified by the Government.

7.26 Clarifying further in the matter the Chairman of the Authority stated during the Oral Evidence held on 14 July, 2011:

“As you correctly mentioned, section 22 has a very clear provision that genetically modified food comes within the purview of the FSSAI. So, when the Government notified all the sections including section 22 but deleted genetically modified portion from FSSAI, we had actually contacted the Government and had a series of discussions with them. We were proceeding on the assumption that we might have to regulate genetically modified food. So, we commissioned a study on what were the current regulatory practices in various countries of the world, what was the current practice in India, and what were the options available in India for genetically modified food. By the time we finished the study and looked at various options on how to regulate we were informed that the Government was considering an alternative regulatory pattern for genetically modified food so that FSSAI might not be responsible for genetically modified food. So, that was apparently the reason they deleted it from section 22. We were in effect told not to proceed with regulating them because the Government wanted to give it to the Bio-technology Regulatory Authority of India. They would be regulating the genetically modified food.”

7.27 About the reasons behind this rethink on the part of the Government Chairman, FSSAI informed the Committee during the Oral Evidence:

“Sir, you will be aware that the Environment Ministry and the GEAC are in charge of genetic regulations along with the Department of Biotechnology. They have got GEAC which considers cases according to the Environmental Protection Act of which we are not a part. When BRAI draft was being prepared, several options were

being considered as to how to regulate GM food. One option that was considered was that regulation of GM food should be with FSSAI and field trials should be with the BRAI. So, they tried to split it into two parts. Processed food will come to us whereas cultivation and environment related impact assessment will be with the other agency. When this draft came to us we started discussing the possibilities. We found the very objective of the Act itself was to have a single window clearance for biotechnology. The conclusion was if we have three regulatory authorities looking at biotechnology; one for process, one for raw and one for something else, there will be a conflict. They may clear a particular product for cultivation, say corn or some other thing when it is converted into food I may appoint another committee to do safety assessment and find what they have cleared is wrong. That will create a very difficult situation for the regulatory system in a country. So, we had suggested, let us not split this responsibility and have it at one place. In fact, we offered that if they want us to do we can do it also. After consultations the conclusion was a separate Regulatory Authority under BRAI, which was recommended by Dr. Swaminathan, will be the most appropriate solution. That is the way the draft has emerged and I now understand that it is coming to the Parliament. So, we did not have any choice in the matter.

7.28 He further added:

“As currently the draft is emerging, GM food regulation has completely gone out of the purview of the FSSAI. It is now with the BRAI and the Environment Ministry. They will undertake the applications, process it, do the safety assessment, clear it and then say that it is coming into the market. Once they take a decision we take it as approved food like any other food. We do not apply our mind. We look at only the labelling part which is now within our purview. Labelling of GM food is the only issue which we will consider. We will not consider the safety assessment again because already an Authority has cleared it. Once they give the approval, the meaning of that approval is that this food is as safe as normal food. So, we will take it as normal food and will apply labelling provisions to that particular food. Labelling of GM food is a highly technical issue, as you

have pointed out. We are now in the process of doing it. We are actually taking it forward. In effect, the GM regulation has gone out of the purview of the Authority by the change.

You may ask whether it is a feasible proposition, whether there will be a conflict now. One of the reasons why apparently it was decided to have a separate Authority was, evaluation of GM food is a highly technical area. If you look at the copies of the surveys which we have circulated, every country has got a different method of doing it. Different types of agencies are doing it. There is no consensus internationally. Even in the Codex Alimentarius, actually India has been last week elected President of it, there is no consensus even on the labelling of GM food. USA allows it free. European Union is very-very rigorous on it. So, we have to choose our own path now. For that it is better that one-point decision is taken regarding safety instead of two-three regulatory authorities considering it. From that point of view, there is a logic in having a separate Authority looking at the entire food safety so that if the stamp of that Authority is there that it is safe for eating, then everybody will be agreeable to it.”

7.29 Elaborating further on this aspect the Authority stated that under the FSSAI Act, it is expected to carry out a risk analysis and scientific review of the hazards involved, risk management options available and after detailed consultations with stakeholders draft the regulation. Department of Biotechnology have moved Biotechnology Regulatory Authority Bill, 2010. The mandate of the Bill is “to promote the safe use of modern biotechnology by enhancing the effectiveness and efficiency of regulatory procedures and provide for establishment of Biotechnology Regulatory Authority of India to regulate the research, transport, import, manufacture and use of organisms and products of modern biotechnology and for the matters connected therewith or incidental thereto”. This overlaps with the existing mandate of FSSAI. Therefore, to have a single point of regulation for GM foods necessary provisions have been made in the draft BRAI Bill, removing FSSAI from the regulation of GM foods. However, labeling of GM foods would be within the mandate of FSSAI. FSSAI has initiated work towards bringing regulation on GM food labelling after consulting concerned stakeholders.

7.30 From the resource document submitted by FSSAI it is observed that after the promulgation of Food Safety and Standards Act, 2006 and the establishment of FSSAI, the Ministry of Environment and Forests published a Notification [SO 1519(E)] in Gazette of India on 23 August, 2007 that exempts the occupier of the processed food stuffs, ingredient in food stuffs and additives including processing aids derived from Living Modified Organisms where the end product is not a Living Modified Organism from Rule 11 of the Rules for Manufacture, Use, Import, Export and Storage of Hazardous Micro Organisms, Genetically Engineered Organisms or Cells, 1989. Rule 11 reads as follows:

"Food stuffs, ingredients in food stuffs and additives including processing aids containing or consisting of genetically engineered organisms or cells, shall not be produced, sold, imported or used except with the approval of the Genetic Engineering Approval Committee."

7.31 It is further observed that, since FSSAI was yet to publish the relevant rules when Rule 11 was rescinded, the Ministry of Health and Family Welfare requested GEAC to continue to regulate GM food stuffs under rules, 1989 as an interim measure. The Ministry of Environment and Forests have issued six notifications, thereafter, to keep SO 1519 (E) in abeyance, five of them conveying extensions of six months each and the last one conveying extension of one year upto 30 September, 2011. With the issue of these six notifications, the question of jurisdiction of FSSAI has as discussed previously in this Report, remained unresolved till date.

7.32 When the version of MoEF was sought on this vexed issue they stated that The MoEF has notified the 'Rules for Manufacture Use, Import, Export and Storage of Hazardous Microorganisms / Genetically Engineered Organisms or Cells, (Rules 1989)' under the Environment (Protection) Act, 1986.

7.33 Rule 11 of Rule 1989 pertaining to GM food and food products derived there from mandate "Food stuffs, ingredients in food stuffs and additives including processing aids containing or consisting of genetically engineered organisms or cells, shall not be produced, sold, imported or used except with

the approval of the Genetic Engineering Approval Committee (GEAC)”. A decision to amend Rule 11 to exclude processed food from the purview of GEAC was taken by MoEF / GEAC on the following grounds:

1. Only Living Modified Organisms (LMOs) have the property to propagate and pose a risk to the environment. There is no risk to the environment from processed food. Accordingly, in the National Environmental Policy, 2006 the mandate of MoEF is to regulate only LMOs.
2. The Task Force on recombinant pharma under Dr. R. A. Mashelkar, former DG, CSIR constituted by this Ministry and the Task Force on Agriculture Biotechnology under Prof. M. S. Swaminathan have recommended that the GEAC should be involved only in the regulation of Living Modified Organisms (LMOs) to avoid regulatory overlaps.
3. The Food Safety and Standard Act, 2006 has been notified by the Ministry of Health & Family Welfare. The Food Safety and Standard Act, 2006 has a special provision for dealing with GM food and food products. The new food safety regulation would address health concerns/ risks in line with the Codex guidelines.
4. Processed food is exempted from the provisions of the Cartagena Biosafety Protocol to which India is a signatory.

7.34 In view of the above, the MoEF had issued a Gazette Notification number SO 1519(E) dated 23.08.2007 exempting GM processed food, ingredients, additives and processing aids from the purview of Rule 11 of the Rules, 1989 provided the end product is not a Living Modified Organisms (LMOs).

7.35 Subsequently, the Ministry of Health and Family Welfare (MoH&FW) vide their communication dated 26.12.2007 requested this Ministry to continue regulation of GM processed food for some more time till the Food and Standards Authority is able to look into the matter in a scientific manner and come out with a notification. The above matter was discussed in the GEAC meeting held on 11.1.2008 wherein the Committee advised that the issue may be resolved through an inter-ministerial consultation. An inter-ministerial meeting was held on 31.1.2008 wherein it was agreed that the Gazette Notification No. S. O. 1519 (E) dated 23.08.2007 issued by the

MoEF would be kept in abeyance for six months or until further notification of MoH&FW regarding regulation of GM processed food by the Food Safety and Standard Authority, whichever is earlier.

7.36 In view of the above decision, the MoEF had issued a Gazette Notification No. S.O. 411(E) dated 3.3.2008 keeping in abeyance the earlier Notification issued by this Ministry exempting processed food from the purview of Rules, 1989 every six months. The said notification is valid upto 30.9.2011.

7.37 The Food Safety & Standards Authority has now decided to delegate the powers pertaining to GM food to the Biotechnology Regulatory Authority of India as and when it is put in place. Until that period, the GEAC will be required to continue regulating the GM foods.

7.38 With a view to assess the ground reality while this game of musical chairs is going on for years together, the Committee sought the views of Department of Commerce on the reports about GM food products coming into India. They were informed that the import guidelines for the genetically modified products issued by the Directorate General of Foreign Trade very clearly stipulate that imports will be allowed only with the approval of GEAC. During the course of their Oral Evidence on 15 March, 2011 when the Committee desired to know as to whether there had been any instances which have come to the notice of the Department or DGFT about non-adherence of these guidelines by some importers, the representative of DGFO stated:

“The provision says that the approval of GEAC is required. No, we have not heard of any cases where this was not followed. No such case has come to our notice. So, we strictly go by that.”

7.39 Queried further as to what is the surveillance mechanism to check that the imports of such products are in conformity with the stipulated guidelines, she admitted:

“To be honest, Sir, there are no checks.”

7.40 Asked further as to whether it could be safely surmised that no cases of violation have been reported only due to the absence of a surveillance mechanism, she admitted:

“Sir.”

(b) Labelling

7.41 The Food Safety and Standards Act, 2006 (Section 23) enjoins upon the Food Safety and Standards Authority of India to notify labeling and related aspects of all items covered under the Act. However, FSSAI informed the Committee that for various reasons they have not been able to notify the provisions of the Act pertaining to labeling of food products derived from transgenic food crops and their produce.

7.42 Elaborating on this, Chairman, FSSAI stated during his oral Evidence on 14 July, 2011:

“Sir, as I mentioned, the labelling continues to be our mandate. We have not shifted that responsibility. Labelling is still with the FSSAI. We have to do that job. In respect to GM food labelling, about five years ago the Ministry of Health developed a draft Notification for labelling. They made GM labelling mandatory and they notified it for public consultation. Then, the amount of input which came on that from both sides was very large and very conflicting. As you said in the beginning, one group of people were saying it is the right of the consumer to know whether it is genetically modified or not. We want to look at it. On the other side, the industry said the problems involved in implementing it in a country of this size will be so huge that you will have a law which is not implemented.

So, after three years of consultation, the Health Ministry took a decision that it is premature to go forward with that notification. At that time, Food Safety and Standards Authority of India (FSSAI) was being set up. So, they took a decision. Since, the Food Authority is going to be set up now, we will pass on this problem to the Food Authority.

Recently, some of the consumers went to the Supreme Court of India and the Supreme Court had called me and asked me why am I not notifying it? You have got this notification lying for five years. So, we had to tell them that for five years it was with the Government and now Government thinks that it is not appropriate because of whole range of issues like no testing facilities, the cost involved and the details. If, we do not have the laboratories to test, then what is the point of doing it now? For testing, if you have to send it to Germany, then there is no point in having a law because you are testing in Germany. You build up the capacity; each test costs about Rs. 75,000. So, those issues were on the back of Government's mind when they took a decision not to move forward."

7.43 Asked as to whether the Authority have worked out some regulations under this Section for the food commodities/products derived from transgenic sources and in view of the reports that such commodities/food products are coming into the Country for sale, have the Authority initiated/contemplated measures to ensure that the such commodities/food products do not breach the stipulations laid down in Section 23 of the Act or the regulations/guidelines issued thereunder it was stated that FSSAI have carried out an initial review of the national GM food labelling regulations in various countries, impact of various international agreements and a few research studies conducted on the subject in India. The matter has also been discussed before Scientific Panel and Committee of FSSAI. FSSAI will forward its recommendations on GM food labelling to the Ministry after considering the recommendations of the Scientific Panel & Committee.

7.44 The Committee, therefore, desired to know from the Department of Consumer Affairs about the measures initiated by them individually or in consultation with FSSAI/Ministry of Health with a view to ensure that the rights and interests of consumers are protected and they are able to make an informed choice of food products they are consuming. In a written submission it was stated that the Department will coordinate with the Ministry of Bio-technology and Ministry of Health to ensure that no harmful GM products are allowed in Indian markets.

7.45 When queried about their take on labeling of GM/transgenic seeds, food crops and commodities derived from them, the Ministry of Environment and Forests stated that labeling of GM seeds or food or food products derived from them is to provide information required to address market and consumer preference. The labeling of GM/transgenic seeds, food crops and commodities derived from them do not fall under the purview of the Ministry. However, for sale of GM seeds (in case of Bt cotton) GEAC has prescribed labeling conditions related to (a) packing, (b) labeling, (c) physical and genetic description of the seeds, (d) information on sowing pattern in packets in addition to complying with the requirements for regulating the quality of certain seeds for sale in accordance with Seed Act 1966 and Seed Control Order, 1983 and subsequent amendments implemented by Ministry of Agriculture.

7.46 MoEF further informed the Committee that according to Food Safety and Standards Act, 2006, no person shall manufacture, distribute, sell or expose for sale or despatch or deliver to any agent or broker for the purpose of sale, any packaged food products (including genetically modified or engineered food or food containing such ingredients) which are not marked and labelled in the manner as may be specified by regulations. The regulations for labelling of GM Foods are being formulated by Food Safety and Standards Authority. Globally different countries follow voluntary or mandatory labeling system for products derived from GM crops. In some countries, the threshold levels of adventitious presence of GM ingredients in non-GM products have also been notified and are usually in the range of 0.9 to 5 percent depending upon the stage of processing and the state of final product.

7.47 When the views of GEAC were sought by the Committee on labeling of GM/transgenic seeds, food crops and commodities derived from them it reiterated the position taken by the Ministry of Environment and Forests i.e. its nodal Ministry and stated that labeling of GM seeds or food or food products derived from them is to provide information required to address market and consumer preference. The labeling of GM/transgenic seeds, food crops and commodities derived from them do not fall under the purview of GEAC. The regulations for labelling of GM Foods are being formulated by

Food Safety and Standards Authority.

7.48 When the question of labeling of GM/transgenic seeds, food crops and commodities derived from them was put by the Committee to the Department of Biotechnology they also reiterated the position taken by MoEF and GEAC almost to the last word.

7.49 Queried on labeling of GM/transgenic seeds, food crops and commodities derived from them, the Department of Science and Technology informed the Committee that they believe that labelling of GM seeds or food or food products derived from them is essential. It needs to provide proactively information required and inform consumers for them to make informed choices at this stage of development of GM food technology. The Department feel that India should position a suitable and robust labelling as well as surveillance and monitoring systems for ensuring the bio safety and environmental safety of GM crops and food products.

7.50 In a Background Note submitted to the Committee on the subject the Department of Food and Public Distribution stated that even though Genetically Modified food have the potential to solve many of the world's hunger and malnutrition problems and help in the protection of environment by increasing yield and reducing reliance upon chemical and herbicide but it also poses challenges in the following areas :

- (i) Food labelling.
- (ii) Segregation & Identity Preservation (IP) at procurement and storage point.
- (iii) Testing facilities of the genetically Modified crops.
- (iv) Provision of separate storage infrastructure and handling practices.
- (v) Regulation of policies regarding Genetically Modified crops.

7.51 Genetically Modified foodgrains are, therefore, required to be labelled as per the Government regulations and segregated from non-genetically modified foodgrains right from the time from sowing in the field to harvesting, procurement in the mandis and storage in the godowns, in order to avoid contamination. Due care is required for providing labelling of the

GM Crops at all stages, and it should be kept in designated storage space. It is, therefore, suggested that before considering allowing Genetically Modified food crops, it is required to develop Standard Operating Procedure (SOP), testing facilities and exclusive storage and transport facilities.

7.52 When asked to give their views on labeling of GM/transgenic seeds, food crops and commodities derived from them the CSIR submitted to the Committee in a written reply that they favoured labelling of GM foods as consumers would have a choice.

7.53 The Department of Agriculture and Cooperation i.e. the nodal Department of this Subject when asked about their views on labeling of GM/transgenic seeds, food crops and commodities derived from them stated that notified kinds/varieties is covered under the Seeds Act, 1966 for Quality Regulations whereas Seeds (Control) Order, 1983 regulates the production as well as distribution of seeds. Under the Seeds Act, 1966 and the Seeds Rules, 1968 when the variety is notified, such variety sold in the market should be labeled as prescribed under section 6(a) of the Seeds Act. If any person contravenes any provision of the Seeds Act 1966, the Seed Inspector notified under Section 13 of the Act is empowered to prosecute him with punishment of fine which may extend to Rs.500 for the first offence and if it is repeated, the fine may be extended to Rs.1000/- or imprisonment for six months or both. The Government of India have prescribed standards/procedure for Bt. Cotton Seeds under the Seeds Act/ Rules. Labeling of GM seeds, food or food products derived from them is to provide information required to address market and consumer preference. The policy relating to labeling of GM/transgenic food crops and commodities derived from them do not fall under the purview of the DAC. However, for sale of GM seeds (in case of Bt Cotton) the GEAC has prescribed labeling conditions related to a) packing, b) labeling, c) physical and genetic description of the seeds, d) information on sowing pattern in packets, in addition to complying with the requirements for regulating the quality of certain seeds for sale in accordance with the Seeds Act 1966 and Seeds (Control Order), 1983 which are implemented and regulated by DAC.

7.54 With the intention of arriving at the bottom of this vexed issue, the Committee sought the views of ICAR on labelling of GM/transgenic seeds,

food crops and commodities derived from them. The Council informed the Committee that according to international agreements such as Cartagena Protocol on Bio-safety, labeling of GM foods is voluntary. No doubt, labeling provides a choice to the consumer. However, the nature of agriculture practiced, socio-economic status of farmers, mode of marketing fruits, vegetables and other agricultural produce in the country make labeling impractical. Moreover, it will further add to the cost of the GM food crops or products thereof. Further, the GM crops are tested for compositional analysis and experiments have shown no difference (substantially equivalent) between GM and non-GM crops.

7.55 During her Oral Evidence on 19 October, 2010 when Director, Centre for Science and Environment was asked about her views on labelling she stated:

“Then, the issue, Mr. Chairman, which I have been raising, is the issue of food labeling. I certainly want my right of choice to eat GM food or not GM food. You, as a Government may decide that GM crops are important but that does not mean that you can take away my right to decide. Now, we have been asking for this. We have found it very difficult to get a labeling regime. I have to tell you, Mr. Chairman, that at CSE we have a laboratory to test, as you know, contaminants. We have recently tested, as you know, antibiotics and honey. We also tested pesticides in colas some years ago. We also wanted to test GM in imported food. We do not have the capacity. I am quite persistent. I am quite a difficult person. In spite of my knocking the doors on every Government laboratory, nobody could test GM in imported oil for us because the capacity to test it is very poor in India. So, the question that I have is this. If you cannot test and if you cannot assure me that I have the right to choose, then do you have the right to introduce the technology? If you do not have the laboratory systems which can actually let any citizen go out and say: “Test this brinjal for me. I want to know whether it has GM or not.” If you cannot do it, then does the Government have the right to introduce a new technology, which is clearly a technology on which the jury is still out? It is not a technology which can be equated with hybrids. It is

not a technology which can be simply said: "Oh, it is all about modern production and modern technologies." It is not. It is a clear technology where different genes are being inserted, and there are health risks, there are environmental risks. So, I think, that is a very important issue."

7.56 Justifying her stand she stated further:

"Now the question that I have as a consumer and as a public advocate is this. Why should I trust Indian science any more if I cannot trust the integrity and the independence of the scientists? GM crops cannot be introduced in isolation of a policy which promotes public science for public good. You cannot tell me that, please have GM crops because it good for you. But, on the other hand, everything that the Government is doing today is to compromise the integrity of publicly funded science and public institutions.

I am certainly saying that this entire effort to create Public-Private Partnerships in which you get companies more and more into the scientific establishments will create less and less credibility for crops like GM. It is something that must be understood that consumer confidence is absolutely critical and that cannot be built unless you have integrity of public scientific establishments."

7.57 Making a strong case for a strong liability regime she added:

"There is another big issue. I think and I hope your Committee will take a look at both the regulatory framework as well as the liability regime which is needed for GM crops. What Bhopal teaches us very clearly is that India has a very weak liability regime. You have just gone through a nuclear Bill. That is also a high risk technology. GM is similarly about high risk technologies, on which we do not know the future impact. That is why, across the world there is concern that any such introduction of technology needs a strong liability regime. It needs corporate liability to be established. It needs the price of that liability to be paid. What was the issue on nuclear? The issue on nuclear was that if you have a liability regime which reflects the cost of risk then the technology would not be competitive. That is why,

Parliament was asked and you did come up with a very compromised solution to actually reduce the cost of that risk. The same question has to be asked when it comes to GM. The same question has to be asked in terms of the regulatory framework that you will arrive upon. The Government is coming up with a Biotechnology Regulatory Authority. I hope that your Committee will take a look at that and will make sure that that authority speaks on behalf of consumer interests, speaks on behalf of farmer interests. The issue of GM technology is not a silver bullet to get rid of hunger. I think, that is an issue, which, I hope, this Committee will take a look at it and will do it very carefully.”

7.58 Dr. Sagari R. Ramdas, Director, Anthra during her Oral Evidence on 28 October, 2010 while dwelling upon the issue of Bt. cotton seed oil that has gone into the food chain stated:

“There is no system of labelling in this country. So, the cotton seed oil, whether it is a GM oil or non-GM oil, we have absolutely no way of assessing that.

So, we cannot identify the source and we cannot trace the source to its being either Bt. or non-Bt. Secondly, our systems of monitoring – this is what I tried to bring out in my presentation – is that usually when a person is suffering from a problem and when he goes to the doctor, our health facilities and our health systems are not able to deal with it because this is something very new. Automatically the doctor will not inquire whether he has consumed this oil. Today, we are not looking for the association between the allergy and the Bt. Toxin, if we begin to institute our mechanisms of our scientific research to look for it, probably we will find a problem. When we do not have a system to locate the problem or to follow it up, naturally we do not have any documented evidence.”

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.

7.60 Section 22, the above mentioned special provision in the FSS Act stipulates that no person shall manufacture, sell or import any novel food, genetically modified articles of food, irradiated food, organic food, foods for special dietary uses, functional foods, nutraceuticals, health supplements, proprietary foods and such other articles of food which the Central Government may notify in this behalf. Surprisingly, however, the GM foods were not included when Section 22 was notified by the Government. The Ministry of Health and Family Welfare instead asked GEAC to continue regulating GM foods under Rule 11 of Rules 1989 by keeping the notification of 23 August, 2007 in abeyance for six months or until the Ministry of Health and Family Welfare notified regulation of GM processed food by FSSAI whichever was earlier. The Committee were able to track

five extensions of six months and a sixth one of one year upto September, 2011 but still the FSSAI regulation for GM processed food is nowhere in sight though so many years have gone by. Resultantly, there is no check on GM processed food and other items coming from outside the Country or being produced here viz. cotton seed oil produced from Bt. cotton in the Country. To compound this inaction further, now the Government seems to entrust this responsibility to the proposed BRAI. The Committee wonder when actually the regulation of GM food and products thereof will commence when BRAI itself is nowhere in sight. In the opinion of the Committee this dilly dallying and delay in bringing GM food and products, thereof, is not a simple act of oversight or a genuine inability to do the needful and needs to be thoroughly investigated and responsibility for this callous neglect of health safety be fixed at the earliest. The Committee would like to be apprised of the results of the investigation and the action taken in pursuance thereof.

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

7.62 A similar dithering by the Government is observed by the Committee on the issue of labeling of GM foods and products thereof.

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

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

(iii) Food Production Scenario

7.64 The growth in agriculture sector during the Eleventh Plan was of the order of 3.5 per cent. In the Tenth Plan it was 2.3 per cent. During the

Ninth Plan it was 2.4 per cent. The Approach Paper to the Twelfth Plan pegs this growth around 4 per cent for the Twelfth Five Year Plan (2012-2017). Transgenic in food crops is being offered as the much needed solution for food security of the Country. In this context the representative of Centre for Science and Environment informed the Committee during her Oral Evidence on 19 October, 2010:

“So, I think, it is important when somebody says that to you, please ask them for more details about which crops are stagnating and indeed why that is the GM is the only answer. When it came to brinjal, for instance, why were they introducing BT in brinjal, which is a fairly high productivity crop already? Now, is that going to be important for food security in this country? I think it is important for us to evaluate that question. The second question that everybody is asking is that in India, “Is it a simple matter of not having food or is it criminal matter of not being able to provide food to hungry people?” That is the question that the entire world is asking: “Where there are food stocks and rotting food stocks, and we have hungry people.” So, the question is not a simple mathematics of looking at a linear line that connects food production and population. The question is to look at whatever food production, how do you get it to people. When you start looking at how do you get it to people, you start looking at policies, which have been designed to first grow the food and then get it to someone else. In fact, today there is more and more understand that if you want to feed people in India, you have to make sure that everybody can grow their own food. If you start talking about growing your own food and getting more self-reliant in States having local production, improving productivity, then GM is not the answer.

So, to me, it becomes such a simplistic thing to hear from the Indian policy makers – so much population; we will go out of food. We are not out of food today, but we have a very large number of hungry people. That is one point.

As far as Bt. cotton is concerned, there is no doubt in my mind. I think that productivity has increased, yields have increased. I hope you will ask people to give you more data on this. When we have

taken a look at where productivity have increased, they have increased in irrigated areas and not in unirrigated areas. They have increased because you have been able to do other inputs that are needed as well. So, it is a very high input yield increase. In fact, the BT cotton only proves my last point, Mr. Chairman.”

7.65 On this very aspect Prof. R.N. Basu, Former Vice-chancellor of Krishi Vishwa Vidyalaya informed the Committee during his Oral Evidence on 22 December, 2010:

“I will add just one point. High population is inevitable and it will increase to 1.5 billion by 2015. But high input farming is equally bad. In the last year, the fertilizer subsidy was Rs. 1.2 lakh crore. Now we are importing 40 per cent of the urea, 97 per cent of phosphate and 100 per cent of muriate potash. Intensive farming means high input farming. We are short of inputs and we will be depending on transnational corporations if we accept GM seeds and another logic is that we should not go in for high input farming because our soil will be spoiled and the cost of inputs will go up.”

7.66 His colleague Prof. T.K. Bose, Former Director, Bidhan Chandra Krishi Vishwa Vidyalaya supplementing him stated:

“The population will increase but there are definite ways by which this can be tackled. Integrated farming will give double income and double benefits to our farmers. There are thousands of evidences. You might have heard of land shaping. That is the only technology left. In West Bengal, low lying areas are there. In arid areas, land shaping will save water for the farmers and they can also go for multi cropping. In GM, multi cropping is a taboo there. In a multi cropping field, you cannot use such things. Lastly, there are definite ways for small and marginal farmers which are based on diversity of crops.”

7.67 Dr. Sujatha Byravan, former Director, Council for Responsible Genetics, USA and Senior Fellow, Centre for Development of Finance, Institute for Financial Management and Research speaking on the aspect of

the food security informed the Committee during the Oral Evidence on 11 November, 2010:

“The other point is with regard to food security and how we can feed the millions of our people. Being able to have food depends on many factors other than just the amount of food that is there. Access to food and livelihood including capacity to store it efficiently are the points on which we really need to focus on to see that there is enough food available.”

7.68 Elucidating on the aspect of food security and related matters – Dr. S. Nagarajan stated during his Oral Evidence on 15 July, 2010:

“Food security, as you rightly said, has to be our major concern looking into the large size of the population and the affordability. First I place before you sir that a major part of Central and Eastern India still has not got the benefit of better agriculture. Therefore, if we make available better seed, better marketing, if we can make the MSP available to all the States, make the Fertiliser Policy a little more friendly, we will be able to increase the food production substantially. As a scientist in agriculture, I am not afraid about food security because we have the technology available to increase foodgrain production and can meet the demand for the next 20 years. So, we have to, therefore, not go in a hurry as though our food security is in danger when the issue of transgenic comes to our mind. We can look into the consequences. We should not be too much worried cornered as though tomorrow we will go hungry.

So far as food price is concerned, access to food will come only when we are able to make food available and affordable. If the input price increases, naturally the price of the commodity is likely to increase. So we have to have a technology which is farmer-oriented and, therefore, even if we develop transgenic crops the seed cost should be affordable. Transgenic root stocks will enhance our horticulture production and biosafety is not a major issue here. If we park the technology on hybrid, then it is likely that the price of

transgenic seed will be high and the price of the produce will also increase. So, as a policy, at least the State funded system should look at variety-based concept rather than a hybrid system. We can make hybrid provided, the Institute is able to give non exclusive rights of both the male and female lines.

The nutritional value of food is of great concern. I think large part of my countrymen suffering due to inadequacy of nutritive food. Our food is primarily starch-based and it is not having the type of minerals, vitamins and nutrition that is required. So, emphasis on vegetables will be a welcome step. Nuclear of hybrid vegetables have been developed by ICAR/SAU system and if vegetable access can be given along with the mid-day meal, it will go a long way in making vitamins and minerals available to the school going children. We have to give a lot of emphasis on vegetables to make sure that the wholesome food is available to our people.

On food export, there are a lot of countries in Europe and America where transgenic food is not welcome. So, if we have to develop transgenic variety in rice, we may have to be very careful that our Basmati trade is not affected because Saudi Arabia and Europe will stay our Basmati rice if there is any transgenic rice contamination. Crops where our trade interest are involved like coffee and Basmati rice, we have to examine them carefully because when it comes to trade, many nations are not very keen to take transgenic food. Therefore, when it comes to transgenic technology, we may focus on Rubber, Jute and other industrial crops.”

7.69 To make an objective assessment of the food production and food security scenario in the Country and also of future requirements in the light of the increase in population, the Committee sought ten years data from Department of Agriculture & Cooperation on seven different parameters.

7.70 The following information was furnished by the Department in this regard:

Year-wise production of food grains, cereals and pulses

(Million Tonnes)

Crop	2000-2001	2001-2002	2002-2003	2003-2004	2004-2005	2005-2006	2006-2007	2007-2008	2008-2009	2009-2010	2010-2011*
1	2	3	4	5	6	7	8	9	10	11	12
Rice	84.98	93.34	71.82	88.53	83.13	91.79	93.35	96.69	99.18	89.09	94.11
Wheat	69.68	72.77	65.76	72.15	68.64	69.35	75.81	78.57	80.68	80.80	84.27
Jowar	7.53	7.56	7.01	6.68	7.24	7.63	7.15	7.93	7.24	6.70	6.75
Bajra	6.76	8.28	4.72	12.11	7.93	7.68	8.42	9.97	8.89	6.51	9.21
Maize	12.04	13.16	11.15	14.98	14.18	14.71	15.10	18.96	19.73	16.72	20.23
Ragi	2.73	2.37	1.32	1.97	2.43	2.35	1.44	2.15	2.04	1.89	2.17
Small Millets	0.59	0.58	0.46	0.56	0.48	0.47	0.48	0.55	0.44	0.38	0.37
Barley	1.43	1.42	1.41	1.30	1.20	1.22	1.33	1.20	1.69	1.35	1.48
Coarse Cereals	31.08	33.37	26.07	37.60	33.46	34.06	33.92	40.76	40.03	33.55	40.21
Cereals	185.74	199.48	163.65	198.28	185.23	195.20	203.08	216.02	219.90	203.45	218.59
Tur	2.25	2.26	2.19	2.36	2.35	2.74	2.31	3.08	2.27	2.46	3.15
Gram	3.85	5.47	4.24	5.72	5.47	5.60	6.33	5.75	7.06	7.48	7.38
Urad	1.29	1.50	1.47	1.47	1.33	1.25	1.44	1.46	1.17	1.23	1.82
Moong	1.03	1.11	0.87	1.71	1.06	0.95	1.12	1.52	1.04	0.69	1.37
Other Kharif Pulses	0.64	0.73	0.32	1.18	0.61	0.54	0.71	0.95	0.80	0.51	1.27
Other Rabi Pulses	2.01	2.30	2.04	2.47	2.31	2.31	2.29	2.00	2.23	2.29	2.30
Total Pulses	11.07	13.37	11.13	14.91	13.13	13.39	14.20	14.76	14.57	14.66	17.29
Total Foodgrains	196.81	212.85	174.77	213.19	198.36	208.60	217.28	230.78	234.47	218.11	235.88

As per third Advance Estimates released on 6.4.2011

Source – E & S. DAC

Production statistics for fruits and Vegetables

P= Production (in 000'MT)

Year	Fruits	Vegetables
	P	P
2001-02	43001	88622
2002-03	45203	84815
2003-04	45942	88334
2004-05	50867	101246
2005-06	55356	111399
2006-07	59563	114993
2007-08	65587	128449
2008-09	68466	129077
2009-10	71516	133738
2010-11(*P)	75853	137632

Source: Indian Horticulture Production at a glance (2001-02 to 2009-10)

Estimated Population of the Country during 2000-01 to 2010-11)

(In millions)

S.No	Year	Total Populations
1.	2000-01.	1020
2.	2001-02	1029
3.	2002-03	1035
4.	2003-04	1042
5.	2004-05	1050
6.	2005-06	1095
7.	2006-07	1110
8.	2007-08	1125
9.	2008-09	1140
10.	2009-10	1156
11.	2010-11	1210

Source – Horticulture Division. DAC Based on 2001 Census website.

Per Capita Requirement (Demand) of Food grains for 2011-12 (As per Demand Projected by Working Group of Planning Commission for 11th Five Year Plan)

(Million Tonnes)

Crop	Total Projected Demand for 2011-12	Per Capita Requirement/Demand for the year 2011-12* (Kgs.)
Rice	98.79	82.20
Wheat	77.36	64.37
Coarse Cereals	38.19	31.78
Pulses	19.91	16.57
Foodgrains	234.26	194.92

Note: Year-wise per capita requirement not available
Source -E&S DAC

PER CAPITA NET AVAILABILITY OF FOODGRAINS IN INDIA
(Kgs Per Year) (AS ON 16.03.2011)

YEAR	RICE	WHEAT	OTHER CEREALS	CEREALS	GRAM	PULSES	FOOD-GRAINS
2001	69.5	49.6	20.5	141.0	2.9	10.9	151.9
2002	83.5	60.8	23.1	167.4	3.9	12.9	180.4
2003	66.2	65.8	17.1	149.1	3.1	10.6	159.7
2004	71.3	59.2	25.3	155.8	4.1	13.1	168.9
2005	64.7	56.3	21.7	142.7	3.9	11.5	154.2
2006	72.3	56.3	22.1	150.7	3.9	11.8	162.5
2007	70.8	57.6	20.3	148.7	4.3	12.9	161.6
2008	64.0	53.0	19.7	143.9	3.9	15.3	159.2
2009	68.8	56.5	23.3	148.6	4.7	13.5	162.1
2010(P)	67.4	61.3	19.8	148.5	4.9	11.6	160.1

NOTE- The net availability of foodgrains is estimated to be Gross Production (-) seed, feed & wastage, (-) exports (+) imports,

(+/-) change in stocks.

The net availability of foodgrains divided by the population estimates for a particular year indicate per capita availability of foodgrains in terms of kg/year. Net availability, thus worked out further divided by the number of days in a year I.e.,

365 days gives us net availability of foodgrains in terms of grams / day.

Figures in respect of per capita net availability given above are not strictly representative of actual level of consumption in the country especially as they do not take in to account any change in stocks in possession of traders, producers and consumers.

For calculation of per capita net availability the figures of net imports from 1981 to 1994 are based on imports and exports on Government of India account only. Net imports from 1995 onwards are the total exports and imports

(on Government as well as private accounts)

Cereals includes rice, wheat and other cereals

Pulses includes all kharif and rabi pulses

Source – E & S DAC

PER CAPITA NET AVAILABILITY OF FRUITS AND VEGETABLES
(GRAMS/DAY)

YEARS	FRUITS	VEGETABLES	TOTAL
2000-01	116	252	368
2001-02	114	236	350
2002-03	120	225	345
2003-04	121	232	353
2004-05	133	264	397
2005-06	139	279	417
2006-07	147	284	431
2007-08	160	313	473
2008-09	165	316	475
2009-10	169	317	486

Source – National Horticulture Board.

Details of minimum buffer norms fixed and the actual stock position of wheat and rice in the Central Pool since 1.4.2001

AS ON	W H E A T		R I C E		T O T A L	
	Actual stock	Minimum buffer norms	Actual stock	Minimum buffer norms	Actual stock	Minimum buffer norms
1.04.2001	215.04	40	231.91	118	446.95	158
1.07.2001	389.2	143	227.51	100	616.71	243
1.10.2001	368.26	116	214.52	65	582.78	181
1.01.2002	324.15	84	256.17	84	580.32	168
1.04.2002	260.39	40	249.12	118	509.51	158
1.07.2002	410.74	143	219.37	100	630.11	243
1.10.2002	356.37	116	157.7	65	514.07	181
1.01.2003	288.3	84	193.72	84	482.02	168
1.04.2003	156.45	40	171.57	118	328.02	158
1.7.2003	241.94	143	109.74	100	351.68	243
1.10.2003	184.27	116	52.41	65	236.68	181
1.01.2004	126.87	84	117.27	84	244.14	168
1.04.2004	69.31	40	130.69	118	200	158
1.07.2004	191.52	143	107.63	100	299.15	243
1.10.2004	142.23	116	60.92	65	203.15	181
1.01.2005	89.31	84	127.63	84	216.94	168
1.04.2005*	40.66	40	133.41	122	174.07	162
1.07.2005	144.54	171	100.71	98	245.25	269
1.10.2005	102.9	110	48.49	52	151.39	162
1.01.2006	61.88	82	126.41	118	188.29	200
1.04.2006	20.09	40	136.75	122	156.84	162
1.07.2006	82.07	171	111.43	98	193.5	269
1.10.2006	64.12	110	59.7	52	123.82	162
1.01.2007	54.28	82	119.77	118	174.05	200
1.04.2007	47.03	40	131.72	122	178.75	162
1.07.2007	129.26	171	109.77	98	239.03	269
1.10.2007	101.21	110	54.89	52	156.1	162
1.01.2008	77.12	82	114.75	118	191.87	200
1.04.2008	58.03	40	138.35	122	196.38	162
1.07.2008 #	249.12	201	112.49	98	361.61	299
1.10.2008	220.25	140	78.63	52	298.88	192
1.01.2009 #	182.12	112	175.76	138	357.88	250
1.04.2009	134.29	70	216.04	142	350.33	212
1.07.2009	329.22	201	196.16	118	525.38	319
1.10.2009	284.57	140	153.49	72	438.06	212
1.01.2010	230.92	112	243.53	138	474.45	250
1.04.2010	161.25	70	267.13	142	428.38	212
1.07.2010	335.84	201	242.66	118	578.5	319
1.10.2010	277.77	140	184.44	72	462.21	212
1.01.2011	215.40	112	255.80	138	471.2	250
1.04.2011	153.64	70	288.20	142	441.84	212
1.07.2011	371.49	201	268.57	118	640.06	319

* New Buffer Norms w.e.f. April, 2005

#Includes Food Security Reserve of 30 lakh tons of wheat from 1.7.2008 onwards and 20 lakh tons of rice from 1.1.2009 onwards.

Source Department of Food & Public Distribution.

POST HARVEST CROP LOSSES

Estimated harvest and post harvest losses in India during 2005-07

Crop / commodity	Losses estimated, %
(i) Cereals	
1. Paddy	5.2
2. Wheat	6.0
3. Maize	4.1
4. Bajra	4.8
5. Sorghum	3.9
(ii) Pulses	
1. Pigeon Pea	5.4
2. Chick Pea	4.3
3. Black Gram	6.1
4. Green Gram	5.5
(iii) Oilseeds	
1. Mustard	8.9
2. Cottonseed	2.8
3. Soybean	6.2
4. Safflower	3.7
5. Sunflower	4.5
6. Groundnut	10.1
(iv) Fruits	
1. Apple	12.3
2. Banana	6.6
3. Citrus	6.3
4. Grapes	8.3
5. Guava	18
6. Mango	12.7
7. Papaya	7.4
8. Sapota	5.8
(iv) Vegetables	
1. Cabbage	6.9
2. Cauliflower	6.8
3. Green Pea	10.3
4. Mushroom	12.5
5. Onion	7.5
6. Potato	9
7. Tomato	12.4
8. Tapioca	9.8

(Source ICAR)

Statement Showing Import of Agricultural Products From 2000-2001 to 2009-10

Qty. '000' tones, Value: Rs. In crores.

Item	2001-2002	2002 - 2003		2003 - 2004		2004 - 2005		2005 - 2006		2006-2007	2007-08		2008-09		2009-10			
	1	4	5	6	7	8	9	2	3	4	5	6	7	8	9	10	11	12
	Qty.	Value	Qty.	Value.	Qty.	Value	Qty.	Value	Qty.	Value	Qty.	Value	Qty.	Value.	Qty.	Value.	Qty.	Value.
Vegetable Oils fixed edible	4322	6465	4365	8780	5290	11683	1	11077	4175	8716	4269	9540	4903	10301	6719	15837	7969	26484
Pulses	2218	3160	1993	2737	1723	2285	1339	1778	1608	2347	2271	3892	2835	5375	2474	6246	3448	9673
Wood & Wood Products		2584		1946		3269		3995		4066		4684		5455		6041		7461
Sugar	26	33	41	33	74	63	933	976	559	652	1	3	1	6	386	583	2424	5961
Cashew Nuts	162	431	403	1236	443	1372	480	1805	544	2090	586	1821	592	1715	614	2672	692	3050
Fruits & Nuts		757		642		802		1101		1377		1913		1858		2373		2871
Spices	86	504	121	586	124	564	107	594	107	678	119	739	145	974	123	1076	150	1419
Cotton raw & waste	387	2054	234	1238	253	1570	21	1136	98	688	81	663	136	912	212	1690	172	1241
Tea	10	67	24	125	11	65	33	147	19	108	23	127	20	131	25	197	34	275
Wheat	1	1			0	0					6080	5850	1793	2658	0	0	160	231
Cereal Preparation	35	82	52	117	33	87	45	112	42	126	38	133	44	162	30	170	40	190
Oil Seeds		1		11		14	4751	28		47		104		149		130		183
Jute, raw	80	96	143	135	112	94	32	32	48	72	83	115	136	148	52	71	63	149
Milk & Cream	1	8	1	10	12	90	2	13	2	14	3	29	2	29	3	38	8	78
Other cereals	5	4	1	1	2	2	7	7	27	29	8	12	10	19	21	45	34	76
Vegetable & Animal fats	1	10	1	12	2	13	192	13	1	14	1	11	1	12	1	12	1	23
Rice (excl. Cashewnuts)	0	0	1	1	1	0					0	0	0	0	0	1	0	0
Total agricultural imports		16257		17609		21973		22812		21026		29638		29906		37183		59368
Contry's total Imports		245200		297206		359108		501065		630527		840506		1012312		1374436		1356469
% Share in total Import		7		6		6		5		3		4		3		3		4

Source:
DGCIS

Statement Showing Export of Agricultural Products From 2001-2002 to 2009-10

Qty. '000'tonnes, Value: Rs. in crores.

Item	2001-2002		2002-2003		2003-2004		2004-2005		2005-2006		2006-07		2007-08		2008-09		2009-10	
	1	4	5	6	7	8	9	2	3	4	5	6	7	8	9	10	11	12
	Qty.	Value	Qty.	Value.	Qty.	Value.	Qty.	Value.	Qty.	Value.	Qty.	Value.	Qty.	Value.	Qty.	Value.	Qty.	Value.
Rice Basmati	667	1843	709	2058	771	1993	1163	2824	1161	3030	1046	2793	1182	4335	1556	9477	2016	10839
Oil Meals	2782	2263	1776	1487	3250	3348	3603	3178	6970	4826	6437	5504	6691	7954	6743	10269	4689	7850
Meat & Preparations	-	1193		1377		1714		1905		2648		3314		3734		5371		6285
Spices	239	1497	277	1655	267	1544	365	1883	403	2218	483	3158	620	4176	674	6338	681	6161
Tobacco unmgfd.	84	582	100	734	121	801	136	940	144	1028	158	1251	174	1430	208	2766	231	3621
Other Cereals	145	116	106	91	604	398	1178	794	659	513	730	599	3228	2979	4000	3921	2904	3005
Tea	180	1719	183	1652	178	1637	183	1840	158	1632	186	1970	199	2022	207	2689	209	2943
Fresh Veg	-	575		643		954		863		911		1547		1473		2454		2904
Cashew	98	1789	129	2053	100	1700	118	2477	124	2563	123	2491	111	2210	126	2901	122	2802
Fresh Fruits	-	417		447		784		862		1101		1414		1447		1945		2269
Castor oil	214	626	178	610	162	656	272	1078	253	934	295	1090	282	1275	357	2129	398	2178
Misc. Processed Items	-	724		910		1059		908		979		1125		1337		2077		2137
Coffee	176	1095	185	994	188	1086	168	1069	178	1577	214	1969	178	1868	174	2256	177	2033
Sesame & Niger Seed	241	610	154	451	207	754	194	773	224	794	263	1006	336	1714	211	1558	222	1520
Ground nut	113	251	68	178	176	544	177	547	185	501	251	798	268	1042	298	1239	340	1425
Processed Fruit Juice	-	513		574		344		369		600		711		769		1099		1156
Guargum Meal	118	403	112	487	121	508	131	689	187	1042	189	1126	208	1111	259	1339	216	1133
Dairy and Poultry Products	-	356	-	359		415	-	741		1112		811		1328		1544		915
Processed Veg	-	199		257		291		362		473		650		606		711		752
Tobacco mfgd.	13	226		289		295		315		302		434		498		695		724
Rice (other than Basmati)	1541	1331	4259	3773	2641	2175	3615	3945	3905	4144	3702	4243	5314	7396	932	1687	139	415
Pulses	162	369	148	345	154	329	271	603	445	1103	251	773	164	527	136	540	100	407

Floriculture Products		127		181		250		223		305		653		338		369		294
Fruits/Veg seeds	5	62	9	98	5	54	7	66	10	90	8	122	10	143	9	120	9	145
Sugar	1456	1728	1662	1769	1201	1217	109	150	317	557	1643	3127	4641	5404	3332	4449	44	110
Shellac	6	73	6	90	11	180	9	165	10	161	8	147	8	124	6	104	4	71
Cashewnut Shell Liquid	2	5	6	9	4	5	5	12	4	7	8	15	15	25	11	30	11	28
Molasses	221	54	208	45	99	19	8	6	72	27	327	133	863	250	172	83	31	20
Wheat	2649	1330	3671	1760	4093	2391	2009	1460	746	557	47	35	0	0	1	1	0	0

Item	2001-2002		2002-2003		2003-2004		2004-2005		2005-2006		2006-07		2007-08		2008-09		2009-10			
	Qty.	Value.	Qty.	Value.	Qty.	Value.	Qty.	Value.	Qty.	Value.	Qty.	Value.	Qty.	Value.	Qty.	Value.	Qty.	Value.	Qty.	Value.
1	4	5	6		8	9	2	3	4	5	6	7	8	9	10	11	12	13		
Marine products	468	5898	528	6928	409	6106	484	6469	461	6356	612	8001	488	6855	465	7066	721	9891		
Cotton Raw incl.waste	8	43	12	50	180	942	87	423	596	2792	1162	6108	1417	8000	458	2866	1360	9543		
Jute Hessain	51	186		349		410		427		489		376		464		416		308		
Paper/Wood products		1524		1950		2363		3237		4431		4915		4937		5442		5639		
Total Agricultural Exports	-	29729		34654		37267		41603		49803		62411		77770		85952		89523		
Country's total Exports	-	209018		255137		293367		375340		454800		571779		640172		840755		845125		
% Share in total Export		14		14		13		11		11		11		12		10		11		

Source : DGI&S Report

Fruits and Vegetables imported as well as exported during each of ten years

(Qty. in 000 MT)

Year	Import	Export
2000-01	145	624
2001-02	866	789
2002-03	889	934
2003-04	744	1291
2004-05	687	1296
2005-06	850	1481
2006-07	1444	2003
2007-08	1805	1725
2008-09	1297	2646
2009-10	1778	2560

Source – National Horticulture Mission.

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 tones to 759 lakh tones during this decade. Similarly, the production of vegetables has also shown a significant rise from 886.22 lakh tones to 1376.32 lakh tones. Throughout this decade barring a year or so India has been a net exporter of food grains and vegetables. The rise in food grains and fruits and vegetable production has continued 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. In spite of sufficient production and more than double the amount of buffer norms food stocks with the Government there is a huge disparity in availability of food. A large

majority does not have access to food due to extreme poverty while colossal amounts of food grains, fruits and vegetables are being lost during post harvest storage. As Secretary, Department of Agriculture & Cooperation confessed before the Committee that a saving of 10% in post harvest crops losses would mean 23 million tones of extra food grains. Primarily faulty procurement policy, mismanagement of stocks, lack of adequate and proper storage, hoarding and lopsided distribution, massive leakages in the public distribution delivery system, etc. are more responsible for the present worrisome situation. If these shortcomings and problems are attended to 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.

(iv) Violation of BD Act

7.72 Section 3 of the Biological Diversity Act, 2002 stipulates as follows:

(1) No person referred to in sub-section (2) shall, without previous approval of the National Biodiversity Authority, obtain any biological resource occurring in India or knowledge associated thereto for research or for commercial utilization or for bio-survey and bio-utilisation.

(2) The persons who shall be required to take the approval of the National Biodiversity Authority under sub-section (1) are the following, namely:-

(a) a person who is not a citizen of India;

(b) a citizen of India, who is a non-resident as defined in clause (30) of section 2 of the Income-tax Act, 1961;

(c) a body corporate, association or organization –

(i) not incorporated or registered in India; or

(ii) incorporated or registered in India under any law for the time being in force which has any non-Indian participation in its share capital or management.

7.73 The following details were furnished by the Authority about cases of violation of Section 3, year-wise, since the enactment of the Act, action

taken in each such case and its present status:

Year	Reported	Violation	Issue Action taken
2006	1	Clandestine transfer of jatropha germplasm from Indira Gandhi Agricultural University, Raipur to a multinational company	Sub judice
2010	1	Alleged misappropriation of local brinjal varieties by M/s. Mahyco and others.	Under investigation
2011	3	1. Alleged illegal transportation of Ongole Bull to Brazil. 2. Alleged export of Rabbit & Rat antigen by M/s. Imgenex India, Orissa to Foreign nations. 3. Alleged export of embryos of Gir breed Cows from Bhavnagar, Gujarat.	Under investigation

7.74 On the basis of a media report about continued inaction of the Authority in respect of case number 2 mentioned above, the Committee sought a detailed status note from NBA. In response the Authority informed that the article referred to deals with alleged violations of the provisions of the BD Act by M/s. Mahyco an Indian seed company. The factual note cum status of the cases is as under:-

Bt Brinjal Case

The National Biodiversity Authority received a complaint from Environment Support Group (ESG) alleging biopiracy by Monsanto and its collaborators in the development of Bt brinjal. Based on this, the Authority with the help of Karnataka State Biodiversity Board began investigating this allegation. Information and inputs from those institutions and agencies involved in the

development of the said Bt brinjal material were procured and legal assessment of this information is being undertaken considering the elements and extent of violation of the provisions of the Biological Diversity Act. Between August and October 2011 more information was sought from the agencies involved in the development of this material. Subsequently, M/s. Monsanto Holding Pvt. Ltd., submitted an application for accessing Onion material developed by Indian Institute of Horticulture Research, ICAR, Bangalore. This application is still to be cleared.

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

Mahyco and others. Allegations about continued inaction of the Authority in respect of this case were also reported in the media. The Committee sought a detailed explanation from the National Biodiversity Authority in the matter. According to NBA on the basis of a complaint alleging biopiracy by Monsanto and its corporate in development of Bt. brinjal, the Authority had began investigating the matter with the help of Karnataka State Biodiversity Board. Information and inputs from the institutions and agencies involved in the development of said Bt. brinjal material were procured and legal assessment of the same is being undertaken considering the elements and extent of violation of the provisions of Biological Diversity Act. Between August and October, 2011 further information was sought from the agencies involved in the development of this material. NBA also informed the Committee that a subsequent application of M/s Monsanto Holding Private Limited for accessing onion material developed by Indian Institute of Horticulture Research, ICAR, Bengaluru is still to be cleared.

7.76 The Committee are not at all convinced by the dilatory response of NBA on this sensitive issue. The matter is very simple as to whether the Company in question has obtained any local biological resource for and in connection with development

of Bt. brinjal without prior approval of NBA and violated Section 3 of Biological Diversity Act, 2002. Taking so long in coming to a conclusion on this simple issue shows the NBA in a very poor light. It would also be worth mentioning here that during this period Chairman, GEAC was simultaneously also holding the charge of Chairman, NBA from 11 November, 2010 to 11 August, 2011. The Committee not only desire a thorough inquiry in the matter of continued paralysis in decision making on a case of this dimension but also recommend that the NBA should decide upon this case without any further delay.

CHAPTER – VIII

TRANSGENICS IN FOOD CROPS

8.1 In view of the controversy surrounding transgenics in food crops the Committee desired to know about the likely effects/ramifications of genetic modification of various food crops in so far as the aspects of bio-diversity, bio-safety, environment, human health and health of livestock and animals are concerned. Different ministries/departments/organisations within the Government had different and often contradictory views in the matter. Varied opinions were also expressed on the Subject by several other stakeholders.

8.2 The Department of Science and Technology informed them in writing that they shared the global concern about the need for rigorous scientific studies of safety aspects prior to introduction of GM food crops. Therefore, the Department maintains that all aspects of biosafety, biodiversity, human and live stock health risk should be addressed and assessed by following globally debated and consensus science based biosafety assessment guidelines evolved from time to time by various international agencies and conventions prior to the introduction of such GM food crops. They further stated that based on the transgenic crops introduced, it is our view that case by case regulatory processes and procedures have to be stringently followed. It is also our view that current regulatory procedures and protocols in India are adequate to address food and environmental safety issues. As the experience grows with different types of GM crops, the regulatory science also evolves globally for assessment and management of even smallest of the risk. Currently in India, all GM crops are evaluated for safety and efficacy as per the protocols and procedures prescribed under the Rules 1989 of Environment Protection Act 1986 and relevant

biosafety guidelines notified from time to time. The biosafety guidelines adopted by RCGM/ GEAC are based on internationally recognized procedures for the comprehensive safety assessment of GM crops. No approval should be granted to the GM crops unless there has been a thorough analysis of its effects on the environment, biodiversity, biosafety, human health, and health of livestock and animals is proven to be safe. Safety and efficacy is evaluated by science based experimentation and analysis on case-by-case basis and therefore, cannot be generalized as these are product specific. The Department considers that the products based on GM food crops should meet three criteria namely bio safety to the consumers, desired socio- economic benefits to farmers and bio safety to maintain the biodiversity of ecosystem of the Country.

8.3 The Secretary, Department of Science and Technology while elaborating on this aspect stated during his Oral Evidence on 17 June, 2011:

“we need a very sound appraisal mechanism based on science and I believe, approval can be a policy issue, but appraisal is a very scientific issue as far as this particular technology is concerned. Therefore, Ministries like us have to work closely with the Ministry of Agriculture in this specific case and ensure that the appraisal process does not err in either side, either in favour or against. Precautionary principle in this particular technology is essential and that is done across the world. When we talk of the precautionary principle, it is necessary to quantify and measure the risk associated with these kinds of products. That is why the Science comes as a very necessary input into this process. In this, of course, I would be frank with you, if I understand the technology more from the general perspective rather than

somebody who is having hands on in this area. There are two divided views in the world. There are those who believe that risk must be eliminated to the level of zero; the risk must be determined, quantified and should be eliminated to zero and there are those who believe that it can only be minimized and to bring it to zero will be very difficult. But we must have sound appraisal and then post-introduction, we must have very strong surveillance method to ensure that even a trace of evidence to the contrary, we must be in a position to go back and retract. That is a kind of system that the people across the world have.”

8.4 On this crucial aspect, the view of the Ministry of Environment and Forests was that in case of modern agricultural biotechnology, the benefits as well as risks would vary from crop to crop, region to region and technology to technology depending on the gene-environment interaction, host-environment interaction and gene-host interaction (the level of protein expression). Safety and efficacy, therefore, cannot be generalized and needs to be evaluated by science based experimentation and analysis on case-by-case basis. Currently in India, all GM crops are evaluated for safety and efficacy as per the protocols and procedures prescribed under the Rules 1989 of Environment Protection Act 1986 and relevant biosafety guidelines notified from time to time. This includes generation and documentation of relevant biosafety information/data and its elaborate analysis to ensure food, feed and environmental safety in accordance with the biosafety guidelines adopted by RCGM/ GEAC. The environmental safety assessment includes studies on pollen escape out- crossing, aggressiveness and weediness, effect of the gene on non-target organisms, presence of the protein in soil and its effect on soil micro-flora, confirmation of the absence of Terminator Gene and baseline susceptibility studies. The food and feed safety assessment studies

include allergenicity and toxicological studies dietary exposure and substantial equivalence using test protocols such as: protein thermal stability, pepsin digestibility, molecular characterization, compositional assessment, acute oral toxicity (mice or rat), 90-day sub-chronic rat feeding, and livestock feeding (case by case basis).

8.5 The regulatory authorities are aware of the issues concerning the release of GMOs and therefore a strict regime of tests/ studies is being carried out for granting approval to the GM crop. No approval would be granted to the GM crops unless there has been a thorough analysis of its effects on the environment, biodiversity, biosafety, human health, and health of livestock and animals and it is proven to be safe. The Ministry consider that the products which are biosafe and have desired socio- economic benefits to farmers and consumers are to be supported for environmental release/cultivation.

8.6 Contrary to this, Dr. Vandana Shiva, Director, Research Foundation for Science, Technology and Ecology during her Oral Evidence before the Committee on 28 October, 2010 while speaking about various aspects of Bt. cotton including circumstances leading to its introduction in the Country, pricing of seeds, monopoly, etc. informed the Committee:

“Hon’ble MPs, the tragedy is Bt cotton entered our country illegally. We have a Genetical Engineering Approval Committee under the Ministry of Environment and this Committee has under the Environment Protection Act, created rules for the control of Genetically Modified crops. In 1998, Monsanto joined up with Mahyco and introduced Bt cotton. They did it through a letter of intent with the Department of Bio-technology which is not the regulatory body. So, our Research Foundation for Science,

Technology and Ecology brought a case to the Supreme Court to say that this was an absolutely illegal set of trials. Because of that case, approvals were delayed till April, 2002. The interesting thing is just before that a Nav Bharat-151 seed in Gujarat was found to have Bt traits in it. Dr. Desai who was the owner of the company Nav Bharat said I have done Genetic Engineering, I have taken the seeds from Monsanto Mahyco and if these traits are there, it has come through contamination. At that point, the Ministry of Environment filed a case against Nav Bharat and said Bt is very dangerous. What it does to the soil, we do not know; what it does to the other plants, we do not know. The entire crop of Gujarat was ordered to be destroyed and within a month when Monsanto Mahyco had to get the approval suddenly Bt was declared safe. In the years since these early Bt trials started and because of our case, the commercialisation could not begin in 2002. But Monsanto Mahyco already started to sell hybrid seeds, and hybrid cotton had a number of impacts on cultivation. In India, we have always grown cotton as a mixed crop. Traditionally, you had cotton and you would grow Jowar with it and then you would grow Tur Dal with it. You might grow some chillies with it. So a farmer had food and a farmer also had a cash crop. With the introduction of hybrid seeds, the farmer now had two new problems. The first, he had to buy the seed every year, and the second, these seeds were grown only as monoculture. So farmer stopped growing food and because hybrid cotton into which the Bt trait was later introduced requires irrigation, farmers also got into debt for irrigation facilities. That started the debt cycle and in 1998, we saw the first farmer suicide in the district of Warangal in Andhra Pradesh. A small farmer who had shifted from mixed crop to hybrid cotton and got into

debt for it. The suicides in the data shows that the suicides increased after 2002 when the Bt cotton was introduced. All the data shows that suicides have increased after 2002 when the Bt cotton was introduced. Records of the National Crime Records Bureau are 200,000 farm suicides have taken place in India. Most of them in the cotton belt. Because there was an attempt by the companies to make it look like that it has nothing to do with the Bt cotton, we did a primary survey and found that in Vidharbha, 84 per cent of the suicides were directly linked to debt created by the cultivation of Bt cotton. The cotton seed used to only cost Rs..5 or Rs.6 as long as the seed was produced by a public sector. The public sector research station is based in Vidharbha. The cotton research institute is one of the most eminent institutions in the world. Till Monsanto and Mahyco entered the market, most of the varieties used to be public varieties, very affordable and most of them open pollinated so the farmers could save seed.

After 1998, you do not see cotton research institute releasing varieties for the Deccan; they are releasing some varieties for north of India but not for the Deccan at all. From Rs.5 the seed cost jumped with GMOs to Rs.3,600 a kg. Of this, Rs.2,400 was royalty payment and most of the Indian cotton companies are now licensed to Monsanto and each company has to make an initial payment of Rs.50 lakh to get license to use the Bt gene. They cannot have anything to do with any other company. They cannot have any technical arrangement with any other company."

8.7 Expressing his serious concerns about the introduction of transgenics in agricultural crops Shri Aniruddha Ramchandra Murkute,

President, Bhartiya Kisan Sangh stated during his Oral Evidence on 10 February, 2011:

“Mr. Chairman, Sir, I am the President of Bharatiya Kisan Sangh. We have branches all over India and all our branches are registered.

We feel that ours is a big country and Genetically Modified Seeds will bring a hazard in this country. Our sovereignty, our right to seed and our right to water are essential. Our grains are rotting in godowns. Under this situation, why should we go for Genetically Modified Seeds when experiments are not done properly? We do not know the good or bad sciences of it and if we go for Genetically Modified Seeds, we will have to take the responsibility.

Now there are 7 lakh villages, 5,000 blocks and nearly 600 districts in our country and the persons living there are actually vacating the villages because they are not in a position to earn anything there. Initially they used to have their own seed with them. If they are deprived of their seed, wherefrom will they bring certified seeds? If something goes wrong somewhere, we have to take responsibility and it will be very difficult for only a 3-member committee to control everything. Our right to go to any court against this committee is also taken out of us. Therefore we are against it. We are not against any development as such. If the Government wants to go in for development, no doubt they should go for it.”

8.8 He further added:

“सर, मेरा यह कहना है कि जो गांवों के हमारे फार्मर्स हैं, वे अपने होश गंवा बैठे हैं। इसके कारण ही इतनी आत्महत्याएं बढ़ रही है। हमारे किसानों का जो विश्वास है वह हिल गया है। जैसे

बंगाल में अकाल पड़ा, लेकिन कभी किसी किसान ने आत्महत्या नहीं की। विदर्भ में किसानों ने आत्महत्याएं कीं, महारा-ट्र में किसानों ने आत्महत्याएं कीं। अब एम.पी. में हो रही हैं। इसका कारण यही है कि हम आज तक गांव के लोगों में विश्वास का निर्माण नहीं कर पाए। इसलिए पहला हमारा काम यह है कि किसानों की जिंदगी के लिए जो आवश्यक चीजें हैं, वे तो उन्हें मिल रही हैं, लेकिन उनमें आत्म-विश्वास पैदा करें। हिन्दुस्तान में इतना अनाज पड़ा है कि उन्हें नहीं मिला, तो भी कभी भी उन्होंने आत्महत्या नहीं की। आज बड़े पैमाने पर आत्महत्या हो रही हैं। इसका कारण ही यह है कि उनका विश्वास हम लोगों पर नहीं रहा है।

बीज निर्माण करना तो आवश्यक है, वह हम करते हैं। पहले हरेक काश्तकार के पास अपना बीज रहता था। कभी पहला बीज फेल्योर होता था, तो वह सैकिंड क्रॉप लेकर निकलता था, लेकिन तब उसका अपना खुद का बीज रहता था। हम बचपन में देखते थे कि जब बीज होता था, तो घर का बीज निकाल कर कहीं ऊपर रख देते थे। उस समय दो प्रकार का बीज रहता था। पहले प्रकार का बीज लगा दिया, यदि कभी वह फेल हो गया, तो दूसरे प्रकार का बीज लगाकर क्रॉप ले ली जाती थी, लेकिन वे दोनों बीज घर के ही होते थे।

आज जैनेटीकली मॉडीफाइड सीड आ रहे हैं, तो उसके घर का तो वह बीज नहीं होता है। इस प्रकार देखें, तो बीज के मामले में किसान की जो स्वतंत्रता थी, वही चली गई। इसलिए हम कहते हैं कि हमारा रा-ट्र तो स्वतंत्र है, लेकिन हमारे गांवों के सब लोग गुलाम होते जा रहे हैं। पहले ऐसा था कि हमारे यहां गांव गुलाम नहीं थे। बाद में जब दूसरा राज आया, तो कम से कम स्वतंत्रता चली गई, लेकिन गांव गुलाम नहीं थे। आज स्थिति यह है कि हम स्वतंत्र हैं, लेकिन हमारे गांव के गांव गुलाम होते जा रहे हैं, क्योंकि हमारे पास हमारा बीज नहीं है, हमारा पानी नहीं है, हमारे जानवर नहीं हैं और हमारी जो ऑर्गेनिक फार्मिंग है, वह नहीं है।

8.9 Another representative of the Organisation while elaborating further stated:

“We have got the report that nowhere the GM crops are high yielding. Many people are now talking about food security, population, getting more food grains and that GM seeds will help us in these regard. But till date nobody has claimed that GM

seeds are high yielding. This is the major question. It is a false propaganda that food security will be achieved by GM technology.

Secondly, as per the latest survey of January 2010 in America it is found that 6.9 billion dollar was the economic benefit to the farmers over the previous year in the Mid-West States and they also found that around 4.3 billion dollars came from non-BT corn. This is the latest survey from the USA. So, it is a false claim that we will grow more food by GM seeds. It has been there in agriculture since 1990s in America but nobody claims that this is high yielding.

When we raise the question of food security, there is a basic question of seeds. Again, to fulfil the question of food security, at least, four to five components are there because we are confusing the green revolution by saying that only seeds can do the performance. But it is not true. Unless we have a better productive soil, unless we have good water, unless the pollination rate is more and unless good Sun shine is there, we cannot produce more food. This is a common science. So, we need productive soil as well and these will be deteriorated by the GM seeds. The GM technology is a permanent perennial irreversible source of poison to these things. We are against chemical agriculture and we are for organic agriculture. It is not permanent, there is scope for change. But every scientist accepts that this is irreversible.

As far as food security is concerned, we cannot take this technology and it is a confusing statement by some companies that GM seeds are high yielding. Food security is our main concern, so at least the scientists or the technocrats of our country should go in for these four major components, that is,

high productive seed, better soil, good water, Sun shine and pollination rate. Many scientists are saying that our productivity has been stagnated and many of them are concerned about the low pollination rate in the cropping system in agriculture. So, we have to look at those chapters also.

As far as health and ecology are concerned, everything has been researched throughout the world. I am coming to only the economy of the farmers. The farmers of our country are small farmers. Once their produce goes to the market and if somebody says that it is poisonous then it will not fetch more money. Our people are cultured and ethical. People buy the products which come directly from the villages without chemicals. I have seen this in many States people would buy products which are free of pesticides.

The GM seeds will be costly, one has to pay more price for the seeds and it may cost ten times more than the present cost of seed. When the produce will go to the market labelled as GM food, people will not purchase that and again it will be hampering the economy of the farmers.

Moreover, the GM technology seeds will be patented. If at any point of time the company which is producing the GM seeds is not able to supply the seeds, what will the farmers do? There will be no control over the price. It will put more burden on the farmers. So, all these aspects have to be considered by the scientists, technocrats, businessmen, etc. of our Country.”

8.10 Since genetical modification as well as transgenics is modern biotechnology based phenomenon, the Committee sought the views of the MoEF on the genetically modified/transgenic food crops from that

angle. In response it was stated that agricultural biotechnology has the potential for ensuring food security, decrease pressure on land use, increase crop yields and reduce use of water and agrochemicals in agriculture. However, there are concerns about the potential risks associated with their use to human health, environment and biological diversity. The Ministry are guided by the statement made by the Prime Minister at the Indian Science Congress on January 3, 2010 at Thiruvananthapuram wherein he has categorically stated that “we should pursue all possible leads that biotechnology provides that might increase our food security as we go through climate related stress subject to the condition that the question of safety is given full weightage, with appropriate regulatory control based on strictly scientific criteria”. Accordingly, we are following a policy of case by case event based approval in case of Genetically Modified foods or food crops. In view of the various concerns, introduction of any new GM food /food crop is preceded by a careful analysis of risks and evaluation of long term benefits for which extensive rules and guidelines have been framed by the Ministry for evaluating environmental and health safety impacts of genetically modified organisms. Evaluation of the safety of GE crops and regulatory approval process takes place right from the research stage. This includes generation and documentation of relevant biosafety information/data and its elaborate analysis to ensure food, feed and environmental safety. The development of GM crops at the laboratory stage, confined multi-location trials for generation of biosafety data known as biosafety research trials – I and biosafety research trials-II (BRL-I and BRL-II) require prior approval of the RCGM and the GEAC set up under the Rules, 1989. The compliance of the regulatory procedures during GM crop field trials is monitored by the Monitoring Committees set up by the RCGM/GEAC. The GEAC takes into consideration the findings of the biosafety and agronomic studies as

well as recommendations of the RCGM and MEC before according approval for environmental release. Only those transgenic crops which are found to be safe for human consumption as well as the environment are recommended for environmental release.

8.11 Elaborating further on this aspect and drawing a comparison of the situation obtaining in USA, EU, etc. and in India Dr. Sagari R. Ramdas, Director, Anthra informed the Committee during her Oral Evidence on 28 October, 2010:

“The issue with the USA is that in USA they have no base line data and subsequent close monitoring. So, there are no systems of keeping track as to the impact of feeding either the Bt or the non-Bt. This is the basic, primary problem with the information coming out of USA. USA has taken a position that they are not going to monitor. So, today, if we go in and try to get the public research institution data as to what is the impact, primarily it is Bt-corn, Bt-soya and Bt-rapeseed which are the three major items, there is no evidence and no data because they do not keep the records.

To bring to your notice a very interesting development in 2009, that the USA EPA has recently instituted a public research grant for US scientists to research on the impact of food allergies, particularly they are investigating food allergies from animals which are being fed, GMOs. They are investigating and looking at GMOs food in general because USA is a country with one of the highest incidences of allergies. So, this is a very recent development. Public research grants have actually been announced because of a concern. Hopefully, in the coming years we should be able to get some kind of more detailed evidence.

Coming to the question of European Union, the information is extremely different and it varies country to country. For instance, we do have reports from Germany of the impact of feeding Bt-corn on swine, pig. We do have some information of feeding of Bt-maize, particularly on cattle but the big difference and the reason of non-comparability between the Indian situation and what happens in the West is, their system of production is the industrial system and we have mixed crop livestock grazing systems. Nowhere else in the world, Sir, are animals grazed on harvested crops. In all the industrial systems in EU, USA and Australia, it is the grain – either Bt-corn grain or Bt-soya grain – which is directly fed to the animals. Sometimes it is crushed and sometimes it is processed and fed. The unique situation of India is that our animals graze on the harvested crops. If Bt-brinjal is not consumed by the humans but it is usually fed to the cows or buffalos. In that situation, it is a completely new situation which demands new protocol of testing. But I will pass on to you two or three cases from Germany where Bt-corn was fed to swine, which is pig and Bt-corn fed to cattle. Similar situation in India, which is grazing on harvested crops, is so unique to our country, because we are still at the extensive system of livestock rearing that we cannot find similar evidence from either USA or from Europe.”

8.12 Ms. Aruna Rodrigues, lead petitioner of the PIL on GM field trials in the Supreme Court of India while highlighting the irretrievability factor of GM crops during her Oral Evidence on 28 October, 2010 stated:

“Furthermore, it is very clear, that unlike a drug, however dangerous or fatal like thalidomide that impacted generations with birth deformities, which can be recalled, GMOs once released into

the environment, on the other hand, cannot be recovered. Therefore, the impacts of genetic contamination are irreversible. At least one Biotech Company has claimed Force Majeure or 'Act of God' as insurance cover for this very reason! The loss of India's even now, rich genetic stock of non GM seeds and genetic wealth in wild species like brinjal, rice and other crops would get contaminated by GM crops with incalculable impacts of far-reaching consequences. It would change the molecular structure of our food for all times. Therefore, there are substantial reasons for caution and the application of the precautionary principle. There is certainly no need to hurry and rush the introduction of any GM crop into our agricultural system."

8.13 Clarifying their stand before the Committee on this crucial aspect the Department of Agriculture and Co-operation stated on this issue that as per recommendations of the "Task Force on Applications of Agricultural Biotechnology", also commonly referred to as the Dr. M.S. Swaminathan Report, biotechnology provides an opportunity to convert bio-resources into economic wealth. This has to be done in a manner that there is no adverse impact either on the environment or on human or animal health. The guiding principle for following a national agricultural biotechnology policy should be the economic well being of farm families, food security of the nation, health security of the consumer, protection of the environment and the security of our national and international trade in farm commodities.

8.14 As per the National Policy on Farmers (NPF), 2007 with regard to Genetically Modified (GM) Crops, there is a need to assess the risks and benefits associated with GM crops in a credible and transparent manner. Priority would be given for genetic modification to incorporate genes which can help impart resistance to drought, salinity and other stresses.

Water-use efficiency as well as improvement of both nutritive and processing quality would also be accorded priority in the research agenda. Training and awareness in agronomic management procedures in respect of GM crop varieties would be introduced.

8.15 The transgenic crops have potential to improve crop production and productivity even in adverse situation. But before commercialization of GM crops, their bio-safety, environmental safety and other safety measures should be examined on a case by case basis. As per information available, significant research, efforts have already been made by Indian Organizations in both public and private sector. The ICAR, Department of Biotechnology(DBT), Public and Private sectors are involved in bio-safety, environmental safety and other safety measures on Bt. cotton in the following areas:

(i) Biosafety Studies with Bt Cotton

Environmental Safety Studies

1. Out-crossing studies for PCR & Aggressiveness and Individual Plant analysis.
2. Study to generate data on the stability of Cry1Ac gene required for seed production for Bt cotton Expressing *cry 1 Ac gene (Mon 531 event)*.
3. Pollen – flow study of Bt cotton
4. Transgenic cotton expressing the *Bacillus Thuringiensis* Endotoxin: Effects on soil micro-flora & non – target soil Organisms with special reference to earthworms.
5. Expression levels of Cry1Ac insect control protein found in Bt cotton hybrids

6. Studies on susceptibility of *Helicoverpa Armigera* (Hubner) to Cry1Ac protein
7. Studies on susceptibility of *Helicoverpa Armigera* and other Lepidoterans to *Bacillus thuringiensis* proteins

(ii) Food and Feed Studies

8. Assessment of the allergenicity of Indian Bt cotton seed proteins relative to conventional seed proteins
9. Allergenicity potential of cottonseed meal from Indian Hybrid cotton and non – transgenic Indian hybrid cotton in a Guinea pig model
10. 90 day goat feeding study
11. Segregation of Bt gene in breeding program
12. Anaylsis of Expressed Proteins in Fibre Fractions from Insect – Protected and Glyphosate - Tolerant Cotton Varieties.
13. Aerobic Soil Degradation of *Bacillus thuringiensis*
14. Dietary toxicity study with Parasitic Hymenoptera
15. Evaluation of the Dietary Effect(s) of Purified B.t.k. Endotoxin Proteins on Honey Bee Larvae and Adults.
16. Dietary toxicity study with Ladybird Beetles
17. Dietary toxicity with Green Lacewing Larvae
18. Effect of *Bacillus thuringiensis* insecticidal Protein Cry 1A(b), Cry1Ac, Cry2A, Cry3A on *Folsomia candida* and *Xenylla grisea* .
19. Dietary toxicity study with MON46003 Meal in the Northern Bobwhite.
20. Evaluation of processed cotton seed meal from insect protected cotton as a feed for atfish
21. One month feeding study with MON 46001 and MON 46002 in Sprague Dawley Rats

22. Similarity in the chemical composition of Bt protected and control cotton seed of four cotton hybrids
23. Quantitative estimation of B.t.k. HD73 Cry1Ac protein degradation in model mammalian digestive fluids
24. Acute oral toxicity of *Bacillus thuringiensis*
25. Effect of feeding Bt cottonseed on feed intake, milk production and composition in lactating water buffaloes
26. Effect of feeding Bt cottonseed produced from Bt cotton on feed intake, milk production and composition in lactating cows in India
27. Comparison of chicken performance when fed with diets containing Bt cotton, parental non – Bt line or commercial cotton
28. Evaluation of raw cottonseed meal derived from Bt cottonseed as a feed ingredient for Indian catfish, Magur

(iii) Others

29. Levels of Cry 1Ac Insect control protein found in Bt cotton hybrids.
30. Detection of Bt protein Cry1Ac in field-grown transgenic cotton in different plant tissues and growth stages .
31. Molecular characterisation of Mahyco Bt cotton hybrids MECH-12, MECH-162, MECH-164
32. Confirmation of the absence of 'terminator gene' i.e., a patented embryogenesis deactivation system in Mahyco Bt cotton hybrids
33. Insect resistance studies on other plant pests

(iv) Agronomic

34. Performance of Bt and non –Bt cotton hybrids at 376 locations in large scale field trials in Central and South India
35. Research field trials of Bt cotton hybrids at 14 locations in South and Central Zone
36. Analysis of socio-economic impact of Bt Technology on Indian cotton farmers

(Source – Biotech Consortium India Limited)

8.16 Prof. G. Padmanabhan, Professor Emeritus, Department of Chemistry, Indian Institute of Science, Bengaluru while presenting a risk=benefit analysis of Genetically Modified Crops stated during his Oral Evidence on 28 October, 2010:

“I would give two examples which I have tried to mention in my talk – Bt for example, at some point of time, resistance would develop. Already people in Gujarat are talking, in some areas, ball worm or pink worm is not responding. Monsanto or Mahyco is saying to shift, from Bollguard I go to Bollguard II. That means, from one gene, you go to two genes. If resistance should happen, it would happen. All our research with pest-resistant GM crops in my opinion should have only two genes at least. We should not release any variety, other than Bt Brinjal, with a single Bt. gene.

The other example I want to give is the herbicide tolerance. Do we need herbicide tolerance in this country? Because you want to remove the weeds and there is so much of labour available in this country; manually we can remove. All that I am trying to tell is assessment should be case by case basis. We may not need

herbicide tolerant variety but we would need a pest-resistant variety. We need a variety that would improve nutrition. Should we blindly go for herbicide resistant crop? Most of the contentions issues are with herbicide Resistant GM Crops. Experts should really look at whether it is needed for this country.”

8.17 With regards to the apprehensions in several quarters about the safety of Genetically Modified crops he stated:

“All I am trying to tell is, scientific facts are exaggerated. If there is a five percent difference, it is magnified as being very toxic. That is where statistics come into play. In fact, if you understand the science you would know the correct position. The other point made out is that the tests are not adequately done with 20 soil organisms but you should do it with 200. You have done it for 90 days (feeding trials), you should do it for 180 or for a very long time. That is where the judgement has to take place. That is why, I said, 90 days in a rodent is equivalent to ten years in man’s life. How long do we do this? I respect all those who oppose. Whatever argument I give, they are not going to buy it. I know that also. They will not accept because they are convinced that GM is not acceptable. I also accept that there is an element of risk in this. My contention is, the advantages weigh far above the perceived risks. That is why, we should go for GM. Especially in the area of nutrition, abiotic stress, etc. where genes can be obtained from another plant. Dr. Asis Datta has demonstrated this in potato. But my point is, by blocking Bt Brinjal, we are blocking the entire chain. People are asking – what is so great about Brinjal and why should we worry about it? We should have stopped it (Bt. Brinjal research) ten years ago. We did not do it. Now, if we stop it, the entire chain is blocked. There are at least

20 crops which Indian scientists are doing. The hon. Member has raised this issue and I respect all those who oppose. My only contention is, the benefits are much higher than the risks. I would not say, it is risk-free. There are certain risks.”

8.18 The contention of ICAR was that while conventional methods of crop improvement have served the needs till date, challenges of ensuring food and nutritional security of burgeoning population with limited land and water resources in recent past have necessitated new and non-conventional approaches. In addition, the adverse effects of global climate change impose new limitations on crop production. Some of the limitations of conventional breeding are:

- (i) lack of germplasm resources resistant to some of the major pests and pathogens of important crops,
 - (ii) the new plant types evolved for higher productivity are more vulnerable to pests and diseases,
 - (iii) problems in sourcing genes from wild relatives,
 - (iv) lack of nutritional qualities in major cereals crops,
 - (v) conventional plant breeding being based on phenotypic selection, and
 - (vi) plant-environment interactions affect the selection process.
- Advances in modern biology, especially biotechnology, offer many advantages over traditional techniques of plant breeding for bringing improvement in food crops. In addition to the enhanced levels of food production, the human society can realize the benefits of nutritional security, low production costs, conservation of biodiversity, enhanced input use efficiency for sustainable agriculture and environment, improvement of economic and social benefits and the alleviation of poverty.

8.19 All crops that are developed through conventional breeding methods are also genetically modified as at least recombination of genetic material of two genomes is involved in such hybridization process. However, conventional breeding involves the same crop species as source of genes for various agronomic traits. In case of genetic modification/ transgenics developed through modern biotechnology, genes are transferred across species barrier as it has been witnessed in several GM crops being cultivated in different countries world over; Bt cotton under cultivation in India has been developed with a gene from a bacterium for resistance to boll worm.

8.20 ICAR was also of the view that the modern tools of biotechnology should be adopted to improve productivity as well as production of our staple food crops, particularly pulses and oilseeds for resistance to insect/pests, major cereal and horticultural crops for tolerance to abiotic and biotic stress factors, and for nutritional enhancement with phyto-nutrients through the process of bio-fortification in crops such as rice, wheat, maize, potato, mustard and groundnut. Saving post-harvest losses is another important objective that could be possible through biotechnological intervention.

8.21 The Department of Agriculture and Cooperation throughout maintained their stand regarding the production and productivity advantages of Bt. cotton and GM crops. However, Secretary of Department of Agriculture and Cooperation while appearing before the Committee on 9 May, 2012 in a different context stated in regard to transgenic agricultural crops:

“महोदय, आपने बीटी कॉटन और बीटी ब्रिंजल के बारे में कहा। हम उसके बारे में इक्वली चिंतित हैं क्योंकि 92 प्रतिशत एरिया बीटी कॉटन का हो गया है। हम लोगों ने शोध किया तो पता चला, उदाहरण के लिए ब्राजीज में ज्यादा बीटी इस्तेमाल नहीं करते हैं लेकिन हमसे करीब तीन गुना

उनकी प्रोडक्टिविटी है। इसको पता करने के लिए हमने अपनी टीम भेजी कि क्या कारण है। हमें पता चला कि उन्होंने अपने प्लांट आर्कीटेक्चर को, अपने वेरायटीज़ को इस तरह से विकसित किया है कि उनकी प्रोडक्टिविटी हमसे तीन गुना ज्यादा है। हम अभी वही कोशिश कर रहे हैं कि हमारी जितनी भी अच्छी वेरायटीज़ हैं, उन्हें हम सीआईसीआर नागपुर के माध्यम से विकसित करें। हाल ही में हमने और हमारी पदाधिकारियों ने बैठक कर के तय किया है कि उसे हम बढ़ावा दें और धीरे-धीरे हमारे वेरायटीज़ में बीटी आए तो ठीक है और नहीं आए तो भी ठीक है क्योंकि भारतवर्ष एक मात्र देश है जिसमें इतने बड़े पैमाने पर बीटी कॉटन यूज़ हो रहा है। हम आपसे पूर्णतः सहमत हैं और अगले दो-तीन सालों में एक मैसिव ड्राइव कर के, हमें चाहिए कि हमारी जो बैटर वेरायटीज़ हैं, उसकी प्लांट आर्कीटेक्चर चेंज करें, उसकी इल्ड कैसे बढ़े, उसे देख कर हम कर सकते हैं। जरूरत पड़े तो ब्राजील या अन्य देश में अगर कोई अच्छी वेरायटी उपलब्ध है, उसे भी ला कर एक्सपेरिमेंट कर सकते हैं। यही सब करने के लिए हम लोग कोशिश कर रहे हैं।”

8.22 When told that it would be a gigantic task to revive the traditional cotton varieties from gene bank and may take years together he admitted:

“I agree. We have to start on it today itself.”

8.23 When he was told that though the Government had belatedly realized this fact, but it was still not too late, the witness further admitted:

“Yes, Sir. It is not too late. We can take care of varieties which will produce the same amount of cotton and not necessarily depend on Bt cotton.”

8.24 In this regard, the Department of Science and Technology were of the view that recombinant DNA technology is one of the breakthrough technologies like that of nuclear energy, super computers, etc. Such breakthrough technologies have revolutionary potential to bring out

paradigm shifts in the existing systems. Policies and governance systems need to be created to ensure that the benefits are achieved and environmental and safety concerns associated are addressed effectively. The scientific community and policy makers all over the world including India during the last two decades have invested resources in the advancement of basic biological sciences and development of new technology tools for Genetic Modification of crops with view to increase food supply and avoid food losses on account of attack by pests etc. The perspective of the Department of Science & Technology has been to promote and develop R&D capacity in the frontier areas of science & technology including recombinant technologies and techniques for genetic modification of crops at research levels. While supporting research in these areas, the Department ensures adequate precautionary measures enshrined in international conventions, protocols and systems. The Department of Science & Technology has been consulting the concerned Departments with domain knowledge and allocation of mandates and agrees with the views of sister departments while supporting work relating to research on GM crops.

8.25 The view of the Department on the subject is that the GM crops offer potentials to increase the crop yield per hectare significantly and therefore such technologies would be required or even become critical for ensuring food security of countries like India in the years to come. India would need recourses to these advanced technologies. However, the Department is committed to the precautionary principle in the introduction of GM crops into the eco system in the country and maintains that rigorous scientific assessments and critical review of safety aspects are necessary as a part of appraisal process prior to approvals for introduction in agricultural practice. This view of the

Department on genetically modified/transgenic food crops is also generally aligned to those of the Department of Biotechnology and Council of Scientific and Industrial Research under the Department of Scientific and Industrial Research.

8.26 On the aspect of transgenics in food crops, DARE/ICAR were of the view that genetically modified or transgenic crops by nature are eco-friendly, sustainable and protective to environment and biodiversity. The most important features of GM crops are:

- (i) increasing crop productivity, and thus contribute to national food, feed and fibre security,
- (ii) lowering production costs,
- (iii) conserving biodiversity as a land-saving technology capable of higher productivity on a per unit land basis,
- (iv) efficiently utilizing the external inputs such as fertilizers and water,
- (v) increasing stability of production to lessen suffering during famines due to abiotic and biotic stresses,
- (vi) improvement of economic and social benefits and the alleviation of poverty, and
- (vii) safer human and animal health through reduction of chemical inputs in agriculture and also ensuring safer soil, water and foods.

8.27 Moreover, there is a comprehensive regulatory mechanism in operation in the country under the aegis of Department of Biotechnology and Ministry of Environment and Forest for the bio-safety on GM crops and products thereof in so far as the aspects of biodiversity, bio-safety, environment, human health, and health of livestock and animals are concerned. Further, recent scientific analysis

by experts on GM maize, oilseed rape, and soybean with two main GM traits, herbicide tolerance and insect resistance grown for ten years in field has shown that cultivation of GM crops for a decade has caused no damage to the environment (Sanvido et al 2007).

8.28 Ms. Kavitha Kuruganti, Trustee, Kheti Virasat Mission while enumerating several negative impacts of Bt. cotton cultivation stated during her Oral Evidence on 28 October, 2010:

“अभी हम साबरमती आश्रम से राजघाट तक 71 दिन की यात्रा लेकर निकले हैं। हमने उसे गांधी जयन्ती के दिन शुरू किया था और हम दिसम्बर 11 को राजघाट पहुंचेंगे। मुद्दा यह है कि खेती में क्या संकट है। मगर जीएम बीज की बात भी बार-बार आ रही है। गुजरात में हम सौरा-ट्र के एरिया में गए थे और मध्य प्रदेश में झाबुआ, इंदौर, देवास के इलाके में गए थे। विदर्भ में अकोला, बुलडाना, are the parts which grow Bt cotton in Maharashtra. कर्नाटक में हावेरी, धारवाड़ भी कॉटन ग्राइंग एरियाज़ हैं। अभी हमारी यात्रा तमिलनाडु पहुंची है जो सेलम का एरिया है। मैं आज इधर आ गई हूं। हम देखते हैं कि गुजरात में सौरा-ट्र के किसान यह कह रहे हैं कि पैस्टीसाइड्स के नम्बर ऑफ स्प्रेज़ फिर से बढ़ते जा रहे हैं। वे कह रहे हैं कि today the average number of sprays on Bt cotton is 12 to 15 times whereas about 6-7 years ago, they brought it down to 2 to 3 sprays in the initial years of Bt cotton entry. उसमें मैं पसर्सनली यह बात जोड़ रही हूं कि इस देश में किसानों को पैस्टीसाइड छिड़कने की जरूरत नहीं है, वह कौन्फीडेंस और डिस्प्लिन किसी ने नहीं दिलाया। लेट नाइनटीज़ का एक जमाना ऐसा होता था when farmers out of tremendous fear inside them, whether they see a pest on the crop or not. मैं गुंटूर से आती हूं और वहां के बारे में बता सकती हूं। वे हर दूसरे, तीसरे दिन अपना पैस्टीसाइड स्प्रेयर लेकर निकल जाते थे। If At all something positive has to be said about Bt cotton, I think the aggressive marketing around Bt cotton helped farmers think around Bt cotton as a way of disciplining their pesticides usage. But the thing is that today pesticide usage is going up in places like Gujarat. हमें गुजरात से यह बात भी पता लगी कि वे देख रहे हैं कि जानवरो, खासकर शीप में मिसकैरेजेस जो बीटी कॉटन के ऊपर चढ़ते हैं, जानवर मर गए, यह उनका अनुभव

नहीं है, मगर वे बता रहे हैं कि मिसकैरेज बहुत हो रहे हैं, रीप्रोडक्टिव हेल्थ इम्पैक्ट्स देख रहे हैं। हमने झाबुआ में देखा कि बीटी कॉटन आने के बाद fertilizer use has gone up by 150 to 200 percent. हर जगह यह बात जरूर आई है कि आज के दिन मार्किट में किसानों को और कोई च्वाइस नहीं है, नान-बीटी कॉटन सीड्स सप्लाई करने वाले कोई नहीं रहे हैं। नान-बीटी कॉटन सीड्स इससे पहले 120 ग्राम जो रैफ्यूज के लिए दिया जाता था, for planting around Bt cotton field, 25 percent or five rows of non-Bt cotton, अभी वह रिकमेंडेशन भी इंडिया के रेगुलेटर्स ने बदल दी हैं। वे कह रहे हैं कि आप तुअर डाल सकते हैं, नान-बीटी डालने की जरूरत नहीं है। कीड़े में रैसिस्टेंस कंट्रोल करने के लिए तुअर के रोज़ लगा सकते हैं। अब वह नान-बीटी भी उपलब्ध नहीं है। There are no choices left for farmers. This is the important thing that came out. अगर आंकड़ों के माध्यम से बताना पड़े, बीटी कॉटन आने से पहले विदर्भ में, 1997 से 2002 तक, average number of annual suicides जितनी होती थी, seven years after Bt cotton came in, there has been an increase of 60 percent in the average annual number of suicides of farmers in Maharashtra as per the National Crime Bureau records. This is the data shared by Mr. P. Sainath. It obviously shows, even if we can't make a cause and affect relationship कि बीटी कॉटन की वजह से ही किसानों में आत्महत्या हो रही है, it at least proves that Bt cotton has not been a solution. After it had come, suicides have increased in numbers. That much it clearly shows in terms of data.”

8.29 Dr. G.V. Ramajanyelu, Director, Centre for Sustainable Agriculture expressing his concerns over the issues like pricing and monopoly of transgenic seeds informed the Committee during this Oral Evidence on 15 November, 2010:

“When Bt. Brinjal discussion was going on, the company already started booking seed at Rs.50000 a kilo. You can imagine to what extent the prices will go up. That is a major issue and this has to come in. One more issue which has happened is, people

say that there is a large-scale spread of Bt cotton, and that since it is good people are adopting it. But what actually happened is that the public sector has withdrawn all the varieties of cotton in the country. In the last three years, not even one kilogram of seed is sold by any of the public sector institutions in the country. No CICR, no agricultural university in the country, no Seed Corporation, has sold even one kilogram of cotton seed. They have withdrawn from the market.

There is another major discussion going on that if the public sector does GM, it will be good. CICR has released GM Bt cotton two years back. This year they have withdrawn from the market because it is already contaminated. A new variety Bikaneri Narma was released this year. They have not sold even ten grams of the seed. That is the situation. So, expecting that the public sector will come and do something is also wrong. In that situation, giving away all rights to the companies and having no powers to regulate them is going to be a serious a problem.

There are four court cases filed on Andhra Pradesh Government today saying you cannot regulate us, you cannot regulate our prices, you cannot regulate our royalties, you cannot ask us to pay compensations. That is the reason why the Andhra Pradesh Government is repeatedly making requests to the Centre that the new Seed Bill should have these clauses in the Bill.

This is not the experience only in India. This is the experience the world over. Many independent studies showed that there is problem with GM crops. In India we have not yet seen these reports because no independent research has been done. All the reports which are coming in are the reports only from the company.”

8.30 About the stand of the Department/ICAR before the competent authority with regard to introduction/field trials/cultivation of GM/transgenic crops in the Country, it was stated that ICAR/ DARE have been supporting the development of GM crops, and research is being carried out in its various institutes over the past several years on development of transgenic crops. ICAR has always been keen to use science based technology for crop improvement. Since the GM technology has given advantage to the farmers and growers across the world, ICAR always feels that GM technology and products, thereof, should be made available to the farmers in India. Only Bt Cotton is currently being cultivated in the country. In 2002-03, Bt cotton with resistance to boll worm was introduced in the country by the private sector. Currently, Bt cotton is grown in over 8.00 million hectares out of 9.00 million hectares and farmers have got immensely benefited as the productivity and production increased two fold in the last about 7-8 years. The area under cultivation of Bt cotton in the country has increased from 20,000 hectares in 2002 to more than 8.0 million hectares in 2010. In 2010, India produced 31 million bales of cotton and now occupies second position in terms of global cotton production. According to ICAR survey in 2002, profit of Bt cotton to farmers ranges approximately between Rs. 4000 to Rs. 8000 per hectare. Bt cotton farmers have not only gained from increased production but have also saved significantly towards the cost of pesticides.

8.31 However, when the question of increase in production was put by the Committee to Director, National Institute of Plant Genome Research during his Oral Evidence on 28 September, 2010, he stated:

“The question of livelihood is very important. Misguided people would, of course, suffer. Therefore, we said that there should be contact with the people. Let me also tell you that for Bt cotton, the advantage of protection of the yield will come only if

there is infestation. If in a particular year there is no infestation, the farmer who has used Bt seed will not get any advantage because there are no harmful effects. So, there is no protection. Therefore, we have to tell this thing and communicate at the block and extension levels all these things because continuous communication with the people must be there. One should know what advantage means. What is the advantage? It is protection of the yield. It is not increase. Anybody who is saying that Bt gene will increase the yield is wrong. It is only to protect the loss of the yield. If in a particular year there is no infestation, then, of course, that advantage will not accrue to this particular farmer and he will not be in an advantageous situation. So, this is very important. That is where the Government intervention is required along with the industry. The Government is supporting the public-private partnership. It is a good concept. We see that there are some benefits of it. Therefore, we cannot nip it in the bud. But, at the same time, as has been written in the academic report, I say that this is so important an issue that it cannot be left to the private industry alone.”

8.32 As regards the extent to which their stand has been accepted by the competent authority while deciding upon each of these cases, it was stated that GM Crop development in different crops by ICAR has been positively accepted by various committees of the Ministry of Science & Technology (RCGM of DBT) and Ministry of Environment & Forest (GEAC) for the conduct of event selection trials and biosafety research level (BRL-1 and BRL-2) trials. To take up such studies in research laboratories at different ICAR’s institutes, an Institute Biosafety Committee first gives permission as per Government of India guidelines, with Director of the respective Institute as Chairman of such a Committee.

8.33 The details of projects being undertaken by various constituents of ICAR is given in the Table below:

S.No	Crops	Year	Institute	Traits
1.	Brinjal	2006	NRCPB, IARI, New Delhi	Insect resistance
2.	Castor	2006	Directorate of Oilseeds Research, Hyderabad	Insect resistance
3.	Potato	2006	Central Potato Research Institute, Shimla	Fungal resistance
4.	Rice	2006	IARI, New Delhi	Insect resistance
5.	Tomato	2006	IARI, New Delhi	Virus resistance
6.	Potato	2009	Central Potato Research Institute, Shimla	Tuber sweetening
7.	Sorghum	2009	National Research Centre for Sorghum, Hyderabad	Insect resistance
8.	Watermelon	2010	Indian Institute of Horticultural Research	Virus resistance
9.	Tomato	2010	Indian Institute of Horticultural Research	Virus resistance
10.	Tomato	2010	IIVR, Varanasi	Insect resistance
11.	Tomato	2010	NRCPB, New Delhi	Fruit ripening
12.	Papaya	2010	Indian Institute of Horticulture Research	Virus resistance
13.	Sugarcane	2010	Sugarcane Breeding Institute	Insect resistance
14.	Sorghum	2010	Central Research Institute for Dryland Agriculture	Abiotic stress tolerance
15.	Groundnut	2010	University of Agricultural Sciences, Bangalore	Abiotic stress tolerance
16.	Mustard	2010	NRCPB, New Delhi	Abiotic stress tolerance

8.34 The field trials and biosafety testing are in progress with respect to above-mentioned events as accepted and approved by RCGM and GEAC.

8.35 The view of Department of Biotechnology on the aspects of bio-diversity, bio-safety, environment, human health and health of livestock and animals was that the level of risk ramifications of genetic modification of various food crops in terms of safety to human, animals, environment and biodiversity varies with the nature of genes, traits and crops. Therefore, such a question is addressed by following globally debated and consensus science based biosafety assessment guidelines evolved from time to time by various international agencies,

conventions and fora. Based on the transgenic crops introduced, it is our view that case by case regulatory processes and procedures have to be stringently followed. It may also be noted that with any technology, *a total certainty of cause and consequences can be assured*. It is our view that current regulatory procedures and protocols in India are robust enough to address food and environmental safety issues. As the experience grows with different types of GM crops, the regulatory science also evolves globally for assessment and management of even smallest of the risk.

8.36 Reiterating the views of MoEF and DARE/ICAR, the Department stated that currently in India, all GM crops are evaluated for safety and efficacy as per the protocols and procedures prescribed under the Rules 1989 of Environment Protection Act 1986 and relevant biosafety guidelines notified from time to time. The biosafety guidelines adopted by RCGM/ GEAC are based on internationally recognized procedures for the comprehensive safety assessment of GM crops, including those from the European Union, FAO/WHO, CODEX alimentarius, and Organization for Economic Cooperation and Development. The GEAC guidelines require a comprehensive safety testing to be conducted for a GM crop including toxicity assessment, allergenicity assessment, dietary exposure and substantial equivalence using test protocols such as: protein thermal stability, pepsin digestibility, molecular characterization, compositional assessment, acute oral toxicity (mice or rat), 90-day sub-chronic rat feeding, and livestock feeding (case by case basis). In addition, there are crop specific requirements for collection of data for confined field trials. The regulatory authorities are aware of the issues concerning the release of GMOs and therefore a strict regime of tests/ studies is being carried out for granting approval to the GM crop. No approval would be granted to the GM crops unless there has been a thorough analysis of its effects on the environment, biodiversity,

biosafety, human health, and health of livestock and animals is proven to be safe. Safety and efficacy is evaluated by science based experimentation and analysis on case-by-case basis and therefore, cannot be generalized as these are product specific. The Department consider that the products which are biosafe and have desired socio-economic benefits to farmers and consumers are to be supported for environmental release/cultivation.

8.37 However, when the matter of substantial equivalence was put before Director, National Institute of Plant Genome Research during his Oral Evidence on 28 September, 2010 he clarified:

“On equivalence, I may tell you, as you said rightly that there are lobbies and they use different words to convince. I may tell you that when we do breeding and two genomes come together, thousands and thousands of changes take place. When a single gene is put, then also it affects the activity of other genes and therefore, if I start to go in molecular sense, certainly they will not be equivalent. So, equivalence has to be checked at the level of overall utility of the product and the tests for the other human needs for that particular product. So, if mango is sweet, this other mango should also be sweet and people should like it and therefore, equivalence should be established in those terms and in terms of general protein content and like that. I can tell you that at molecular level there will be differences. People are not talking of it today, but tomorrow they will start to talk of it also.

We know that these changes are there. I have put one gene into a rice plant. I have reported in my research also that there are 600 other genes which are getting affected because of

this. But the overall trait of the plant is that the plant develops tolerance. It is able to grow in water-deficit conditions a little bit. So, that trait is used for the equivalence or comparison to the control.”

8.38 It was further stated by the Department of Biotechnology that recombinant DNA technology is one of the breakthrough technology like that of electricity, steam engine, nuclear energy, internet and others. Such breakthrough technologies have revolutionary potential because they often lead to major changes in the existing paradigms. Profit policies and governance systems have to be created to ensure that the benefit is achieved and at the same time potential concerns are effectively addressed. The scientific community and policy makers during the last two decades invested time and money in the advancement of basic biological sciences and tools of development to a point that it is expected that breakthroughs in applications and product development for social-economic benefits are possible.

8.39 It was further stated that the perspective of the Department of Biotechnology in the last two decades has been to promote and develop R&D capacity in the field and deploy recombinant DNA technology for application in health care, agriculture, animal husbandry, environmental protection and bio-industrial development with adequate precautionary measures enshrined in international conventions, protocols and systems. In agriculture, the technology has been the preferred option with demonstrated effects on growth, yield and tolerance to pests and diseases, drought, salinity, etc. and where there is no natural resistance or variability in a given crop species the existing management practices are of limited value for optimal performance of agriculture crops. The Department is also monitoring closely the global development and

experience in transgenic crops and foods as well as evolving scientific basis of regulations and legal frameworks so that learning from the experience are suitably incorporated in policies and programmes. In addition, the Department also support non-GM technologies such as tissue culture propagation, molecular marker assisted crop breeding, etc. The overall goal is to ensure responsible use of technologies for the benefit of farmers and consumers ensuring safety for consumption and to the environment. The areas of applications are focused on the use of modern biotechnology tools in agriculture that will reduce not only the damage due to pests and diseases but also ensure environment protection from adverse effects of pesticides/insecticides, reduce cultivation costs of agriculture produce, develop crops with tolerance to drought and salinity, herbicide tolerance, virus resistance, improved product quality, improved nitrogen use efficiency, enhanced yield, quality and nutritional status, etc. It will make agriculture more efficient and competitive to meet the challenges of hunger, poverty, malnutrition and food security. Accordingly, the Department promotes R&D in public sector institutions, case-by-case for application of genetic engineering in various crops of national importance and at the same time provides support and facilitates safety assessment of these crops as per the prevailing regulatory system. The Department implemented National Biotechnology Development Strategy (2007-till date) wherein the policy goal is to ensure that research and application in biotechnology is guided by a process of decision making that safeguards human health and meets environmental observance of the highest ethical standards. A scientific, rigorous, efficient, predictable and consistent regulatory regime for biosafety evaluation and release of protocols is essential for achieving this objective.

8.40 Querried further by the Committee as to what role did the Department perceive for themselves in so far as research into the effects of Genetically Modified/transgenic Crops/edible commodities on bio-diversity, bio-safety, environment, human health, flora and fauna are concerned the Department of Biotechnology stated that they support R&D activities for development of GM crops with desired characteristics. Approval is granted for R&D activities only after a thorough scientific peer review including need and relevance to Indian agriculture alongwith potential implications of new technology on biodiversity, biosafety, environment, human health, flora and fauna. Each proposal also requires the permission of Institutional Biosafety Committees (IBSCs) set up in each of the university/ institutions / private sector for implementing the projects. Special projects are also commissioned for generating biosafety data in some crops to generate scientific information on food and environmental safety aspects. The country has best scientists and experts with proven track record in the respective subject areas of risk assessment and technology development. A National Bioresource Development Board is also operational in the Department for inventorization, documentation and mapping of bioresources with a view to promote conservation, propagation and bioprospecting utilizing modern biotechnological tools and techniques.

8.41 Querried about their specific role and responsibility in cases where the import, research, development, field trials, introduction for cultivation purposes of a genetically modified/transgenic food crop is involved, DBT stated that under Rules 1989 notified under the Environment (Protection) Act, 1986 for the purpose of the manufacture, use, import, export & storage of hazardous microorganisms, genetically engineered organisms or cells, the Review

Committee on Genetic Manipulation (RCGM) shall function in the Department of Biotechnology (DBT). Under Rules 1989 of Environment Protection Act 1986 (EPA 1986) the Terms of Reference (TOR) of RCGM include the following:

- (i) Monitor the safety related aspects in respect of ongoing recombinant DNA (r-DNA) projects and activities involving Genetically Engineered (GE) organisms/ hazardous microorganisms.
- (ii) Review all ongoing projects including high risk category and confined field experiments to ensure that adequate precautions and containment conditions are complied with as per the Guidelines and Standard Operating Procedures (SOPs) issued by DBT from time to time.
- (iii) Lay down procedures restricting or prohibiting production, sale, importation and use of such GE organisms or products thereof for research and applications as mentioned in the Schedule of Rules, 1989.
- (iv) Issue the clearance letters/permits for import or exchange of genes, DNA fragments, vectors, plasmids, cosmids, etiologic agents and transgenic organisms or germplasm(s) including transformed calli, seeds, plants and plant parts for research use only. It will also take note of all such commercially available agents which are acquired from commercial sources through Institutional Biosafety Committee (IBSC).
- (v) Act as a regulatory body for receiving and reviewing the applications to conduct confined field trials (such as event selection trials, Biosafety Research Level I trials (BRL I), pollen flow studies or any other trial involving GE

organisms) and recommend appropriate studies to be conducted for data generation for biosafety assessment as per Clause IV , as per the decision of the Genetic Engineering Appraisal Committee (GEAC) or its authorization.

- (vi) Constitute sub groups/sub committees to visit periodically the experimental sites where r-DNA projects and activities involving GE organisms/ hazardous microorganisms are being pursued to ensure that adequate safety measures have been taken as per the guidelines and compliance of SOPs.

8.42 It may be noted that the introduction of genetically modified / transgenic food crop into environment for cultivation is not under the purview of RCGM or the Department of Biotechnology. Approval for environmental release of all genetically engineered crops is under the purview of the GEAC constituted by Ministry of Environment & Forests under Rules 1989 of Environment Protection Act 1986. The approvals for confined field trials are also being given by GEAC. RCGM currently reviews R&D projects and facilitates scientific risk assessment of applications for field trials/environmental release of GM crops. The inputs and recommendations case-by-case are forwarded to GEAC for consideration and approvals.

8.43 Therefore, role and responsibility of the Department in this aspect is limited to facilitating RCGM activities and compliance as per TOR of RCGM enshrined in Rules 1989 of EPA Act. The Department has no role either in decision making process or recommendations of RCGM as it is an independent regulatory committee under the EPA act.

8.44 CSIR, however, counselled caution in the matter. To a pointed query of the Committee about the likely effects/ramifications of genetic modification of various food crops in so far as the aspects of bio-diversity, bio-safety, environment, human health and health of livestock and animals are concerned, the Council stressed that adequate scientific impact assessment of use of GM technology on biosafety, environment, human health and health of livestock and animals is needed. Marker assisted molecular breeding is to be encouraged.

8.45 Elaborating on this aspect the Secretary, Department of Scientific and Industrial Research and Director-General, Council for Scientific and Industrial Research stated during his Oral Evidence on 10 June, 2011:

“I am very glad that this Committee is looking at such an important aspect of cultivation of genetically modified food crops, its prospects and effects. CSIR has been involved in agro based R & D since its inception – whether it was development of pesticides, development of tractors and contribution to Green revolution. CSIR has been a major player in developing these technologies. Subsequently, CSIR has four laboratories – Center for Cellular & Molecular Biology, Central Institute of Medicinal and Aromatic Plant, Institute of Himalayan Bioresource Technology and Indian Institute of Integrative Medicine, which are involved in plant-based research in various activities. Any new technology, when it comes, it comes with its positive as well as negative effect. However, technology is a context specific; its application is decided context-wise and country-wise. India has used the cell phone technology very successfully much better than even Europe or any part of the world. When a new technology like genomic technology comes, we have our own strategy. I have been responsible for leading that strategy from 1990s in this country. It

was different from the strategy taken by America or other countries. With that background, I would like to set, as a scientist, my view and the view and approach CSIR has taken on this problem. There is no question about it that GM is very important. New technology adaptation to improve food productivity is an important component. However, there are many new methods coming. We have been focusing ourselves on what we call Molecular Breeding. That means, this country has huge diversity of plants and variations. You screen this diversity to see what change the nature has made, and select those for further propagation through modern technology. This is what we call Marker Assisted Molecular Breeding and it is what person like Dr. Ramesh Sonti extraordinarily demonstrated - how it can be done.

The second technology is what we call Transfer of Genes. This again is done through screening and technology. The success of BT Cotton has tempted everybody to get into large-scale BT technology application into edible food.

Our perception is that for non-edible items Bt. application has been very successful. We need to see for ten more years as to how resistance gets developed and how things happen. For food items, when there is so much of food shortage, we have to take multiple approaches. We have to worry about finding the right seed for the right soil through using genomics technology. We have to find bio-fertilizers which will improve productivity without spoiling the soil. We have to create intercrop technology so that we can do multiple production in the same soil without spoiling the soil. We have to do the next technology of gene transfer called molecular assisted technology so that we do not put in a non-edible gene into an edible item. This is the choice we have

drawn in the Eleventh Plan and we are doing for the Twelfth Plan the way CSIR is propagating. For Ashwagandha 146 strains have been screened and from this the best screened strain was given to farmers in six States, which has increased their productivity as well as value of the plant. Therefore, improving productivity is an issue that needs to be addressed using the very modern technology. However, case to case it has to be built. It cannot be just that because you were successful with Bt. Cotton, you should apply Bt. to everything else. That is the view of the Department.”

8.46 He further added:

“CSIR has been the leader in patent in India. We have understood how the Bt. patent will affect the Indian farmer. So, a strategy was taken to design a new gene which is Bt. equivalent with modifications necessary to create a transgenic Bt. Cotton at the National Botanical Research Institute of CSIR. Then, this technology was transferred. I will give you the principle. The biggest problem was monopoly. CSIR has been responsible for generic drug and we have developed so many technologies and gave licenses non-generic to multiple people. This is the principle in our head. We gave Bt. Cotton to a consortium of Indian private companies so that they can take it to field trial and develop the product. The toxicity and allergicity have been tested and this is presently under trial with Indian companies. We cannot afford our farmers to be subjected to any monopoly of technology and its outcome over decades to come. My perception is that when you bring in any such technology, it should be built into a concept like a generic drug. It should be multiple licensing and no monopoly. This is I think what the Government can do. The possibility exists. We are working on it. That is why in a new technology called

Apomixis farmers themselves can retain the best seeds and propagate themselves. However, this is also a gene transfer technology from a good strain you bring in from another food edible item and then you propagate it. Normally when you propagate it, you lose the value. Normally it becomes weaker and weaker. But, this technology permits you to propagate absolutely safe. So, for cotton or for a non-edible item using approaches to genes that will be expressed only in insects and not in humans is okay. But, when it comes to edible items, one needs to be more careful and needs to do more tests, more toxicity and allergicity tests and go through the process very carefully.”

8.47 Based on these inputs received from CSIR, the Committee asked ICAR about their views on molecular breeding. ICAR informed the Committee that molecular breeding and transgenic development are two independent but parallel approaches of crop improvement which are applied based on availability of the source of the gene for the target trait. Molecular breeding can be used only if the genes for targeted traits are available within the gene pool of that crop species. But in case of non availability of the desired gene in the gene pool of a crop species the transgenic is the only option to introduce the foreign gene. In both the approaches the recipient variety/ hybrid or GM crops are genetically modified. The molecular breeding or conventional crosses involves transfer of a chunk of genetic material from the donor source which is also a modification of the endogenous genetic make-up.

8.48 DSIR/CSIR views were also sought about the extent to which they felt that the Country’s health care and health research system, National Agricultural Research System, Agriculture Sector, farming community, Regulatory System as also the Department themselves, ready to enforce effective surveillance and monitoring of the fall out of cultivation

of GM/transgenic Crops/commodities on bio-diversity, bio-safety, environment, human health, flora and fauna, both in long term as well as short term perspective. In response they stated that there is need to further strengthen inter department collaborative research. Nodal responsibility could be taken either by ICAR and/or DBT. Asked further that if the extant system was not geared to meet such challenges what were their suggestions to ensure that the constraints/short comings are removed before introduction of GM/transgenic crops/commodities. CSIR informed the Committee that they were in agreement. In order to bridge the gaps, we need to have a large number of collaborative projects which will help in creating necessary scientific evidence and appropriate national perspective.

8.49 Asked about their views on the other technological options available for ensuring that the food security of the Country is ensured in the short as well as long run, ICAR stated that there are few other approaches besides the transgenic and molecular breeding approaches for crop improvement to ensure food security. For example, collection of trait-specific germplasm based on recent GIS tools, selection and utilization of the diverse plant genetic resources (PGR) with enhanced potential of yield and nutrition or any other specific needs to ensure food security. PGR can be utilized through system biological approach for identification of its potentials in ensuring food security and its promotion.

8.50 As regards their assessment of genetically modified/transgenic food crops, it was stated that DSIR/CSIR appreciate the advances in modern biotechnology, genetic modification, transgenics, etc. The Department also support initiatives such as Bt. cotton which do not involve consumption by humans. At present the Country has limited expertise in the field. Further, the GM crops are context driven.

8.51 Clarifying further during his Oral Evidence on 10 June, 2011 Secretary, DSIR and DG, CSIR stated:

“This is where I say that the context of the country is important. In America or Europe, every food item that you pick up from super-store is plastic-covered, labelled, etc. It is impossible in this country, that is, for a nation of this dimension. Therefore, it becomes more of a responsibility of the Government before releasing to be sure about it. One cannot subject people to risk. The issue is not the risk of people also. The issues are, are you risking bio-diversity and are you risking soil bacteria to become antibiotic resistance? Those are more serious issues. You are not talking about this generation of people who will eat the brinjal, but you are talking about the next generation of children who will live on this earth. Therefore, we have no choice. In 1950s and 1960s, when we have had famine, we had to put pesticides and we put so much of pesticides that its effects we cannot get out of even today. We also had to put DDT. We overdrew water in Punjab, Haryana, and Northern parts of India for green revolution to give hungry people food, and the water table has gone down there. There the water table has gone down. We have over-irrigated in some places as a result, you have to go down much deeper to get drinking water and there you get fluorine. So, every decision of the Government, however positive or good intention it has, can have a consequence. That is why a wise body like this has to sit down, debate and discuss. We need to get everybody’s point of view. That is why I said that it is important that we debate this issue, look at this issue longer, before we take any disruptive decision very quickly.”

8.52 Expressing similar concerns Shri K. Nageswara Rao, Vice-Chairman of All India Kisan Sabha (Windsor Place), another farmers' organization with substantial membership, stated during his Oral Evidence on 19 October, 2010:

"When we think about cultivation of GM food crops, prospects and effects, I think, we have to discuss it from four aspects. One is food security; second is health, hygiene of the people and environment; third is exorbitant exploitation by multinational companies, particularly, Monsanto Company; and fourth is livelihood security. We have to think over it from all these aspects.

Of course, biotechnology is very much useful for the development of agriculture at high yielding level, hybrid level. It has contributed enormously. But when it comes to genetically modified crops, as far as my knowledge goes, productivity has not been enhanced by the use of genetically modified crops. It is a fact. I have got this fact from the ICAR, and I would like to quote one paragraph from it. It says: "Biotechnology holds great promise for increasing production and productivity in India but eradication of hunger through GM crops is proved to be false. In food cereals like rice, wheat and grain, yield is controlled by not a single gene but by a group of gene. In spite of huge success in crop molecular biology and genomics genes for high yield or high protein percentage have not yet been discovered. By inserting a single BT gene, yield cannot be enhanced; only the Lepidopteran pests can be controlled for a limited time. Biotechnology can speed up conventional breeding programmes and may offer solutions in boosting agricultural production." I took these facts from the professors of the ICAR."

8.53 Corroborating this view-point Ms. Sunita Narain, Director, Centre for Science and Environment stating during her Oral Evidence on 19 October, 2010:

“We are not against GM crops per se, but we are very concerned that India is not as yet ready and does not have the regulatory systems to manage the risks of new technologies which GM crops pose. That is what we have raised also when it came to BT brinjal. When it came to BT brinjal, we made the point very clear to the Union Environment Minister, who was at that stage considering its introduction into the country, that it was important to recognise that the BT brinjal would be the first vegetable crop perhaps in the whole world to be introduced. Brinjal is something that we use in our homes. We use it regularly. The question we had for him, and we have for this Committee, is whether we are absolutely confident that the science on GM crops is both well understood and can be trusted. That was an issue that we raised at the time of BT brinjal and I think that is a very key issue that this Committee must take cognisance of. When it came to BT brinjal, it was very clear that the science which was needed to establish the chronic toxicity of eating brinjal over long time was really not done. If you look at the data which was the basis of the decision making, most of the research was done on acute toxicity, not on chronic toxicity. Chronic toxicity is what impacts our body over long time. That has really been our concern when it comes to pesticides, when it comes to other toxins that these are not about ingesting something which will kill you today; it is about long-term impacts on our bodies, and we need to understand that.”

8.54 Dwelling upon the regulatory mechanism she added:

“This really raises a second very fundamental issue in my respect because it is not just about brinjal, it is about GM crops, and your Committee is looking at GM crops. When you are looking at GM crops, to me, the biggest issue your Committee has to look at is whether we have the ability to conduct scientific research and regulate this technology. When I look at the scientific systems today, they are extremely poor. We have completely compromised public science in the name of Private-Public Partnerships (PPPs). Today, most Indian public science has been starved of funds. There is very little independence that Indian science has today. Most Indian scientific institutions are being asked to go to companies and get money to pay for science. I hope that this Committee will take a look at the new memorandum that has been signed by the Rajasthan Government with Monsanto which makes it very clear that all agricultural universities and public seed corporations will now have a partnership with Monsanto and other agri-business companies. These companies will determine the research that is done in the universities. These companies will pay for the research. The universities will do field trials of seeds that have been promoted by companies.”

8.55 Justifying her stand, she stated further:

“Now the question that I have as a consumer and as a public advocate is this. Why should I trust Indian science any more if I cannot trust the integrity and the independence of the scientists? GM crops cannot be introduced in isolation of a policy which promotes public science for public good. You cannot tell me that, please have GM crops because it good for you. But, on the other hand, everything that the Government is doing today is to

compromise the integrity of publicly funded science and public institutions.

I am certainly saying that this entire effort to create Public-Private Partnerships in which you get companies more and more into the scientific establishments will create less and less credibility for crops like GM. It is something that must be understood that consumer confidence is absolutely critical and that cannot be built unless you have integrity of public scientific establishments.”

8.56 Making a strong case for a comprehensive liability regime she added:

“There is another big issue. I think and I hope your Committee will take a look at both the regulatory framework as well as the liability regime which is needed for GM crops. What Bhopal teaches us very clearly is that India has a very weak liability regime. You have just gone through a nuclear Bill. That is also a high risk technology. GM is similarly about high risk technologies, on which we do not know the future impact. That is why, across the world there is concern that any such introduction of technology needs a strong liability regime. It needs corporate liability to be established. It needs the price of that liability to be paid. What was the issue on nuclear? The issue on nuclear was that if you have a liability regime which reflects the cost of risk then the technology would not be competitive. That is why, Parliament was asked and you did come up with a very compromised solution to actually reduce the cost of that risk. The same question has to be asked when it comes to GM. The same question has to be asked in terms of the regulatory framework that you will arrive upon. The Government is coming up with a

Biotechnology Regulatory Authority. I hope that your Committee will take a look at that and will make sure that that authority speaks on behalf of consumer interests, speaks on behalf of farmer interests. The issue of GM technology is not a silver bullet to get rid of hunger. I think, that is an issue, which, I hope, this Committee will take a look at it and will do it very carefully.”

8.57 The Committee, therefore, sought feedback from ICAR on the points brought to their notice by CSIR and several other stakeholders viz. only products not consumed by humans be developed, India’s limited experience in the field, transgenic crops being context driven, antibiotic marker free genes only should be favoured, etc. In response they were informed that DARE/ICAR considers GM crops are vital for ensuring food and nutritional security of the country. GM crops are an integral part of eco-friendly, sustainable agriculture for not only enhancing crop yields manifold but also for promoting environmental protection, conservation of biodiversity, effective pest and disease management, nutrient use efficiency, amelioration of nutrient and vitamin deficiencies, protecting human and animal health, etc. GM crops are context driven, and according to ICAR, GM crops are produced only when alternative technologies fail to supplement a particular trait (for example, insect resistance in cotton) and the GM crop production has clear advantages over the conventional breeding methods. No doubt, development of marker free transgenics is an attractive alternative but not essential.

8.58 On the question of introduction/field trials/cultivation of GM/transgenic crops in the Country, CSIR informed the Committee as follows:

- (i) Bt-cotton development work was supported and also conducted at CSIR/NBRI.

- (ii) Regarding Bt-brinjal: DG's nominee to GEAC in the area of agricultural biotechnology elaborately explained the steps needed to be followed while clearing a GM food crop for cultivation. Also, it was emphasized that time was needed for a national consensus to emerge on the issue.
- (iii) Regarding the right of individual State Governments to ban field trials of transgenic crops within state boundaries: The department has argued that State Governments should have the right to ban field trials of transgenic crops, if they wish to do so. The GEAC agreed.

8.59 Apart from this the Committee also sought the views of Department of Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) on the effects of the genetically modified crops on the medicinal values of food crops as also on the medicinal values of other crops (food and non-food) which may be affected by the introduction/cultivation of Genetically modified crops in the surroundings. They were also asked about their stand before the competent authority with regard to introduction/field trials/cultivation of GM crops with medicinal value in the Country.

8.60 In response they stated that the Department of AYUSH had in June, 2010 conveyed its concerns to Secretary, MoEF that genetically modified Brinjal (Bt. Brinjal) may have implications on AYUSH sector. The Department had also requested that open trials or permission for commercial cultivation of Bt. Brinjal or other medicinal plants should not be given until a detailed analysis of their impact on Indian System of Medicines is done by a Group of Experts. A copy of the letter had been endorsed to the Secretary, Department of Bio-technology. The Department had also requested Ministry of Environment and Forests to co-opt Chief Executive Officer, the National Medicinal Plants Board,

Adviser (Ayurveda), Department of AYUSH and Director General, Central Council for Research in Unani Medicine (CCRUM) in GEAC or at least give them a hearing about the concerns of the Department of AYUSH.

8.61 About the likely effects/ramifications of genetic modification of various medicinal plants/crops in so far as their medicinal value is concerned, the Department submitted that the Ministry of Environment & Forests has informed that so far no transgenic medicinal plant has been developed and none are under field trial. Research being conducted on eucalyptus, brahmi, amla, ashwagandha, ginger and anantmool is preliminary in nature. The Department of AYUSH is of the view that the chemical profile and bioactivity of genetically modified medicinal plants should be compared with the conventionally produced/cultivated medicinal plants to know the alteration in the medicinal values of these plants.

8.62 The Department of Commerce, which is represented on the GEAC was also asked by the Committee about their stand before the competent authority/agencies with regard to introduction/field trials/cultivation of GM crops keeping in view the effect of such crops may have on the international trading and exports of genetically modified food grains and commodities derived/produced from food crops,. They stated that presently only Bt. cotton is commercialized in India. Around 90% of the cotton grown is Bt. cotton and only 10% of the area grows organic cotton. GEAC has approved the trials of transgenic mustard, corn, brinjal and tomato which are under various stages of testing and trials in the country. They further admitted that the role of this Department is very limited in view of the technicalities involved in the process. Asked further about the issues they would like to bring to the notice on the subject, the Department stated that

Genetically Modified Organisms are not allowed in National Programme for Organic Production. There is no doubt over the incompatibility of the GMOs with organic agricultural principles as it causes negative and irreversible environment impacts through release of organisms which have never existed in nature and which could not be recalled. In view of the danger, for the biosphere and in particular the economic and environmental risks it poses to the organic produce, the above said risk can be prevented if the following steps are considered during the cultivation of GMO crops in India:

- (i) Field identified for GMO crops should be restricted to only certain areas which could prevent the contamination of GMOs with crops of the same species or varieties grown conventionally or organically nearby.
- (ii) Surveillance and monitoring of the GMO trials and cultivation is required to be strengthened as presently it is not monitored efficiently resulting in contamination to non-BT grown field among the same species.

8.63 Some of the other stakeholders, however, differed from these views about transgenics in agricultural crops. Shri Samit Aich, Executive Director, Greenpeace India Limited while deposing before the Committee on 19 October, 2010 stated:

“Greenpeace’s vision is an earth which can nurture life in all its diversity. At the core of our view of the world is what we call equitable sustainability. This debate about genetically modified crops strikes at the heart of the matter of equitable sustainability. It represents what is flawed in our current agricultural paradigm, be it of high input usage, corporate control, destruction of farmland and farmers’ livelihood.

In the genetically modified crop debate, we are also seeing the wrong assumption that GM foods can feed the world. The fact of the matter is that genetically modified crops are a threat to our biodiversity, they are a threat to our agriculture, they are a threat to our farm labour, they are a threat to our citizens' health, and they are of course a threat to consumers' choice. Genetically modified crops are a false solution to climate change and are actually coming in the way of actual solutions.

The world over many countries, both developed and developing, have banned GM crops at the policy level: countries like France, Italy, Austria and countries like Thailand and Vietnam. In India, we seriously need to deliberate on this issue. We also need to ascertain the current genetically modified regulatory system in the country as it is inherently flawed. It fails to see the importance of the precautionary principle, the issues of irreversibility and the issue of transparency in decision-making."

8.64 The Committee also sought the viewpoint of Industry in the matter. A representative of Federation of Indian Chambers of Commerce and Industry (FICCI) told the Committee during Oral Evidence on 22 December, 2010:

"The approval process, which I think we put into place as a country was done after a reasonable bit of thought and also looking at what are best practices in other parts of the world. A little bit area of concern is the consumer. At the end of the day if you introduce a GM product, the key is that the Indian consumer, which is also you and us when you go out of this room, is always worried about GMO and there are enough people to create bigger fears. That is the reason why science exists. I and you will never know whether this product is safe or not safe. It is really that a

scientist and a scientific method has to go to test it and we have to make sure that the methodology and all the safeguards are defined by us and they come back with a right result to us. So, my feeling is that the system is perfect. It needs better clarity and elaboration to the rest of the consumer segment and the others that this is the system. If anyone says that you want to extend testing from three months to six months, we can always do that because the ultimate aim is also to make sure that our consumers are satisfied. So, my general feeling is that it is a good robust system.

The second part which you have really mentioned about what is the impact on farmers in terms of smaller farms and monopolies. GM is not the heritage of the Western world. We have allowed it to be the heritage of the Western world because we have not had our own country and our scientists develop GM. Today, ICAR has been working on GM for a long time and I am sure they will come up with the breakthrough products even in the GM category. It will only be that the western companies will be monopolising the GM seed by itself. We have probably one of the best brain parts when it comes to biotechnology. Pharma-biotechnology in this country is doing absolutely well and there is no reason why agri-biotechnology will also not do well if they are given encouragement to develop.

The other point is about pricing. I have been in the agri-business for a long time. The farmer will only pay the price for a seed if he finds it makes him much more money than using any conventional seed. No multinational or seed company can take more money from him in that sense. The GM seed is no different from any other hybrid seed. Today if you have to have a hybrid

seed for sunflower and a Gm seed for sunflower, the seeds are absolutely the same and the pricing will be only on the extra yield or the extra benefit which the farmer is getting. It is not easy to even convince the Indian farmers to buy a new seed. If you see the percentage of hybrid seeds used in India, it is very-very small. So, the difficulty that the small or marginal farmer faces is that he has the money to buy hybrid seed. That will be something which we as both Government and private players need to make sure how do we make these kinds of seeds more affordable to the farmers, once we have found them to be good for them, through different schemes. We have so many other kinds of farmer schemes which we are currently running. So, that should be not only for GM but also hybrid seeds in my view.

One more element which I wanted to take time on is the consumer. I think the biggest challenge that we have not yet crossed is the consumer. The consumer needs to know, because he wants to know, what he is buying does it contain any GM ingredient. That is one big item which even if tomorrow all of us agree that GM crops should be allowed, some consumers may not be ready to buy them. So, with this would come in the requirement of labelling and the requirement of accountability of the manufacturers to make sure that if they are introducing any product which has a GM ingredient, it must be labelled prominently and the consumer has to be given a choice.

8.65 Adding further, another representative stated:

“Just supplementing what Shri Sachid has been saying. If you look into the Note, European Union has a regulation 1830/2003 concerning the traceability and labelling of genetically modified organisms. These countries have put in a very strong

regulatory framework in order to give ample choice to the consumer whether to go in for a GM or a conventional product through a mechanism of labelling. Probably these are some of the elements that the new framework could adopt in India. There is also very strong need for traceability of these products, which company seeds are being used. If traceability and labelling aspects are taken care probably the consumer will have more choices whether to go for GM or non-GM products.”

8.65A Shri M. Prabhakar Rao, Chairman and Managing Director, Nuziveedu Seeds Pvt. Ltd. While emphasising the need for transparency in the functioning of the regulatory mechanism stated during his oral evidence on 10 November, 2010:

“The first and foremost issue with regard to GM technologies, be it in the food crops or be it in the industrial crops or in whatever other crops, is the bio-safety evaluation. The bio-safety evaluation procedure has been laid down under the Environment Protection Act and there are several Committees which are formed as per EPA. But there is a need for bringing about consistency and total transparency. These Committees are formed, they function and ultimately they give approval. The whole process has to be completely transparent and also very consistent. It cannot be subjected to frequent changes and it cannot be kept in a non-transparent way. This is very important which has to be achieved. By keeping all the data and all the trials open to the public, the unfounded fears of anybody will not be there which can create difficulties as happened in the case of Bt. Brinjal. This is one view which I have with all experience in the background of seed industry. ”

8.65B Further, clarifying on the monopolistic tendencies in the transgenic seeds industry, he stated:

“With regard to the operational issues as I have mentioned just now, most of the GM traits are loss preventing mechanisms. They are not yield enhancing mechanism. Since it is a loss preventing mechanisms, the balance between the breeding companies which are mostly domestic seed companies and the GM technology providers in terms of technology licensing agreements that balance has to be ensured by a competent authority. At present, either in the present Seed Act or in the newly proposed Seed Bill, there is no provision for a regulatory commission or a regulatory authority to whom either farmers or the licensee seed companies or anybody can go and make an appeal. So only the civil courts are the available option as of now and civil courts already are over-burdened with so many litigations. It becomes very difficult for getting any appropriate remedy on specific issues which are highly technical, highly complex like the GM Crops. Therefore, if the regulatory commission is formed at least in the Seed Bill which is now under consideration, then probably the balance can be achieved with regard to the interest of the farmers, with regard to the interest of the seed companies which are breeding companies and with regard to the interest of the technology developing companies. So, all the stakeholders should get appropriate justice and that can be only done by a competent commission that can be formed under the proposed Seed Bill. So, this aspect I feel will be very important and will go a long way in serving millions of farmers as well as the industry. I think both sides will be happy with such a commission if this idea becomes operative. Then, I would like to quote here the example of the USA. USA is the first country in the world to adopt GM crops. In

the mid nineties, the GM traits were approved in the USA. Today, in respect of crops like Soyabean, maize etc more than 85-90 per cent of the area is under GM hybrids and varieties.

In that country, of late, in the last one year, the farmers have started making the issue about the high seed prices more particularly because the GM technology is coming into the seed industry. The US Government has now launched the anti-trust investigation which is now widely reported in the media. This is an indication that India has to take preventive steps now, even before the farmers like in the US go to the court, the Government itself probably can look into the matter and start the anti trust kind of investigation. We have, what is known as the Competition Commission in our country so that such bodies can do investigation into the way the system is now operating, whether it can be corrected or how it can bring in some improvements to bring in more competition and more transparent practices which will help in bringing competitive prices in the market, availability of better hybrids, availability of more choices to the farmers.”

8.66 It has been brought to the notice of the Committee by some of the stakeholders that the movement of genes from Genetically Modified/transgenic Crops into conventional crops or related species in the world (outcrossing), as well as the mixing of crops derived from conventional seeds with those grown using Genetically Modified/transgenic seeds may have an indirect effect on food safety and food security.

8.67 The Committee, therefore, sought the views of the GEAC in this regard. They also sought to know that in case GEAC concurred with the above view what steps/actions had been taken by it for positive interventions in the matter.

8.68 In a written submission GEAC informed the Committee that Gene flow (often used synonymously with the term “out crossing” or “cross pollination”) is a natural biological process that occurs in most crop species. Pollen-mediated gene flow is a term used to describe the movement of plant genes from one plant to another via pollen. The rate of pollen-mediated gene flow depends on biotic and biotic factors such as plant biology, pollen biology/volume, plant phenotype, overlap of flowering times, proximity of the pollen source, ambient conditions such as temperature, humidity, etc., therefore, the impacts of the gene flow to conventional crops or related species needs to be assessed on a case-by-case basis. The regulatory authorities are aware of the issues concerning the release of GMOs and ,therefore, a strict regime of tests/ studies is being carried out for granting approval to the GM crop. No approval would be granted to the GM crops unless there has been a thorough analysis of its effects on the environment, biodiversity, biosafety, human health, and health of livestock and animals is proven to be safe. As the impact on human health or environmental aspects are examined in depth through biosafety assessment of the transgene before it is allowed for release, it is unlikely that pollen flow to conventional crops or mixing of crops derived from conventional seeds with those grown using GM seeds may have adverse effect on food safety and food security. Further, post release surveillance which is a part of the regulatory requirements for GM crops will also provide for mid course corrections, if necessary.

8.69 The Ministry of Environment and Forests shared the views of GEAC. And so did the Department of Biotechnology.

8.70 On this very aspect ICAR informed the Committee that out crossing is a natural phenomenon that occurs normally within a species. Transfer of genes across species is a very rare occurrence. The

horizontal flow of transgenes is also negligible as several studies have shown. Transfer of a transgene, the protein product of which is determined to be biosafe, will not cause any adverse consequences in terms of food safety and food security. Moreover, transgenics are developed with well known characterized genes (known to be safe); thus, even if gene flow takes place, it would not affect other crops or the environment in any way. So far, no toxic effect on human or animal health has been reported due to the transfer of one or two genes. Further, mixing of transgenic seeds with conventional seeds may not cause a threat to the biodiversity and food security. Thus the benefits of GM crops outweigh the concerns of GM-gene flow into the environment. The regulatory approvals are provided to GM crops on case-to-case basis depending upon the gene, crop species, trait and geographical distribution of the crop. In cases such as herbicide tolerant GM crops, wherein transgene flows to a weed and which develops tolerance to a herbicide, suitable steps such as replacement of the herbicide or development of a transgenic event tolerant to the novel herbicide can be undertaken.

8.71 Similarly Department of Science and Technology submitted before the Committee that the question concerns the possibility for gene flow from GM to conventional crops. Food safety and security concerns as a result of such gene flows should be assessed based on specific product and generalization is difficult at this stage of scientific understanding based on global experience so far. The Department holds the view that the positive interventions in specific cases in the matter are better addressed by agencies like DBT, ICAR and MoEF rather than DST at this stage of development of GM technologies in the country.

8.72 Elaborating on this aspect the Department of Agriculture & Cooperation informed the Committee that the outcrossing and its

adverse impact, if any, from GMO to conventional crops are evaluated prior to approval by GEAC. Once a GM crop has been evaluated from environmental and health point of view, it is considered as safe as a conventional crop. The monitoring of GM trials should be strictly adhered to as prescribed by the regulatory mechanism.

8.73 In a background note submitted to the Committee, NBA while dwelling upon the aspect of escape of genes stated that one of the important fears of ecologists and conservation specialists is the uncontrolled and/or unintended escape of transgenes (genes that are introduced) into non-target varieties and species. Such escape can happen through transfer of pollen, contamination from transformed seed and horizontal transfer. Careful assessment of these mechanisms of escape needs to be done in order to arrive at a logical conclusion, based on science, to determine the safety of modified crops. Scientific evidence exist both for and against pollen –mediated escape of transgenes and the ability of the passive transformation to create ecological imbalances in native breeds and land races. Accidental mixing of transforming seed with non-transformed seed in the fields, storage areas and during packaging is also an important means to enhance risk of mix-up of transformed and non-transformed seeds. Proper handling and storage, especially in the hands of farmers will be critical to ensure such escapes do not happen. This is more a logistical and awareness problem in India. Research on horizontal gene transfer is still emerging in order to provide concrete examples that could be irrefutable with regard to potential dangers of such escapes and introgression into non-transformed crops.

8.74 However, subsequently in response to a query of the Committee expressing its inability to profer advice on this complex issue the National Biodiversity Authority informed the Committee that the

mandate of the Authority is to facilitate conservation, sustainable use and access to biological resources. It also regulates issues related to exchange of biological material and sharing of benefits arising from their use. Besides, the Authority performs an advisory role on issues related to conservation, sustainable use, access to biological resources and benefit sharing. Given these mandates the role of the Authority with regard to GMOs relate to providing advice, as appropriate and upon request, to Central Government on the issues of impact of GMOs of biodiversity.

8.75 When this question was put to the Department of Health Research, they stated that these issues essentially relate to agriculture and are being addressed by scientists in ICAR. We are aware that outcrossing would vary from crop to crop. With reference to Brinjal it is self pollinating but deliberate cross pollination has been done with varying results. The Bt Gene and its product the Cry protein has been established to be safe through animal studies and history of safe human use elsewhere in the world for almost 8 years. Therefore safety will not be an issue even if it were to move into other species. For other events (other genes) which may come up in future , case to case risk assessment must be carried out. GM seeds do have a bearing on the food safety and security as a major aim of the GM crops is to promote yield of crops.

8.76 When queried in the matter, CSIR informed the Committee they generally are in agreement that the movement of genes from Genetically Modified/transgenic Crops into conventional crops or related species in the world (outcrossing), as well as the mixing of crops derived from conventional seeds with those grown using Genetically Modified/transgenic seeds may have an indirect effect on food safety and food security & believe that extensive research must be carried out

to evolve methodologies which would insulate the conventional crops from adverse impact of GM crops.

8.77 About the steps/actions have the Department/CSIR taken for positive interventions in the matter they stated that CSIR is working in the area and in the XIIth Plan, more research in the area is envisaged. However, DSIR/CSIR does not have where-with-all for field trials of crops. ICAR is more suitable for field trials.

8.78 As CSIR had opined that extensive research must be carried out to evolve methodologies which would insulate the conventional crops from adverse impacts of GM/transgenic crops the Committee sought the views of DARE/ICAR in this regard based on their own research and experience and measures, if any, they would like to suggest to insulate conventional crops from adverse effects of GM/Transgenic crops.

8.79 ICAR informed the Committee that extensive research has been carried out at laboratory scale in different scientific institutions to evolve and refine methodologies that would prevent any adverse effect of GM crops on the non-GM crops. Moreover, DARE/ICAR is of the view that GM crops that are thoroughly evaluated and deregulated by a regulatory system following the internationally accepted guidelines will not cause any adverse impacts either to conventional crops or to the environment in general. Further, recent scientific analysis by experts on GM maize, rape seed oil, and soybean with two main GM traits, herbicide tolerance and insect resistance grown for ten years in field has shown that cultivation of GM crops for a decade has caused no damage to the environment (Sanvido et al 2007). It was further stated that no adverse effects of GM crops have so far been noticed socially or observed scientifically. To the best of knowledge of the Department, since the commercialization of the first transgenic crop, there have been no adverse reports regarding human, animal or environmental safety.

8.80 The Committee, however, got a totally divergent feedback in this regard from a representative of Greenpeace India Ltd. during the Oral Evidence on 19 October, 2010. On being asked about the reported increase in incidence of cancer in USA after introduction of GM crops, he stated:

“This particular issue of what is happening in US has been one of the major points of discussion in almost all forums on GM food. It is a fact that starting from 1996, people in the US have been consuming GM crops. But there are two points which we need to look at. There has not been any direct consumption of GM food in US. All the four crops which are being cultivated in US are either used as oil like corn or it goes to cattle feed. Corn is not consumed directly. It is used as oil or it goes to cattle feed. Similar is the case with canola and soya. Soya is being consumed as soya oil and not as soya directly. So, the chances of protein being present in that is reduced. There could be problems even with these products from the GM crops. But the problem with US is that there is no baseline data. To understand what is happening right now there and to compare the situation, you need to have baseline data. That is something which I think the industry had effectively stopped from happening in US. I am afraid that the same thing is happening in India also. If you go ahead with GM food crops at that point of time, there is no baseline data five or six years down the line to say that things have changed and that there have been impacts. That is one of the major concerns. While one could speculate that there are issues in US because of GM food consumption, the chances of doing a study has been killed by not having baseline data.”

8.81 The Government have justified the introduction of GM crops in India on the ground that they are being cultivated and consumed in USA for several years without any adverse reports on human health, etc.. When a clarification was sought on this aspect, a representative of Greenpeace India Ltd. informed the Committee during the Oral Evidence on 19 October, 2010.

8.82 The Vidharabha region of Maharashtra is reeling under one of the severest agrarian crisis for several years now. Some of the stakeholders attribute the agrarian crisis among other reasons to the farmers of the region taking to cultivation of Bt. cotton in a big way during last decade or so. The Committee, therefore, undertook a Study Visit to Vidharbha region in March, 2012. The Committee visited Maregaon Village in Yavatmal District on 2 March, 2012. This District had witnessed the maximum number of farmer suicides totalling 1874 for the period 2006 to 2011. Maregaon has a population of 569. The male population is 278 and that of females is 291. The village has 185 people engaged in agriculture. Farmers owning land between 0-2.02 hectares number 134 and those owning above 2.02 hectares number 51. Average annual rainfall varies from 910- 925 mm. The village has 28 wells and irrigated area is 37 hectares out of the total cultivable area of 418.66 hectares. Cotton is grown in 252 hectares, Soyabean in 84.20 hectares, Tur in 50.43 hectares, Jowar in 27.11 hectares, wheat in 14.60 hectares and Moong in 1.68 hectares.

8.83 While interacting with the villagers, the Committee got first hand information about the plight of the farmers of Maregaon. The farmers very candidly blamed the policies of the Government which they felt was responsible for their plight. In particular, their ire was targeted towards BT Cotton. The Committee were informed that with the inception of BT Cotton, input costs had gone high resulting in farmers

falling into the debt trap. Further, the falling price of cotton in the international market resulted in farmers not getting remunerative price for their produce. They also stated that in the absence of a buffer zone, those wanting to cultivate non- BT Cotton were not able to do so. Bt. cotton was pushing the farmers into the vicious cycle of debt and being unable to repay the debt due to decreasing earning farmers were under severe stress and developing a feeling of loss of their self-respect which was ultimately pushing them to commit suicide.

8.84 The Committee also interacted with a couple of widows who in the aftermath of their husband's suicide were hard pressed to make both their ends meet. The villagers implored upon the Committee to voice their request to the concerned central authorities to ban farming of BT Cotton in the country. They also voiced their unhappiness with the relief offered to them via the Prime Minister's Relief Package especially in terms of milch animals. They were given exotic breeds like Jersey and Holstein who were unable to adjust to the local environmental conditions and as a result died. They wanted indigenous breeds instead.

8.85 During the course of their interaction, farmers from the village of Bhambraja requested the Committee to visit their village as well.

8.86 The Committee acceded to their request and visited Bhambraja Village in Yavatmal District on 2 March, 2012. This village has witnessed 14 cases of suicide by farmers post BT Cotton, i.e. from 2002. They also rubbished the claims of their village being a model village for BT Cotton as reported 28 August, 2011 in the edition of a national daily under the caption 'Reaping Gold through BT Cotton' and other articles. Rather than driving the farmers towards prosperity, it was driving them away from agriculture as was evident from lots of land lying fallow. Also many

have lost faith in farming and some have shifted to soyabean where the losses are less. It was further stated that over a hundred people including landed farmers have migrated from this model farming village showcasing Mahyco-Monsanto Biotech's BT Cotton as farming no more remained a paying proposition. They were also voiceferous in voicing their disapproval of the virtues of BT Cotton and wanted to revert back to non BT Cotton. The farmers did not relate the issue of the suicides or the crisis only the Bt Cotton. But they punctured many myths about its miracles, costs and `savings.

8.87 On 01 March, 2012 the Committee held discussions with the representatives of Government of Maharashtra, Relief and Rehabilitation Commissioner, Vasantao Naik Sheti Swavlamban Mission, Amravati, Insurance Companies and farmers. They were informed that as a large number of incidences of farmers' suicides were found in six districts of the Vidharbha Region viz. Amravati, Akola, Yavatmal, Buldana, Washim and Wardha, Government of Maharashtra had declared a Special Rehabilitation Package for these districts on 19th December, 2005. For the period 2006-2011 Amravati District witnessed 1523 instances of farmer suicide out of which 360 related to agrarian reasons. Akola District witnessed 974 instances of farmer suicide out of which 480 related to agrarian reasons. Yavatmal District witnessed 1874 instances of farmer suicide out of which 475 related to agrarian reasons. Buldana District witnessed 1019 instances of farmer suicide out of which 340 related to agrarian reasons. Wardha District witnessed 707 instances of farmer suicide out of which 198 related to agrarian reasons. On being queried by the Committee about the reasons for these suicides, it was stated that crop failure and indebtedness were the agrarian reasons and illness, addiction, unemployment, family dispute and other reasons were also responsible.

8.88 The Committee asked Shri P. Sainath, Rural Editor, The Hindu, who has been extensively covering farmers issues for more than 18 years, mostly in Vidharbha, about the reasons behind these suicides. During this Oral Evidence on 3 November, 2011 he stated:

"I would like to make three points. जो किसान आत्महत्या कर रहा है, वह कौन है? वह 80-90 परसेंट कैश क्रॉप फार्मर है। जो पैड़ी की फसल लेते हैं, वे किसान बहुत कम सुसाइड करते हैं। यू.पी., बिहार में यह आंकड़ा बहुत कम है, क्योंकि वहां फूड क्रॉप फार्मर्स हैं। जहां कैश क्रॉप ज्यादा है जैसे महाराष्ट्र, मध्य प्रदेश, कर्नाटक, केरल आदि में किसानों की आत्महत्या ज्यादा हो रही है। Suicides are overwhelmingly committed by the cash crop farmers because the risks of cash crop are higher, the indebtedness is higher, the expenditure is higher, the bank loans and money lenders' loans are higher and the prices are more volatile on the global market because cash crop prices are controlled by half-a-dozen multinational corporations in the world.

Lastly, the highest number of suicides committed by the cash crop farmers is that of cotton farmers. वह कपास का किसान है। सबसे ज्यादा, सबसे बड़ा ग्रुप जो आत्महत्या कर रहा है, वह कपास का किसान है, जो बी.टी.कॉटन यूज कर रहा है। So, my question is, at a time when suicides are overwhelmingly committed by the farmers engaged in areas of cotton, groundnut, vanilla, coffee and pepper; at a time when the highest number of suicides are in Bt. Cotton areas, should we then introduce GM in food crops where there are relatively no suicides at all ?

As a Reporter, I have to tell you that when I work in the countryside, I live with the people I write about. I do not fly into Nagpur and cover from there. I live in the villages that I write about. I stay with the farmers I write about. I have seen incredible misery for these last 18 years. It would be irresponsible for me to advise you to say let us have GM in food crops also.

No European country is doing it. We are being asked to do it. It would be totally irresponsible on my part to make such a recommendation when our food crop farmers earn less, stagnate but they are not committing suicides.”

8.89 Blaming the high input costs also for the miseries of the farmers, he informed the Committee:

“I think the Central Institute for Cotton Research (CICR) has already given a new data in this hon. Committee. The 2010-11 data on cotton production in India is the same as 2004, which is pre Bt. technology. There was hybrid cotton in 2004 and very, very little Bt. cotton. There was no Bt. technology. Seventy eight per cent of Maharashtra’s cotton was hybrid. Eighty nine per cent of the country’s cotton was hybrid. Today, the level of productivity of Bt. is back to 2004 level. It means the decline has begun very steeply. You have incurred incredible costs without commensurate benefits.

Let me give you some numbers and some figures on the productivity. I have brought some documents for you, which I will give you. According to International Research of Cotton Journal, there are six poor African countries like Uganda, Nigeria, Morocco, Ethiopia, Mali and Burkina Faso, which do not have a cotton research centre. They do not have a single cotton scientist. They do not have a single large corporation. They have very poor topsoil. Their topsoil is not like our rich soil of India but very poor topsoil. They use virtually no fertilizer. They use very little pesticides and their productivity level is the same as ours. Without any of our scientists and technology, their productivity level is equal to us. This is the International Research Journal on cotton. I am leaving these sheets for you. The productivity level of kilograms per hectare of lint is not different from ours. So, we

have put in billions of dollars to give what? That is my first question.”

8.90 The witness also attributed the agrarian crisis to the fact that yield benefits to the farmers were not in consonance with what were being publicized hence the returns were not matching the high input costs. Dwelling upon further on this aspect he stated during the Oral Evidence on 3 November, 2011:

“Firstly, in areas like Vidharbha and Maharashtra it is not even 80 per cent; in Vidharbha more than 95 per cent of the cotton area is under Bt. Cotton. Very little of any other variety of cotton is being grown. Let me read you the latest figures of the Government of Maharashtra which I have obtained yesterday on the productivity and you can see how productive it is. I will come to the history of cotton in India because the other claim about the net export and import is untrue. On 90 lakh acres of cultivated land the Maharashtra Government expects just 253 lakh quintals of cotton.

This is yesterday’s announcement by the Government of Maharashtra. Two hundred and fifty three lakh quintal of cotton is produced on 90 lakh acres of land, which comes to about 2.81 quintal per acre. So, where is the productivity? That is the estimate. They gave it six months ago. They gave an estimate of 410 lakh quintals and brought it down to 350 lakh quintals. Now, last week they bring it down to 253 quintals. I can assure you that they will bring it down to 220 lakh quintals. In fact, yield per acre will be much less than 2.81 quintals.

If, we take the national data of cotton and acreage, it is not productivity that has increased in the last two years but it is

acreage that has increased. The tonnage and the quintalage have increased. Nowhere, it is exceeding four quintals per acre and in return for input cost that are many times higher.

Secondly, India imports of cotton went up dramatically in the last few years through end-users certificates. The Americans are dumping cotton on us because they are subsidising their cotton with billions of dollars. This is my question and appeal to the Committee. If, Bt. cotton is so profitable, if Bt. cotton is very good then why must the United States of America give it four billion dollars of subsidy? It is because they cannot beat our farmers and our prices. Our industrialists and textile Mughals are using subsidised American cotton for several years in the last decade. It comes through various end-users certificates from Singapore and from non-cotton growing countries also. But please see the overall figures. Why did the Government ban export of cotton from India in the last year? It is because there was not enough American cotton and our textile mills wanted to keep the cotton cheap, so they would not give our farmer a remunerative price."

8.91 Voicing similar concerns, Chairman, National Biodiversity Authority informed the Committee during his Oral Evidence on 21 October, 2011:

"I think this has been an issue which basically, personally for me has been a little bothering. As you rightly said, the reason why there have been so much of investments in terms of developing this technology is to improve livelihoods, is to improve food security, and is to manage environment better. But, again, as I said, in this background document, if you look at the investments that have gone in to development specially in

agricultural biotechnology, in terms of the focus on crops, so far majority of the investments have gone in to crops which have got a little more commercial viability than essentially focussing on food security. The focus or the attempt that is made here is not to say that the investments actually should not be on the crops where they should be. But it is just a kind of anxiety to share that the investment should also be on crops where the local food security needs to be secured. Actually, if you look at the information available including in India, majority of the investments are going in to commercially viable crops where they have attracted a lot of attention in terms of both research and development as well as in terms of transformation. But we hardly have examples or experience to show that there is enough investment which is supplementing the investments we are having in terms of genetic transformation, moving forward biotechnology to secure food in terms of other food crops which actually form the food basket of day to day nutrition and day to day food security of the local communities. So what I have said here is essentially to bring the point that investments are happening but these investments are happening in a little imbalanced way.”

8.92 In view of the divergent views obtaining on the Subject and the complexities involved, the Committee sought the considered views of the National Biodiversity Authority on effects of genetically modified food crops on bio-diversity, bio-safety, human health and related aspects.

8.93 NBA informed the Committee that ever since the transgenic technology found its way into agricultural production systems, the debate about the need and safety of this technology exist. While the primary arguments for promoting agricultural biotechnology include

increasing food supply, reducing losses, stabilizing the economic well-being of farmers and reducing use of pesticides and herbicides, the arguments against genetic modification focus on the safety and stability of the modified crops, the impacts on biological diversity (biodiversity) and the socio-economic impacts of deployment of such crops. While agriculture in India has been progressive in achieving both self-sufficiency and self-reliance in food production, the proponents of genetic transformation opine that such technology must be developed and deployed as a pro-active measure to deal with food security and economic security of farming families for the future. From what emerged as a 'Precautionary Approach' within the Agenda 21 discussions prior to the UN Conference on Environment and Development (UNCED, Rio 1992) to dealing with environmental issues that is enshrined in the overall context of sustainable development, a stage has been reached where the 'Precautionary Principles' are re-validated and re-designed. The question now is whether it is 'evidence of absence' or 'absence of evidence' with regard to safety in biotechnology that is driving policy making on some critical issues of science and technology in terms of development and deployment.

8.94 Debates in India about transgenic technology are as old as biotechnology itself. While the use of transformation and biotechnology in medical and pharmaceutical sciences has attracted limited public attention, such technology in agriculture received considerable attention for many years. Three fundamental reasons can be attributed to this. First, India is an agrarian economy. Second, the socio-economic impact of agriculture and related technologies are critical for securing livelihoods of the poor. Third, India is a vibrant democracy that provides space for all possible views on issues of national interest, including agriculture.

8.95 Tracing out the development of transgenic technology NBA informed the Committee that genetic transformation technology, especially in agriculture, is seen as a great opportunity for increasing productivity both in terms of quality and quantity by many scientists. The quantitative aspect here is more to do with reducing crop losses than others. The technology peaked at a time when the intellectual property regime also provided platforms for multinationals to invest in promoting and using the technology. But the history of transgenic crops tell one story – the investments are in crops that have better commercial markets than crops that secure nutrition and livelihoods. This is evidenced by the investments made around the world in crop biotechnology where it is just a handful of crops that received the luxury of caring and improvements while the crops that secure the livelihoods and nutrition for poor farmers such as millets, greens and others were the losers. Such imbalance in focus and investments itself started the debate about the intentions of such technology as well as the transfer of such technologies in countries that have limited technical and policy over-sight to deal with biotechnology and its impacts. At the same time, biotechnology is a classic case of scientific anthropological research when it comes to limited efforts to gain public confidence in many parts of the world.

8.96 Clarifying further in this regard, Chairman, National Biodiversity Authority informed the Committee during his Oral Evidence on 21 October, 2011:

“I think this has been an issue which basically, personally for me has been a little bothering. As you rightly said, the reason why there have been so much of investments in terms of developing this technology is to improve livelihoods, is to improve food security, and is to manage environment better. But, again,

as I said, in this background document, if you look at the investments that have gone in to development specially in agricultural biotechnology, in terms of the focus on crops, so far majority of the investments have gone in to crops which have got a little more commercial viability than essentially focussing on food security. The focus or the attempt that is made here is not to say that the investments actually should not be on the crops where they should be. But it is just a kind of anxiety to share that the investment should also be on crops where the local food security needs to be secured. Actually, if you look at the information available including in India, majority of the investments are going in to commercially viable crops where they have attracted a lot of attention in terms of both research and development as well as in terms of transformation. But we hardly have examples or experience to show that there is enough investment which is supplementing the investments we are having in terms of genetic transformation, moving forward biotechnology to secure food in terms of other food crops which actually form the food basket of day to day nutrition and day to day food security of the local communities. So what I have said here is essentially to bring the point that investments are happening but these investments are happening in a little imbalanced way.”

8.97 India also entered the scene in developing and deploying transgenic crops (genetically modified crops) since early 1990s, with very good intentions and preparations to deal with ensuring the safety of such technology so that it does not harm the environment and human health. The policy and regulatory frameworks suggested, developed and implemented had all the good provisions to ensure public safety and ensure food sovereignty of the country. The policy and regulatory frameworks were put in place using well thought-out plans.

However, the developments in technology and deployment over-took the speed of policy implementation which caused apprehensions in the minds of general public about the technology and the over-sight for its deployment.

8.98 NBA also submitted that the environmental, ecological dimensions of impacts of genetically modified food crops are perhaps the single largest gap in our scientific knowledge base, globally. Such impact assessments are site specific as well as crop specific. There is an urgent need to establish relevant centres of excellence in India to generate authentic data and information on the short, medium and long term impacts of genetically modified crops on our environment and biodiversity. If environmental and health safety are prime concerns of developing and using genetically modified crop plants, then we have lagged behind in generating evidence about the positive and/or negative impacts of the technology on biodiversity.

8.99 Elucidating on this point further during his Oral Evidence on 21 October, 2011, Chairman, National Biodiversity Authority stated:

“But, over the years, the research progression has been that we were able to gather a lot of evidences in terms of the human impacts of genetically modified crops and quite a bit of research in terms of general environmental impacts of genetically modified crops. Even though research has commenced in terms of understanding the impacts of such crops on native biodiversity, the local varieties and the impact of such genetically modified crops on the overall biodiversity, we are in a situation where the results of such research are still inconclusive. The reason why the results are inconclusive is based on a very simple fact that the interaction that happens in the field between a new variety or a new crop or a modified crop and the native crop, the local variety,

has to be studied over a longer period of time because normally the evaluation of these issues are to be carried over several years..... First, whenever a technology like this is developed and whenever this technology is being tested to be commercialised or to be deployed for consumption, for commercial harvesting for use, we come into play in terms of looking at the safety of such modifications and its impact on biological diversity. But as I mentioned before, unfortunately in India we still do not have any scientific protocol or institution to deal with it because the Biodiversity Authority has its own limitations in terms of human resources, mandates and our own oversight on some of these issues. So, certainly our guidance will be to develop such kind of protocols and safety mechanisms as soon as possible so that we can be a little bit more clear and authentic in terms of providing our guidance, advice and direction on the safety of many of these crops species.”

8.100 The witness further added:

“In terms of undertaking impact assessment, certainly it is an important prerequisite before we can rule out either the invasiveness of the species or the possibility of GM crop to be contaminated into the local varieties and breeds. So, certainly there is the issue of environmental impact assessment. But specifically looking at the impacts of biological diversity it is essentially a prerequisite before we move forward in terms of agreeing, adopting the GM technology. That definitely is the case because in the absence of information, in the absence of clear data available, many of the apprehensions are going to be a bit of speculations only. So, in that context, doing an environmental impact assessment is definitely essential and that is something

which is going to be a prerequisite for us to make an informed decision on the safety of GM crops.”

8.101 Queried about the lack of protocols and a well established mechanism for the purpose, the witness stated:

“Certainly as it is said both in the background note and in the answer to the question, no doubt there is a need for us to establish protocol systems and a form of regulatory oversight focussing on the issue of many of GMOs on ecology biodiversity and local varieties of germplasm. But as of date, we do not have a formal mechanism that can be looked upon to provide a guidance or advice. We do have protocol in terms of looking at food safety on certain elements of environmental safety in terms of human health, but certainly as of now we do not have an institution or an established protocol to look at the impacts on eco system and biodiversity.

So, in that context or in that situation, we actually have two options. One is to immediately, as soon as possible, address this particular gap in terms of our research knowledge and understanding in establishing such kinds of institutions, facilities or protocols so that we can move forward the technology in terms of its development and deployment. But in the absence of it, as it is being done now, we need to look at some of these issues on a case by case basis and certainly in some of these issues the experience is going to be as and when we move forward in terms of undertaking the research.

So, specifically in answer to your question, one, as of now, we do not have the facilities and protocols to do it; we need to establish those. But whether the GM technology should wait for

such protocol to be established before we move forward on deployment, certainly it will be a prerequisite.”

8.102 In addition, like other regulatory areas, the biotechnology regulatory issue has also suffered from differing institutional mandates and coordination challenges.

8.103 About the impact of genetically modified food crops on biodiversity, NBA informed the Committee that the impact as well as benefits and risks of GM crops depend on the interactions between the ecological functions and natural history of the modified crop with the ecosystem within which it is embedded. Proper understanding and assessment of evolutionary, ecological and agronomic factors of the modified crop in question must be considered when assessing GM crops and their impact on biodiversity and ecosystems. The assessment of GM crops should be broadened to include identification of possible alternative agricultural practices, suitable ecosystem management, impacts on biological diversity and related policies that include agriculture, science and technology, conservation, socio-economic components and intellectual property protection. Such an assessment would be facilitated by a clearer understanding of the costs of agriculture and the ecological services. The benefits of GM crops should be compared to those of other means of agricultural intensification such as organic farming, integrated pest management, and agricultural policy reform. A gradual and cautious approach to the use of GM crops that relies on a truly comprehensive risk assessment could allow people to reap substantial benefits from GM crops while mitigating their serious risks (Patteson et.al. 2000).

8.104 According to NBA a fair assessment of the relative merits of different agricultural practices mentioned above requires a systematic understanding of these alternatives. However, there has been little

systematic research on the relative ecological and economic merits of alternate agricultural systems. One of the key reasons for this is the sectoral/differential approach to agricultural management systems, its safety, efficacy and impacts. Such challenges are also faced by institutions and systems as well around the world. Research and assessments have shown us that introduction of new species in agricultural systems are not new. Combination and re-combination of new characters and traits into agricultural crops form the basis of present day production systems. Introduction of crops and fish species with good intentions of boosting productions have caused havoc in many countries where the exotic species have replaced native species. The economic loss of invasive alien species in this regard is considered to the tune of USD 3 trillion per year (GISP, 2009). The comparative advantage of new species, in general, has been their ability to adapt to new environments and grow better out-competing the native varieties. Therefore careful environmental impact assessment of new species, including genetically modified species will be required to assess their impacts on ecosystems and biodiversity.

8.105 As regards effect of genetically modified food crops on human health, NBA stated globally, the regulatory oversight on genetically modified organisms functions on two basic premise. Firstly, the transformed organism is effective and secondly it does not cause any adverse impact on the environment and/or human and/or animal health. Risk assessment and risk management form the core of decision making systems with regard to such safety assessments.

8.106 The human health assessment of modified crops is based on the following questions – what will be the impact of inserted gene on human health?; will there be any negative impacts on human health due to the consumption of the new food crop in any form? and whether there will

be any un-intended impacts of products of inserted gene on other functional elements of human body, including other genes?

8.107 Safety assessment protocols available today are fairly comprehensive and robust with regard to assessing the human health safety of transformed food crops. India has one of the most comprehensive safety assessment protocols in this regard. Apart from human health, the assessments conducted in India also focus attention on animal health. National protocols on the safety assessments include the Recombinant DNA Safety Guidelines (1990 & 1994), Revised Guidelines for Research in Transgenic Plants and Guidelines for Toxicity and Allergenicity (1998), Guidelines and SOPs (standard operational procedures) for the Conduct of Confined Field Trials of Transgenic Plants (2008), Guidelines for the Safety Assessment of GM Foods (2008) and Protocols for Safety Assessment of Genetically Engineered Plants/Crops (2008).

8.108 Dwelling upon the current scenario NBA quoted the following from the Inter Academy Report on Bt. Brinjal.

"Most countries growing transgenic crops or importing transgenic food or feed have a regulatory system in place. According to a recent report already, 762 approvals for 155 Events in 24 crops have been provided world-wide. These approaches are also influenced by Substantial Equivalence, Principle of familiarity and Generally Regarded as Safe (GRAS) as working principles as well as by multilateral negotiations related to environmental and human health safety (e.g., Cartagena Protocol on Biosafety, International Plant Protection Convention, Codex Alimentarius) and trade (e.g., Agreement on the Application of Sanitary and Phytosanitary Measures, Agreement on Technical Barriers of Trade, Agreement on Trade-related Aspects of Intellectual Property Rights and United Nations Convention on Biological Diversity.

The regulatory system in India involves multi-layered recommending and approval committees. The Institutional Bio-safety Committee (IBSC) and

Review Committee on Genetic Manipulation are concerned with laboratory research, green house experiments, contained field trials and multi-location research trials as well as bio-safety. A Monitoring and Evaluation Committee (MEC) monitors multi-location research trials and large-scale field trials and makes an appropriate recommendation to RCGM. The Genetic Engineering Appraisal Committee is responsible for approvals related to large-scale field trials, experimental seed production and commercial release by de-regulation. These committees work on behalf of the Ministry of Science and Technology or Ministry of Environment and Forest or Ministry of Agriculture. The regulatory guidelines, first proposed in 1990, have been up-dated from time-to-time and recently in 2008, Guidelines and standard operating procedures for confined field trials of regulated, genetically engineered plants, Protocols for food and feed safety assessment of GE crops, and Guidelines for the safety assessment of food derived from genetically engineered plants, were introduced. Further, in 2009, an Event Based Approval Mechanism has been notified. Recently, a blueprint for Biotechnology Regulatory Authority of India has been prepared and made public. Some of the concerns raised are being addressed in the proposed Bill”.

8.109 However, a comprehensive assessment methodology or protocol related to evaluating the impacts of GM crops on biodiversity does not exist as of today. Given the need for long-term monitoring of effects of GM crops on biological diversity, it is important to note that none of the agencies or frameworks mentioned has been provided with a mandate to look into this aspect. Environmental Impact Assessments is the most time consuming of all risk assessments if it needs to be done appropriately. EIA is not a one-time assessment but should be a periodical assessment. Such assessments need to be done *ex-ante* and *post-ante* as well.

8.110 NBA also suggested the following as a way forward to deal with safety issues related to genetically modified crops in India. The table below outlines the key questions that need to be answered with regard to the risks and benefits of such modifications:

Types of Impact	Benefit-Related Questions	Risk-Related Questions
Agricultural	<p>What are the alternatives to GM crop development and deployment that could contribute to greater agronomic, economic, social, and ecological benefits?</p> <p>Does the GM crop prevent some specific harm to humans or ecosystems, e.g., does it reduce excessive use of pesticides?</p> <p>Does the modification increase the resilience of ecosystems in a manner that contributes to maintain crop production?</p>	<p>What are the risk assessment and management strategies to ensure there is no adverse impact on agrobiodiversity?</p> <p>Has the crop in question been properly examined to determine whether genetic modifications to produce a desired trait have not also inadvertently produced possible risky changes?</p>
Ecological	<p>Does the modification help environmental and production system problems?</p> <p>Does the modification contribute to improving the means for preservation and conservation of agrobiodiversity?</p>	<p>Does the modification threaten the local agrobiodiversity through introgression/out-crossing and other means?</p> <p>Does the modified crop/trait have the potential to increase the fitness of the organism outside of the managed environment?</p> <p>Will the modification create a situation where mono-cropping exposes chances for break-down of</p>

		resistance?
Social	<p>Who will benefit from the genetic modification and how will the benefits be shared?</p> <p>Does the modified crop increase the local and house-hold capacities of resource poor farmers to secure their food and incomes?</p> <p>Does the modification help increase the resilience of local people and farmers in their dependence on external inputs for farming practices?</p> <p>Will the benefits of modification be shared with communities and farmers by the developers of the technology in a manner that builds the trust and confidence of the underlying premise for such an intervention?</p>	<p>Is there a socio-economic risk in deploying the technology?</p> <p>Will be farmers become more dependent on promoters of the technology in terms of procuring the material and subsequent sale of seed/crop?</p> <p>Who will cover the risks of the technology in case of any adverse impacts?</p> <p>Is there proper institutional mechanisms and safety nets in place to deal with risk management with minimal impacts on farmers?</p>

8.111 There is an urgent need for concerned agencies working on biotechnology to support and establish appropriate protocols, methods and tools to assess the environmental and biodiversity-related impacts of genetic modification and such assessment procedures does not exist in a comprehensive manner, efforts should be made to establish programmes and support systems to generate scientific and credible data on ecological and environmental impacts of modified crops. It is

high time such an approach is put in place. In the absence of agreed methodologies and procedures to deal with socio-impacts on transgenic research with regard to crops in India (with the exception of impacts of Bt-cotton to some extent), we are running the risk of pronouncing judgements without must evidence. Lastly, but importantly, we need to augment our public sector agencies with more to generate data since the assessee cannot also double up as an assessor. However, such support should come with accountability, frameworks for transparency and appropriate capacities to deal with economic, environmental, social and legal analyses.

8.112 In conclusion, the NBA stated that the following four elements form the core of moving forward the genetically modified crop related debates in India:

1. Establishment of dedicated centre(s) of excellence who will be mandated to develop and undertake environmental and safety assessments of genetically modified crops, including assessments on impacts to local biodiversity with appropriate independence as well as accountability.
2. Creation of independent, neutral and credible public-sector research facilities that will undertake all safety related assessments related to genetic modifications.
3. Establishing agreed methodologies and assessment procedures to undertake socio-economic and communication analysis with regard to genetically modified crops and
4. Ensuring appropriate networking of relevant agencies working on various aspects of biotechnology with suitable

re-mix of mandates and responsibilities supported by both flexible frameworks to operate and accountability to be responsible for decisions.

8.113 The Committee note that Biotechnology has made salutary contributions to the agriculture sector for decades together. Plant breeding, tissue culture, cropping practices, etc. are all practiced worldwide by farmers. Most of these biotechnologies are locally developed with local research support and have significantly contributed to the farmers well being. The Committee further note that in last two decades or so transgenics in agriculture crops is being propagated as the panacea for several ills besetting the agriculture sector. Several Ministries/ Departments/Agencies in their submissions before the Committee have expounded the virtues of this comparatively new technology. The Industry has also been very supportive of transgenics in agricultural crops. According to ICAR transgenic crops by nature are eco-friendly, sustainable and protective to environment and biodiversity; increase productivity, thereby, contributing to national food, feed and fibre-security, lower production costs, conserve bio-diversity as a land saving technology capable of higher productivity on a per unit land basis; efficiently utilize inputs such as fertilizers and water; increasing stability of production to lessen suffering during

famines due to abiotic and biotic stresses, improving economic and social benefits, ensuring safer human health through reduction of chemical inputs in agriculture alongwith safer soil, water and food. The Department of Science and Technology have also recommended recombinant DNA technology as one of the breakthrough technologies like nuclear energy, super computers, etc. and have stated that such breakthrough technologies have revolutionary potential to bring paradigm shifts in the existing systems. Ministry of Environment and Forests, DBT, DHR/ICMR, GEAC have all supported transgenics/genetical engineering in agricultural crops, including the food crops more or less for the same reasons. All of these Ministries/Departments/Agencies have also assured the Committee that the assessment and evaluation protocols and regulatory mechanism in place are adequately robust albeit, they will need to be upgraded as the technology acquires more finesse. The Government have also cited the success of transgenics crops cultivation in countries like USA, Argentina, China, etc. as a justification for introducing transgencis in India. Locally, the substantial increase in the cultivation of Bt. Cotton during the last decade or so has been showcased before the Committee as the measure of success. It is being said that the area under Bt. cotton cultivation has gone up from 24000 ha. in

2001 to 8 million ha. plus now. The Committee have also been informed by the Government that apart from production, productivity has also increased due to cultivation of Bt. cotton. The drop in usage of pesticide due to Bt. cotton cultivation is also being quoted as a plus point of the transgenics technology. The Government have also informed the Committee that Bt. cotton has not affected bio-diversity, is a sustainable crop and has improved the income of the farmers.

8.114 About the safety concerns, which are aplenty, transgenics being a comparatively new technology, the Government have told the Committee that no approval is granted to the transgenic crops unless these has been a thorough analysis of its effects on the environment, bio-diversity, bio-safety, human health and health of livestock and animals. The Government have also informed the Committee that safety and efficacy is evaluated by science based experimentation and analysis on a case by case basis and, therefore, cannot be generalized as these are product specific. Simultaneously, some of the Departments/Ministries/Agencies of the Government viz. DSIR/CSIR, Department of AYUSH, Department of Commerce, Department of Consumer Affairs, Department of Food and Public Distribution, National Biodiversity Authority and Food Safety

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

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

8.116 The Committee have critically analysed the evidence placed before them both for and against the transgenic agriculture crops. And pure science, within its restrictive realm, has not been the only benchmark of this analysis. Some of the most compelling concerns factored in by the Committee include India being one of the richest centres of bio-diversity, agriculture providing sustenance to almost 70% of rural populace, more than 70% of India's farmers being small and

marginal farmers for whom agriculture is not a commercial venture but a way of life and a means of survival; food security and safety; manpower intensive nature of agriculture in India; the severe agrarian crisis afflicting the Country for years now; 60 per cent of cultivated area still being rainfed; the irretrievability of transgenic crops once released in the environment; effects on environment, human health and livestock and animal health, to quote a few.

8.117 The experience of the Country with Bt. cotton shows that with the advent of the transgenic variants and the initial hype surrounding it, the traditional cotton varieties have just been wiped out. The Committee could very well sense the desperation of farmers of Vidharbha with whom they interacted during their Study Visit in March 2012, due to non-availability of traditional varieties of cotton. In spite of their best efforts, they are now not able to shift from transgenic cotton cultivation to cultivation of traditional and more farmer friendly varieties due to total non-availability of seeds. The Committee witnessed with their own eyes these serious disadvantages caused by the practice of monoculture. The National Bio-diversity Authority has further proved with concrete instances that transgenics affect bio-diversity in a big way. Several other stakeholders

including eminent scientists, farmer's organization, etc. have also informed the Committee about the adverse and lasting impact of transgenic crops on bio-diversity. The Government's assertions that our bio-diversity will be safely stored in gene banks may be a museologist's delight but do not comfort the Committee a bit, as bio-diversity can only evolve further in nature and not in gene banks. It has also to be borne in mind that India has a substantial stake in Nagoya Protocol on Access and Benefit sharing which will be affected adversely with any tinkering with our rich bio-diversity.

8.118 Coming to the aspect of food security, the Committee are more than convinced that there are better options available for increasing food production and productivity than transgenics technology about whose safety, sustainability and a host of issues of concern, the last word is still long long away. Most importantly, India today is not in the situation of desperation that was obtaining before the first Green Revolution. Hence any short cuts or desperate measures are not required to be experimented with. Integrated Pest Management, organic farming, bio-fertilisers, molecular breeding, increasing irrigation potential, minimizing post harvest crop losses, efficient and leak proof distribution system, etc. in the opinion of the Committee,

are far more simpler, easy to do, sustainable, bio-diversity friendly options which also do not have any ill effects on human health and livestock and animal health.

8.119 While summing-up, the Committee would also like to comment further on the regulatory mechanism although it has already been dealt with in a separate Chapter in this Report. The Internal Bio-Safety Committee functions in the promoter company and performs all basic assessments and evaluations of a transgenic product being developed by that very company. It also generates data on the basis of which RCGM and GEAC base their evaluation, as stated previously in this Report. This mechanism does not inspire confidence for obvious reasons. The Department of Biotechnology which is mandated with the promotion of bio-technology in the Country, funds various transgenics research projects and activities both in public, as well as, private sector companies. This funding is of a significant order. The transgenic products created through these projects and activities are then assessed and evaluated by an adjunct of DBT viz. RCGM. On top of it, the final approval for environmental/commercial release is granted by GEAC which is co-chaired by a DBT nominee. With the Chairman of GEAC as well as the Vice Chairman being civil servants, it is not very

difficult to appreciate the primacy of DBT nominated co-Chair in GEAC in the decision making process. The Committee, inspite of DBT's protestations to the contrary, have strong reasons to agree with the opinion of several stakeholders that in a regulatory set-up where the promoter has an overwhelming say and presence in the regulatory mechanism, an element of subjectivity in assessment and evaluation is unavoidable. The entire system, therefore, reflects a pro-DBT/pro-industry tilt which is best avoided. Apart from this major shortcoming, the Committee's examination has revealed that the extant system is grossly inadequate and antiquated to face the typical challenges a population intensive, agrarian economy like India poses when the question of introduction of such modern technologies in agriculture sector crops up.

8.120 The Government have been for some years now toying with the idea of a Biotechnology Regulatory Authority. The Committee feel that regulating biotechnology is too small a focus in the vast canvas of biodiversity, environment, human and livestock health, etc. and a multitude of other such related issues. They have, therefore, already recommended in a previous Chapter setting up of an all encompassing Bio-safety Authority through an act of Parliament, which is extensively

discussed and debated amongst all stakeholders, before acquiring shape of the law. Unless and until such an authority is in place, any further movement in regard to transgenics in agriculture crops will obviously be fraught with unknown consequences. While there is a lot of apprehension about the safety of the technology, what is more worrying is the absence of any liability clause or mechanism in the system which could compensate the poor farmers and the consumers in the eventuality of crop loss and harm to bio-diversity health, environment, etc. With the various crop insurance schemes also not being of much help to a majority of farmers any prospective losses to the farmers due to cultivation of transgenic agricultural crops would have a crippling effects on their fortunes, reeling is they already are under severe agrarian crisis for years together now.

8.121 In such a situation the various players in the system of governance, who have some role or the other in the regulation, management, handling, oversight, distribution, consumer affairs, human health, livestock health, etc. have to shoulder the responsibility of ensuring that any potential harm or damages to the system are eliminated/controlled. However, as has been very clearly brought out in a previous Chapter most of the

Ministries, Departments and other agencies of the Government who have to shoulder major responsibility, when the transgenic agricultural crops come into the system, are not at all ready to optimally perform their designated roles. In fact some of the Ministries/Departments have been revved into action only after the Committee took this subject for examination and interacted with them. FSSAI, which has to play the most important role in the scheme of things alongwith NBA is still grappling with teething troubles and is not in a position to deliver atleast for coming years. NBA and PPV & FRA, as has been brought out previously in the Report, are virtually non-existent. In such a scenario how the Government intends to deal with the effects of cultivation of transgenic crops outside containment defies logic.

8.122 On another plane, long term environment impact assessment and chronic toxicology studies of the effects of transgenic agriculture crops have not even been attempted till now. The Government are yet to take a final call on labeling. There is a complete lack of post market surveillance, as has been pointed out in one particular example of lacs of tons of Bt. cotton seed oil having gone into the food chain during last ten years without anybody in the Government being aware or concerned about it.

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

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

8.125 The Rashtrapati in his maiden address in the Central Hall of Parliament on 25 July, 2012 observed 'trickle down theory do not address the legitimate aspirations of the poor. We must lift

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

NEW DELHI;
ACHARIA
7 August, 2012
Chairman,
16 Shravana, 1934 (Saka)
Agriculture

BASUDEB

Committee on

**COMMITTEE ON AGRICULTURE
(2009-10)**

MINUTES OF THE TWENTIETH SITTING OF THE COMMITTEE

The Committee sat on Thursday, the 4 March, 2010 from 1505 hours to 1640 hours in Committee Room 'C', Parliament House Annexe, New Delhi.

PRESENT

Shri Basudeb Acharia - Chairman

MEMBERS

Lok Sabha

2. Shri Narayan Singh Amlabe
3. Shri Thangso Baite
4. Shri Jayant Chaudhary
5. Smt. Shruti Choudhry
6. Smt. Ashwamedh Devi
7. Shri Biren Singh Engti
8. Shri Sk. Nurul Islam
9. Shri Naranbhai Kachhadiya
10. Shri Surendra Singh Nagar
11. Shri Prabodh Panda
12. Shri Premdas
13. Shri Uday Singh

Rajya Sabha

14. Shri Satyavrat Chaturvedi
15. Shri Sharad Anantrao Joshi
16. Shri Mohd. Ali Khan
17. Shri Bharatsinh Prabhatsinh Parmar
18. Prof. M.S. Swaminathan

SECRETARIAT

1. Shri S. Bal Shekar - Joint Secretary

2. Shri P.C. Koul - Additional Director

MINISTRY OF AGRICULTURE (DEPARTMENT OF AGRICULTURE AND CO-OPERATION)

- | | | |
|----|----------------------|--|
| 1. | Shri P.K. Basu | Secretary (A&C) |
| 2. | Shri N.K. Das | Special Secretary |
| 3. | Shri A.S. Lamba | Additional Secretary & Financial Adviser |
| 4. | Shri Ashish Bahuguna | Additional Secretary |
| 5. | Shri G.C. Pati | Additional Secretary |
| 6. | Mrs. Upma Chawdhry | Joint Secretary |
| 7. | Shri Mukesh Khullar | Joint Secretary |

INDIAN COUNCIL FOR AGRICULTURAL RESEARCH

Dr. Swapan K. Datta DDG (CS), ICAR

2. At the outset the Hon'ble Chairman welcomed the members and the representatives of the Ministry of Agriculture (Department of Agriculture and Co-operation) and other Ministries/Departments/Agencies to the Sitting of the Committee. He also felicitated the newly appointed Secretary of the Department of Agriculture and Co-operation on behalf of the Committee and on his own behalf. The Hon'ble Chairman then gave a brief background on the selection of the Subject 'Cultivation of Genetically Modified Crops - Prospects and Effects' by the Committee for examination and asked the representatives of the Department to brief the Committee on the subject. Thereafter, the witnesses after introducing themselves, briefed the Committee. After the briefing, they responded to the queries of the members on various aspects of the subject.

3. The Chairman then thanked the witnesses for appearing before the Committee as well as for briefing the Committee on the subject. He also directed them to send at the earliest information on points which had remained unclarified during the Sitting or on which information was not readily available, to the Secretariat of the Committee.

(The witnesses then withdrew).

4. Before the Sitting adjourned, the Committee decided to seek a list of stakeholders related to the subject from the Department.

A verbatim record of the proceedings has been kept separately.

The Committee then adjourned.

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**COMMITTEE ON AGRICULTURE
(2009-10)**

MINUTES OF THE THIRTY SIXTH SITTING OF THE COMMITTEE

The Committee sat on Thursday, the Fifteenth July, 2010 from 1500 hours to 1745 hours in Committee Room 'B', Parliament House Annexe, New Delhi.

PRESENT

Shri Basudeb Acharia – Chairman

MEMBERS

LOK SABHA

2. Shri Narayan Singh Amlabe
3. Smt. Ashwamedh Devi
4. Shri Anant Kumar Hegde
5. Shri Surendra Singh Nagar
6. Shri Prabodh Panda
7. Shri Premdas
8. Shri Nripendra Nath Roy
9. Shri Jagdish Thakor
10. Shri Hukmdeo Narayan Yadav

RAJYA SABHA

11. Shri Satyavrat Chaturvedi
12. Shri A. Elvarasan
13. Shri Mohd. Ali Khan
14. Shri M. Rajasekara Murthy
15. Shri Bharatsinh Prabhatsinh Parmar
16. Prof. M.S. Swaminathan
17. Smt. B. Jayashree

SECRETARIAT

1. Shri S. Bal Shekar - Additional Secretary
2. Shri P.C. Koul - Additional Director

WITNESS

1. Prof. Deepak Pental - Vice-Chancellor, Delhi University, Delhi
2. Dr. S. Nagarajan - Chairperson, Protection of Plant Varieties &

- | | | | |
|----|--|---|--|
| | Farmers
Delhi | | Right Authority, New |
| 3. | Prof. V.S. Chauhan
Centre
&
Delhi | - | Director, International
for Genetic Engineering
Biotechnology, New |

2. At the outset, the Chairman welcomed the members to the Sitting. Thereafter, he directed that the witness be ushered in.

(At around 1505 hours Prof. Deepak Pental was ushered in)

3. The witness made an audio-visual presentation before the Committee. He also briefed the Committee about the effects of Cultivation of Genetically Modified Crops on human health, livestock health, environment, genetics, molecular biology, etc.. The Members sought several clarifications on issues pertaining to the Subject to which the witness responded in detail. The Chairman thanked the witness for appearing before the Committee.

The witness then withdrew.

(At around 1625 hours Dr. S. Nagarajan was ushered in)

4. The witness made an audio-visual presentation before the Committee. He also apprised the Committee about the likely impact of cultivation of genetically modified food crops in India on Indian agriculture. The members put several queries on the Subject to which the witness responded in detail. The Chairman then thanked the witness for deposing before the Committee.

The witness then withdrew.

(At around 1710 hours Prof. V.S. Chauhan was ushered in)

5. The witness apprised the Committee about the developments taking place in the field of Genetically Modified Food crops and their ramifications on the Indian agriculture. The members raised several questions pertaining to the Subject to which the witness answered in detail. The Chairman thanked the witness for appearing before the Committee.

The witness then withdrew.

A verbatim record of the proceedings has been kept separately.

The Committee then adjourned.

**COMMITTEE ON AGRICULTURE
(2010-11)**

MINUTES OF THE SECOND SITTING OF THE COMMITTEE

The Committee sat on Tuesday, the Twenty-eighth September, 2010 from 1500 hours to 1755 hours in Committee Room 'D', Parliament House Annexe, New Delhi.

PRESENT

Shri Basudeb Acharia – Chairman

MEMBERS

LOK SABHA

2. Shri Narayan Singh Amlabe
3. Shri Thangso Baite
4. Shri Jayant Choudhary
5. Smt. Ashwamedh Devi
6. Smt. Paramjit Kaur Gulshan
7. Shri Anant Kumar Hegde
8. Shri Sk. Nurul Islam
9. Shri Prabodh Panda
10. Shri Premdas
11. Shri Nripendra Nath Roy
12. Shri Hukmdeo Narayan Yadav

RAJYA SABHA

13. Shri Shashi Bhusan Behera
14. Shri Narendra Budania
15. Shri A. Elavarasan
16. Shri Vinay Katiyar
17. Shri Mohd. Ali Khan
18. Shri Upendra Kushwaha
19. Shri Rajpal Singh Saini
20. Shri S. Thangavelu

SECRETARIAT

1. Shri P.V.L.N. Murthy - Director
2. Shri P.C. Koul - Additional Director

WITNESSES

1. Dr. C.R. Bhatia - Former Secretary,
Department of Biotechnology,
Government of India
2. Prof. A.K. Tyagi - Director,
National Institute of Plant
Genome Research, New Delhi
3. Dr. Rakesh Tuli - Director,
National Agri-Food
Biotechnology Institute, Mohali,
Punjab

4. Shri Devinder Sharma - Forum for Biotechnology & Food Security, Noida

2. At the outset, the Chairman welcomed the members to the Sitting of the Committee. Thereafter, he directed that the witness may be ushered in.

(At around 1505 hours Dr. C.R. Bhatia was ushered in)

3. The witness made an audio-visual presentation on the Subject "Cultivation of Genetically Modified Food Crops – Prospects and Effects" before the Committee. The Members sought clarifications on the several issues pertaining to the Subject to which the witness responded in detail. The Chairman thanked the witness for appearing before the Committee.

The witness then withdrew.

(At around 1610 hours Prof.. A.K. Tyagi was ushered in)

4. The witness made a presentation before the Committee based on the Memoranda already submitted by him to the Committee on the Subject. He also explained in detailed the various implications of Genetically Modified Food Crops. The members queried the witness in regard to several aspects of the Subject. The witness clarified the same. The Chairman thanked the witness for appearing before the Committee and directed him to submit replies to the points on which information could not be readily provided, to the Secretariat by 5 October, 2010.

The witness then withdrew.

(At around 1700 hours Dr. Rakesh Tuli was ushered in)

5. The witness made an audio-visual presentation before the Committee and also briefed them at length on the Memoranda which he had submitted previously. The members sought certain clarifications from the witness on the Subject. The Committee also decided that in view of the vast ramifications of the Subject, the witness be called to depose before them again. The Chairman thanked the witness for deposing before the Committee and also directed him to appear before the Committee for further Oral Evidence on 11 October, 2010.

The witness then withdrew.

(At around 1740 hours Shri Devinder Sharma was ushered in)

6. The witness briefly presented the views of the Forum for Biotechnology & Food Security on the Subject before the Committee. Since the oral evidence of the witness remained inconclusive, the Committee decided that the witness be asked to tender further oral evidence before them in future. The Chairman thanked the witness for appearing before the Committee

and also directed him to appear before the Committee for further Oral Evidence on 11 October, 2010.

The witness then withdrew.

A verbatim record of the proceedings has been kept separately.

The Committee then adjourned to meet again on 11 October, 2010.

**COMMITTEE ON AGRICULTURE
(2010-11)**

MINUTES OF THE THIRD SITTING OF THE COMMITTEE

The Committee sat on Monday, the Eleventh October, 2010 from 1430 hours to 1800 hours in Committee Room 'B', Parliament House Annexe, New Delhi.

PRESENT

Shri Basudeb Acharia - Chairman

MEMBERS

LOK SABHA

2. Shri Narayansingh Amlabe
3. Smt. Shruti Choudhry
4. Smt. Ashwamedh Devi
5. Shri Biren Singh Engti
6. Shri Prabodh Panda
7. Shri Premdas
8. Shri Nripendra Nath Roy
9. Shri Hukmdeo Narayan Yadav

RAJYA SABHA

10. Shri Shashi Bhusan Behera
11. Shri Narendra Budania
12. Shri Satyavrat Chaturvedi
13. Shri A. Elavarasan
14. Shri Mohd. Ali Khan
15. Shri Upendra Kushwaha
16. Shri Rajpal Singh Saini
17. Shri S. Thangavelu

SECRETARIAT

1. Shri S. Bal Shekar - Additional Secretary
2. Shri C. Vanlalruata - Under Secretary

WITNESSES

1. Dr. Ajay Parida - Executive Director,
M S Swaminathan
Research Foundation,
Chennai
2. Dr. Rakesh Tuli - Director,
National Agri-Food

Biotechnology Institute,
Mohali, Punjab

3. Shri Devinder Sharma - Forum for Biotechnology &
Food Security, Noida

2. At the outset, the Chairman welcomed the members to the Sitting of the Committee. Thereafter, he directed that the witness may be ushered in.

(At around 1435 hours Dr. Ajay Parida was ushered in)

3. The witness made an audio-visual presentation on the Subject "Cultivation of Genetically Modified Food Crops – Prospects and Effects" before the Committee. The Members sought clarifications on the several issues pertaining to the Subject to which the witness responded in detail. The Chairman thanked the witness for appearing before the Committee.

The witness then withdrew.

(At around 1550 hours Dr. Rakesh Tuli was ushered in)

4. The witness had appeared before the Committee during their previous Sitting on 28 September, 2010. However, his evidence remained inconclusive on the said day. The witness, therefore, in the first instance completed the audio-visual presentation on the subject, which could not be completed during the previous Sitting of the committee. He, thereafter, briefed the Committee at length on the Subject. The Members queried the witness in regard to several aspects of the Subject which were duly clarified by the witness. The Chairman thanked the witness for appearing before the Committee.

The witness then withdrew.

(At around 1710 hours Shri Devinder Sharma was ushered in)

5. The oral evidence of the witness had also remained inconclusive during the Sitting of the Committee on 28 September, 2010. The witness made an audio-visual presentation on the Subject. He also briefly presented the views of the Forum for

Biotechnology & Food Security before the Committee. The Chairman thanked the witness for deposing before the Committee.

A verbatim record of the proceedings has been kept separately.

The Committee then adjourned to meet again on 19 October, 2010.

**COMMITTEE ON AGRICULTURE
(2010-11)**

MINUTES OF THE FOURTH SITTING OF THE COMMITTEE

The Committee sat on Tuesday, the Nineteenth October, 2010 from 1030 hours to 1725 hours in Committee Room 'B', Parliament House Annexe, New Delhi.

PRESENT

Shri Basudeb Acharia – Chairman

MEMBERS

LOK SABHA

2. Shri Thangso Baite
3. Shri Jayant Choudhary
4. Shri Biren Singh Engti
5. Smt. Paramjit Kaur Gulshan
6. Shri Anant Kumar Hegde
7. Shri Prabodh Panda
8. Shri Premdas
9. Shri Nripendra Nath Roy

RAJYA SABHA

10. Shri Shashi Bhusan Behera
11. Shri Narendra Budania
12. Shri Satyavrat Chaturvedi
13. Shri A. Elavarasan
14. Shri Vinay Katiyar
15. Shri Upendra Kushwaha
16. Shri Rajpal Singh Saini
17. Shri S. Thangavelu

SECRETARIAT

1. Shri P.V.L.N. Murthy - Director
2. Shri P.C. Koul - Additional Director

WITNESSES

1. Dr. R.S. Paroda - Chairman, Trust for Advancement of Agricultural Sciences and Former DG, ICAR
2. (i) Shri Sekhar Natarajan - Chairman, Monsanto India Ltd.
(ii) Dr. Gyanendra Shukla - Director, Corporate Affairs

- (iii) Dr. Santanu Dasgupta - Scientific Affairs Lead
3. Shri S. Ramchandra Pillai - President, All India Kisan Sabha (Ashoka Road), New Delhi
4. Shri K. Nageswara Rao - Vice-President, All India Kisan Sabha (Ajoy Bhavan), New Delhi
5. (i) Shri Samit Aich - Executive Director, Greenpeace India Society, Bengaluru
- (ii) Shri Rajesh Krishnan - Campaign Manager, Sustainable Agriculture
- (iii) Smt. Divya Raghunandan - Campaigns Director, Greenpeace India
6. Prof. N.K. Ganguly - Former DG, ICMR and Distinguished Biotech Scientist, Transnational Health Science and Technology Institute
7. Ms. Sunita Narain - Director, Centre for Science and Environment, New Delhi

2. At the outset, the Chairman welcomed the members to the Sitting of the Committee. Thereafter, he directed that the witness might be ushered in.

(At around 1030 hours Dr. R.S. Paroda was ushered in)

3. The witness made an audio-visual presentation on the Subject "Cultivation of Genetically Modified Food Crops – Prospects and Effects" before the Committee. The Members sought clarifications on the various issues pertaining to the Subject to which the witness responded in detail. The Chairman thanked the witness for appearing before the Committee.

The witness then withdrew.

(At around 1135 hours Shri Sekhar Natarajan and his colleagues were ushered in)

4. The witness made an audio-visual presentation before the Committee based on the Memoranda already submitted by him to the Committee on the Subject. He

alongwith his colleagues also explained in detail the various implications of Genetically Modified Food Crops and the activities of Monsanto in this field. The members queried the witnesses in regard to several aspects of the Subject. The witnesses clarified the same. The Chairman thanked the witnesses for appearing before the Committee.

The witnesses then withdrew.
(At around 1235 hours Shri Ramchandra Pillai was ushered in)

5. The witness presented the views of his Organization before the Committee based on the Memoranda submitted earlier. The members sought certain clarifications from the witness on the Subject which were replied to. The Chairman thanked the witness for appearing before the Committee.

The witness then withdrew.
(At around 1310 hours Shri K. Nageswara Rao was ushered in)

6. The witness presented the views of his Organization before the Committee. He also replied to the various queries raised by the members. The Chairman thanked the witness for appearing before the Committee.

The witness then withdrew.
**(The Committee adjourned for lunch at 1350 hours to meet again at 1500 hours)
(At around 1500 hours Shri Samit Aich and his colleagues were ushered in)**

7. The witness briefed the Committee about the views of Greenpeace India Society on the Subject. Thereafter, with the permission of the Chairman, two of his colleagues made an audio-visual presentation before the Committee. The members asked several queries related to the Subject to which the witnesses responded to in detail. The Chairman thanked the witnesses for appearing before the Committee.

The witnesses then withdrew.
(At around 1615 hours Prof. N.K. Ganguly was ushered in)

8. The witness spoke at length about the various aspects of the Subject concerning human health. He also presented his views on the various aspects requiring systemic improvement. The members asked several questions on the Subject and related matters, to which the witness responded. The Chairman directed the witness to submit the document on ethics and equity referred to during the evidence. The Chairman thereafter thanked the witness.

The witness then withdrew.

(At around 1650 hours Ms. Sunita Narain was ushered in)

9. The witness made a presentation before the Committee based on the Memorandum and other documents submitted by her to the Committee previously. She also explained in detail the practices obtaining elsewhere in the field of transgenic crops and genetically modified food crops. She also dwelt upon the various implications of the genetically modified food crops on human health, rural livelihood, economy, exports, etc. The members raised several queries during her presentation, which were responded to by the witness. The Chairman then thanked the witness.

The witness then withdrew.

A verbatim record of the proceedings has been kept separately.

The Committee then adjourned to meet again on 28 October, 2010.

CONFIDENTIAL

**COMMITTEE ON AGRICULTURE
(2010-11)**

MINUTES OF THE FIFTH SITTING OF THE COMMITTEE

The Committee sat on Thursday, the Twenty-Eighth October, 2010 from 1100 hours to 1355 hours before adjourning for lunch and from 1430 hours to 1820 hours in Committee Room 'B', Parliament House Annexe, New Delhi.

PRESENT

Shri Basudeb Acharia – Chairman

MEMBERS

LOK SABHA

2. Shri Narayansingh Amlabe
3. Shri Jayant Choudhary
4. Smt. Shruti Choudhry
5. Smt. Ashwamedh Devi
6. Shri Anant Kumar Hegde
7. Shri Sk. Nurul Islam
8. Shri Naranbhai Kachhadia
9. Shri Prabodh Panda
10. Shri Vitthalbhai Hansrajbhai Radadiya
11. Shri Nripendra Nath Roy
12. Shri Bhoopendra Singh
13. Shri Uday Singh
14. Shri Jagdish Thakor
15. Shri Hukmdeo Narayan Yadav

RAJYA SABHA

16. Shri Shashi Bhusan Behera
17. Shri Narendra Budania
18. Shri Vinay Katiyar
19. Shri Mohd. Ali Khan
20. Shri Upendra Kushwaha
21. Shri Bharatsinh Prabhatsinh Parmar
22. Shri Rajpal Singh Saini
23. Shri S. Thangavelu

SECRETARIAT

1. Shri P.V.L.N. Murthy - Director
2. Shri P.C. Koul - Additional Director

WITNESSES

1. Dr. Vandana Shiva - Navdanya, New Delhi
2. Dr. Sagari R. Ramdas - Anthra, Secundrabad, A.P.
3. Ms. Kavitha Kuruganti - Kheti Virasat Mission, JAITU, Faridkot
4. Prof. G. Padmanabhan - Department of Biochemistry, Indian Institute of Science, Bengaluru
5. Ms. Aruna Rodrigues - Sunray Harvesters, Mhow
6. Shri Prashant Bhushan - Sr. Advocate, Supreme Court of India

2. At the outset, the Chairman welcomed the members to the Sitting of the Committee. Thereafter, he directed that the witness might be ushered in.

(At around 1105 hours Dr. Vandana Shiva was ushered in)

3. The witness made a presentation before the Committee based on the Memoranda already submitted by her. She also elaborated upon the ramifications of GM crops on environment, bio-diversity, human health, livelihoods, etc.. The Members sought clarifications on several issues pertaining to the Subject to which the witness responded in detail. The Chairman thanked the witness for appearing before the Committee.

The witness then withdrew.

(At around 1240 hours Dr. Sagari R. Ramdas was ushered in)

4. The witness made an audio-visual presentation before the Committee. She also explained in detail the various implications of Genetically Modified Food Crops with particular emphasis on veterinary science, human health, liability aspect, labelling, livelihoods, etc.. The members queried the witness in regard to several aspects of the Subject. The witness clarified the same. The Chairman thanked the witness for appearing before the Committee.

The witness then withdrew.

***(The Committee adjourned for lunch at 1355 hours to meet again at 1430 hours)
(At around 1430 hours Ms. Kavitha Kuruganti was ushered in)***

5. At the outset the witness sought the permission of Chairman to circulate additional papers on Kisan Swaraj Yatra. Thereafter, she put forth her views on the Subject with the help of an audio-visual presentation. The members sought several clarifications from the witness on the Subject which she clarified in detail. The Chairman thanked the witness for deposing before the Committee

The witness then withdrew.

(At around 1550 hours Prof. G. Padmanabhan was ushered in)

6. The witness made an audio-visual presentation before the Committee. The Chairman asked the witness to also explain to the Committee effects of Genetically Modified Food Crops on human health. The witness briefed the Committee on the pros and cons of cultivation of

GM food crops. The members sought several clarifications pertaining to the various aspects of the Subject to which he responded. The Chairman thanked the witness for appearing before the Committee.

The witness then withdrew.

(At around 1650 hours Ms. Aruna Rodrigues was ushered in)

7. The witness presented her views on the Subject before the Committee based on the Memoranda already submitted by her previously. The Chairman put forth some questions to the witness which she responded to. The Chairman thanked the witness for appearing before the Committee.

The witness then withdrew.

(At around 1740 hours Shri Prashant Bhushan was ushered in)

8. The witness made a brief presentation before the Committee based on the Memoranda already submitted by him. He also explained in detail the various legal implications of Cultivation of Genetically Modified Food Crops, the international practices, their impact on health of both human beings and livestock, conflict of

interest between regulatory bodies and commercial entities, etc. The members queried the witness in regard to several aspects of the Subject. The witness clarified the same. The Chairman thanked the witness for appearing before the Committee.

The witness then withdrew.

A verbatim record of the proceedings has been kept separately.

The Committee then adjourned to meet again on 10 November, 2010.

**STATUS OF GM CROPS APPROVED FOR FIELD TRIALS BY
THE RCGM / GEAC DURING 2007-till date**

S.No.	Crop	Company Name	Trial	Trait / Gene/ Event	Approved Locations	Present Status
1	Cauliflower	Sungro Seeds Research Ltd.	BRL-I	Insect Resistance <i>cry1Ac event CFE 4</i>	Own R&D centers at Jatheri (Haryana) & Bangalore	Not initiated
		Nunhems India Pvt. Ltd.	Event Selection	Insect Resistance <i>RST08-30, 15 events</i>	Own R&D Centre	Not initiated. Project has been discontinued.
2	Cotton	Dow AgroSciences India Pvt. Ltd.	BRL-I	<i>Insect Resistance and Herbicide Tolerance</i> <i>cry1Ac& cry1F (WideStrike = Event 3006-210-23 and Event 281-24-236)</i>	Aurangabad (MH) & Vadodara (Guj) in July 2010 Guntur (AP), Attur (TN) and Dharwad (KN) during August 2010	Ongoing about to harvest. Trials are in progress
			BRL-II			
		JK Agrigenetics Ltd.	BRL-I	Insect Resistance <i>cry1Ac (Event-1) and cry1EC (Event-24)</i>	Bathinda (Punjab) and Sriganganagar (Rajasthan) during Kharif 2010	Ongoing

		MAHYCO	BRL-II	Insect resistance and Herbicide tolerance (Round up Ready Flex) <i>cry1Ac & cry2Ab</i> (MON 15985) and <i>CP4EPSPS</i> (MON 88913)	Bathinda (Punjab), Sirsa (Haryana), Hanumangarh (Rajasthan), Surat (Gujarat), Khandwa (MP), Nagpur (Mahatashtra), Ranga Reddy (Andhra Pradesh), Dharwad (Karnataka) in Kharif 2010 Coimbatore (Tamil Nadu) in Kharif 2010	Completed Ongoing
		Krishidhan Seeds Ltd. Jalna	Event selection	Insect resistance <i>Cry1Ac and cry1</i>	<i>Company owned farm at Jalna in Kharif 2010</i>	Not initiated.
		Central Institute of Cotton Research (CICR), Nagpur	BRL-1	Insect resistance and G hirsutum tolerance <i>cry1Ac gene</i>	CICR, Panjari Farm in Kharif 2010	Ongoing
		Central Institute of Cotton Research (CICR), Nagpur	BRL-1	Insect resistance and G hirsutum tolerance	CICR, Panjari Farm in Kharif 2010	Ongoing

				<i>cry1F gene</i>		
		Central Institute of Cotton Research (CICR), Nagpur	BRL-1	Insect resistance and G arboretum tolerance <i>Cry1Ac gene</i>	CICR (RS), CICR, Sirsa, Haryana in Kharif 2010	Ongoing
3	Rice	Bayer Bioscience Pvt. Ltd.	Event selection	Insect resistance <i>cry 1 Ab, cry 1Ca & bar genes</i>	Chinnakanjrala Patancheru and Bayer Bioscience Pvt Ltd., Davangere, Karnataka.	Trials at one location Chinnakanjrala initiated.
		Avesthagen Ltd.	Event selection	Hybrid vigour <i>Oryza sativa taipae 309</i>	Company's own research farm at Hyderabad	Not initiated
		Mahyco	BRL-1	Insect resistance <i>cry 1Ac gene</i>	Coimbatore & Tanjore (TN), South 24 Parganas & Midnapur (WB), Bhandara & Raigad (Maharashtra), Davangere & Mandya (Karnataka), Gaya (Bihar), Ranchi (Jharkhand), Anand (Gujarat) in 2007	Trials completed in all locations except at Midnapore where trial was uprooted.
		Metahelix Life	BRL-1	Insect	Vattinagulapalli Village, RR Dist,	Initiated

		Science Ltd.		resistance <i>Cry 1Ac and Cry1Ab gene</i>	AP.	
		M/s. El DuPont India Pvt Ltd, Hyderabad	BRL-1	Insect resistance SPT maintainer ZM-AA1-Os-MSCA1-DsRED2 genes and Os-MSCA-1-ZM-AA1-DsRED2	Sardar Krishi Farm, Krishak Nagar, Labhandi Raipur, Medek, AP.	Not initiated
		University of Calcutta, Kolkata	BRL-1	Insect resistance <i>Ferritin gene</i>	Rice Research Station,	<i>Not initiated</i>
		BASF, Mumbai	BRL-1	Insect resistance OS ARGOS and containing OS-hox5, Homeobox-Leucine Zipper gene	Tamil Nadu Agriculture University (TNAU), Coimbatore	Not initiated because of the impending approval of the State Govt
4.	Tomato	Avesthagen Ltd.	Event selection	Increased lycopene content unedited <i>NAD9</i>	Own Research Farm, Hyderabad.	Not initiated.

		National Research Centre for Plant Biotechnology (IARI)	Event selection	Stress tolerance Antisense ACC synthase gene	NRCPB, Genetics Farm, IARI Campus, PUSA, New Delhi	Trials are in progress.
		Mahyco	Pollen flow study	Insect resistance Cry 2Ab gene	Company's Research Station at Jalna	Not initiated
		Institute of Horticultural Research (IIHR), Bangalore	BRL-1	Insect resistance to Topso virus Peanut Bud Necrosis virus (PBNV)	At IIHR R&D centre at Bangalore	Initiated
		Institute of Horticultural Research (IIHR), Bangalore	BRL-1	Insect resistance to leaf curl virus TLCV	At IIHR R&D centre at Bangalore	Initiated
		Institute of Horticultural Research (IIHR), Bangalore	BRL-1	Insect resistance to PBNV and TLCV Peanut Bud Necrosis virus (PBNV) & TLCV	At IIHR R&D centre at Bangalore	Not initiated
5.	Groundnut	ICRISAT	Event Selection	Insect resistance Chitinase gene	Research farm at Patencheru	Ongoing

		ICRISAT	Event Selection	Coat protein gene (cp) for tobacco streak virus against peanut stem Necrosis Disease	Research farm at Patencheru	Ongoing
		University of Agricultural Sciences (UAS), Bangalore	Event Selection	Insect resistance (stress tolerance) DREB 1A	R&D, UAS, Bangalore	Not initiated – scheduled for April 2011
		University of Agricultural Sciences (UAS), Bangalore	Event Selection	Insect resistance (stress tolerance & drought tolerance) DREB 1B	R&D, UAS, Bangalore	Not initiated – scheduled for April 2011
6.	Cabbage	Nunhems India Pvt. Ltd.	Event Selection	Insect Resistance <i>cry 1b and cry 1c</i> gene.	Own R&D Centre	Not initiated. Project has been discontinued.
7.	Potato	Central Potato Research Institute, Shimla.	Event selection	Insect resistance RB transgenic	At own R&D Farm (Kufri Giriraj) located at CPRI Campus	Not initiated

				potato clones two lines (904/SP951) of RB		
		Central Potato Research Institute, Shimla.	Event selection	Insect resistance Solanum tuberosum subsp. Tuberosum KchipLnvRNAi-2214	Central Potato Research Station located at Jalandhar, Punjab	Completed
		Indian Agricultural Research Institute (IARI), New Delhi	BRL-1	Insect resistance to GR=PVY Potato Virus Y	At their own Research Land	Completed
8.	Corn	Monsanto India Ltd.	BRL-II trials	Insect resistance and herbicide tolerance <i>cry 2Ab2</i> and <i>cry 1A.105</i> genes, (event MON 89034 and CP4EPSPS genes)	For Rabi Season at Begusarai/ Samastipur, Bihar and Bhagalpur (Bihar), TNAU, Coimbatore (TN), UAS (Dharwad), ANGRAU, Karimnagar (AN). For Kharif 2011 at nine locations namely BHU Varanasi, UP; Begusarai Bihar; Bhagalpur Bihar; TNAU Coimbatore;	Trial at Samastipur terminated. Trial at UAS, Dharwad ongoing. Not initiated.

					UAS Dharwad; ANGRAU Karimnagar; MPUAT Udaipur; AAU Vadodara and DWSR Jabalpur MP.	
		Pioneer Overseas Corporation	BRL-1 trials	Insect resistance and herbicide tolerance <i>Cry1F and CP4EPSPS genes (stacked event of TC 1507 X NK 603)</i>	Guntur, ANGRU and UAS, Dharwad	Ongoing.
		Dow Agrosciences	BRL-1	Insect resistance <i>Cry 1F (event TC 1507)</i>	TNAU, Coimbatore and Bhavani Sagar	Trials were initiated but terminated.
		M/s. Syngenta Biosciences Pvt Ltd, Pune	BRL-1	Insect resistance <i>Cry 1Ab gene (Event Bt 11)</i>	MPUA&T, Udaipur and BHU, Varanasi	Ongoing.
9.	Sorghum	National Research Centre for Sorghum	BRL-1	Insect resistance <i>Cry1B gene NRCSCRY1B event 4 and NRCSCRY 1B event 19</i>	At own Research Farm, Hyderabad	Not initiated
		Central Research Institute for Dryland Agriculture	Event selection	Insect resistance <i>Cry 1B gene</i>	At own Research Farm, Hyderabad	<i>Completed</i>

		(ICAR), Hyderabad		(M35-1)		
10.	Okra	Mahyco	BRL-1	Insect resistance. <i>Cry 1Ac gene</i>	Jalna, Jalgaon (Maharashtra), Vadodara (Gujarat), Durg (CG), Jaipur (Rajasthan), Karnal (Haryana), Gaya (Bihar), Nadia (WB), Haveri (Karnataka), Coimbatore (TN) in 2007	Completed
11.	Brinjal	Bejo Sheetal Seeds Pvt. Ltd.	BRL-1	Insect resistance <i>Cry 1Fa1 (event 142)</i>	Jalna, Guntur and Varanasi	Completed
		Sungro Seeds Research Limited	BRL-1	Insect resistance <i>Cry 1Ac gene</i>	Company owned farm in New Delhi in 2007	Completed.
12.	Mustard	Delhi University	BRL-1	Yield increase <i>barnase / barstar gene</i>	Agricultural Research Station experimental Farm, Navgaon (RAU, Bikaner), Agricultural Research Station, Sriganganagar (RAU, Bikaner) & KVK, Kumher (Bharatpur)	Ongoing
		National Research Centre for Plant	BRL-1	drought stress	HAU, Hissar, PAU, Ludhiana, Bharatpur,	Trials are in progress.

		Biotechnology (IARI)		<i>Osmotin gene</i>	DRMR, ICAR.	
13.	Wheat	National Research Centre for Plant Biotechnology (IARI)	BRL-1	Effect of mutant strains <i>Azotobacter</i>	Within IARI Campus, PUSA, New Delhi.	Trials are in progress.
14.	Watermelon	Institute of Horticultural Research (IIHR), Bangalore	BRL-1	Insect resistance <i>Bud Necrosis Virus</i>	At IIHR, R&D	Not initiated.
15.	Transgenic Papaya	Institute of Horticultural Research (IIHR), Bangalore	BRL-1	Insect resistance <i>PRSV</i> <i>cp –gene.</i>	At IIHR, R&D	Not initiated.
16.	Transgenic Sugarcane	Sugarcane Breeding Institute (ICAR), Coimbatore	Event Selection	Insect resistance <i>Cry1Ab gene</i>	At Institute Research Farm in Coimbatore	Not initiated
17.	Para Rubber Tree	Rubber Research Institute of India, Kottayam	BRL-1	Insect resistance dismutase gene (cDNA)	Dapchari, Thane in Maharashtra and Chethackal, Thombikandom in Kerala	Not initiated in Kerala due to objection from State Government To be initiated in Maharashtra in July 2011.

Minutes of the meeting of the Genetic Engineering Appraisal Committee (GEAC) held on 27.04.2011.

The meeting of the GEAC was held on 27.04.2011 in National Agriculture Sciences Centre, Pusa under the chairmanship of Shri M. F. Farooqui, Additional Secretary, MoEF and Chairman, GEAC.

List of participants is annexed.

Agenda item 1: Consultation with experts and scientist on regulatory process for Genetically Modified Crops as part of Bt brinjal post moratorium follow-up.

1.0 At the outset, the Chairman welcomed all the experts and thanked them for sparing their valuable time in attending this important meeting. He further informed that the meeting has been convened as a follow-up to the direction given by the Hon'ble Minister to the GEAC in his decision document dated 9.2.2010 while imposing moratorium on Bt Brinjal Event EE-I developed by M/s. Mahyco, TNAU, Coimbatore and UAS, Dharwad.

2.0 To facilitate a focused discussion on the outcome of the public consultation, he requested Dr. Ranjini Warriar, Member-Secretary GEAC to make a brief presentation on the outcome and key concerns that emerged during the public consultations. Dr Warriar in her presentation explained in brief (i) Purpose of this meeting, (ii) Documents Circulated to Members; (iii) Legal and Statutory Requirements; (iv) Facts on Bt. Brinjal development; (v) Process followed by the GEAC; (vi) Process followed in the public consultation; (vii) Summary of key concerns. The following points were noted:

- I. The purpose of this meeting is to deliberate
 - a. key concerns that have emerged as outcome of the public consultation
 - b. need of additional studies to assess the safety of Bt Food Crops
 - c. protocols and procedures to be followed while conducting the additional studies

- II. To a query on why the Inter-Academy Report on GM Crops (updated) was circulated to the Members as it has not been discussed in the GEAC, it was clarified that all post-moratorium analysis document received by the GEAC which include (i) Dr Lou M Gallagher report pertaining to the scope and adequacy of the GEAC toxicology risk assessment; (ii) David A. Andow report on the scope and adequacy of the GEAC environmental risk assessment pertaining to Bt Brinjal, (iii) updated Inter-Academy Report on GM Crops; (iv) Socio-Economic Analysis of Production and Marketing of Brinjal and Ex-ante Assessment of Economic Benefits of Bt Brinjal in India have been circulated for information.

- III. The CEE report contained statements made by 631 stakeholders in the public

consultations meeting (both propositions and concerns). The concerns raised by various stakeholders have been studied in detail and broadly categorized under

six categories, viz. general issues, molecular/genetic aspects, health/food and feed safety concerns, environmental concerns, market/trade issues and other issues. Specific comments reflected in the decision document have been further sub-categorized under each category as indicated below:

A. HEALTH/FOOD AND FEED SAFETY CONCERNS

1. Sub chronic 90 day rat feeding study not adequate
2. Feeding study design flawed to mask statistical differences in laboratory studies
3. Need for long term chronic toxicity studies
4. Concerns about the concept of substantial equivalence
5. Enhanced potential toxins, allergens and anti-nutrients
6. Reduced nutritional value of Bt brinjal/GM food
7. Transfer of novel genes to humans and animals and bacteria
8. Need for human trials
9. Issues related to Ayurveda and Siddha

B. ENVIRONMENTAL CONCERNS

10. Potential gene transfer to related cultivated and wild species
11. Impact on biodiversity/traditional varieties
12. Impact on non-target organisms
13. Accumulation of residue levels of expressed proteins in agro- ecosystem
14. Risk of becoming weedy/invasive
15. Insect resistance development
16. Environmental risk assessment not in accordance with Cartagena Protocol on Biosafety

C. MOLECULAR /GENETIC ASPECTS

17. Bt brinjal expresses chimeric gene (fusion of cry 1Ab & cry1ac). Safety testing has been done only for cry 1 Ac gene
18. Contains gratuitous cassette for antibiotic resistance (*aad* gene encoding spectinomycin/streptomycin resistance) The cassette has a promoter for bacterial expression
19. Use of *Agrobacterium* based transformation system can cause cancerous tumors.
20. Effect of transferring viral sequences to plants, viruses and other organisms (CaMV 35 can activate dominant viruses.
21. Proteomics, transcriptomics (high throughput sequencing), metabolomics, 2D gel electrophoresis required for hazard identification or identifying

unintended effects not carried out.

D. MARKET/ TRADE ISSUES

22. Need for post market surveillance

23. Labeling issues

24. Impact on organic farming

25. Socio economic issues

26. Liability issues due to contamination

E. OTHER ISSUES

27. Use of company data/lack of independent studies

28. Lack of public consultation in decision making

29. Lack of public awareness

30. Technology ownerships by the MNCs

F. GENERAL ISSUES

31. General opposition to GM crops

32. Need of Bt. Brinjal / Use of Alternative Strategies

33. Inefficient regulatory frameworks/mechanisms – Not compliant with Codex and Biosafety Protocol

34. Lack of independence in the regulatory agency.

IV. It was also clarified that the list of concerns presented is only an indicative list but covers key areas of concerns, which need to be addressed by the Committee.

3.0 Subsequent to the presentation, the Chairman, GEAC invited views of the experts on general and specific issues covering the following:

- I. Gaps, if any, in the sub-chronic/acute toxicity studies
- II. Need for long term toxicity studies to assess the impact of Bt brinjal on human health.
- III. Need for profiling techniques/non-targeted approaches to identify unintended effects
- IV. Use of Antibiotic Resistance Marker (ARM) genes in GM food crops
- V. Impact on biodiversity/ traditional varieties due to gene flow
- VI. Crossability with the wild relatives
- VII. Insect Resistance Management Strategies
- VIII. Socio-economic and trade concerns
- IX. Reliability of the company's data/ independent testing.
- X. Lack of independence in the regulatory agency

4.0 The Committee extensively deliberated on the above issues. The following points were noted:

A. General Issues

I. On the general issue, many experts were of the view that the Government should give a clear cut direction on whether GM Food is required or not for the country. If the

perception is not clear; it is going to affect ongoing research in public institutions and universities.

B. Specific Issues

On specific issues, three points namely (i) need for additional biosafety studies to assess the safety of cry 1 Ac protein; (ii) acceptance of company data & (iii) the way forward were discussed. Details of the deliberations are summarized below:

I. Need for additional biosafety studies to assess the safety of Bt protein

i On whether additional studies are required to assess the safety of Bt protein, most of the Experts were of the view that the studies prescribed under the current regulatory system and studies conducted with Bt brinjal are adequate. However Dr P M Bhargava, representatives of Department of AYUSH and Dr Ram Vishwakarma, Director, Indian Institute of Integrative Medicine, Jammu were of the view that additional studies may be required.

ii Experts who were of the view that additional studies are not required to assess the safety of Bt protein provided the following justification:

- Given that *cry1Ac* protein has been used extensively in global agriculture and has gone through biosafety clearances in so many countries, there should be no doubt about the safety of the *cry1Ac* gene. Adequate tests have been conducted for Bt Brinjal also. Cry1AC protein in corn has been tested in human and animal for more than 15 years.
- The safety data generated by NIN has been elaborated by experiments carried out within and outside the country that demonstrate (i) Cry1Ac interacts specifically with receptors aminopeptidase and cadherin of pest *Helicoverpa* only; (ii) divergence in the structure of cadherin and aminopeptidase results in lack of activity of Cry1Ac protein. Thus structurally diverse orthologous receptors of human corresponding proteins do not react at all with Cry1Ac; (iv) protein Cry1Ac is degraded in 20 seconds to non toxic molecules at acidic pH (v) specificity is further demonstrated by the observed lack of activity against larvae of *Spodoptera litura* (vi) aminopeptidase of *S.litura* does not interact with Cry1Ac protein.

- No new data or evidence has been established to prove that Bt protein is unsafe or hazardous. Even the reports of international experts are an analysis of the EC-II Report and their main concern is that the GEAC had set a too narrow scope. Their recommendations/ conclusions are based on “indications” or “possibilities”
- Bt technology is best suited and an alternative way to control cryptic borers such as bollworms, which are internal feeders, much like the brinjal fruit and shoot borer.
- Data from CICR has clearly shown reduced application of pesticides in cultivated Bt cotton crop. The reduction in insecticide usage from Rs 718 crores in 2004 for lepidopteran caterpillars to Rs 110 crores (Rs 23 crores for

American bollworm) in 2010, can be seen as a spectacular achievement of Bt cotton technology.

- Sizeable quantities of highly toxic insecticides such as carbosulfan, carbofuran, triazophos, metasystox, monocrotophos, phorate, methyl parathion, phosphomidan, dicofol etc which are considered to be extremely hazardous to the environment and which have been severely regulated by the FAO (Food and Agricultural Organization), WHO (World Health Organization) and the UNEP (United Nations Environment Programme) are being used on Brinjal crop. The three organophosphate insecticides (phosphamidon, methyl parathion and monocrotophos) belong to the category of either ‘banned or restricted use’ in India. But, it is a matter of immense concern that these are regularly used on Brinjal crop just before harvest. All these insecticides are systemic and are translocated into fruits, thus posing immense dangers.
- Bt cotton seed meal is being fed to cattle in India for a number of years now. No authenticated cases of adverse effects on farm animals have been reported so far.
- A large diversity of wild/weedy forms related to brinjal exists in India. Among these, the group comprising *S. incanum-S. insanum* complex is crossable with brinjal under artificial cross-pollination. The amount of crossability varies with genotypes, but successful crosses produce viable hybrids. As Bt is not a dominant gene, it will not result in any fitness advantage even if it is transferred.
- *S. melongena* (brinjal) and *S. incanum-S. insanum* have never been reported as invasive or difficult to eradicate weeds. The probable hybrids existing in nature also do not pose any problems as serious weeds. In our experience of nearly two decades of work on Indian Solanums, we have never found these plants growing in dense populations. They exist as individual plants or sparse populations of 10-15 plants in nature or as sporadic plants around cultivated fields.
- The fear that adoption of Bt brinjal will lead to loss of indigenous diversity of cultivated forms is rather exaggerated. If Bt cotton is any example and Bt brinjal is as successful, we will see numerous seed companies transferring Bt gene into their varieties/hybrids that are already acceptable to the farmers and

consumers. While Bt gene would be common among these, the rest of the genome will be as diverse as it is at present.

- About 4,000 accessions of brinjal germ plasm are available in the gene bank with NBPGR. It is the responsibility of public institutions like NBPGR to preserve the natural forms as India is a centre of diversity of not only brinjal but several other crops.

iii Several members also expressed concern about the sustainability of the technology. They opined that the main concern about *cry1Ac* gene is resistance development of the fruit and shoot borer to Bt brinjal, especially because it is a monophagous pest. The transgenic line under consideration does not provide full protection against the target insect pest. Also this insect pest has only one host plant, brinjal. The recommended refugia of 5% would be grossly insufficient to delay resistance significantly. However, globally acknowledged expertise available in the country, and at

CICR can be utilized to devise effective resistance management strategies immediately prior to the release based on stochastic models developed by CICR.

iv Dr P M Bhargava did not support the above views. He opined that the need for additional studies to assess the safety of Bt protein needs to be reviewed in light of new evidences available. He further stated that the objective regarding purpose of the tests, such as where; how; the list of tests needed to be conducted; etc has not been achieved by today's meeting. He suggested that a separate meeting with additional experts may be convened to discuss the list of 39 studies suggested by him in his letter to the Hon'ble Minister for Environment & Forests and to the GEAC. In response, Members were of the view that additional tests if prescribed, should be on the basis of international best practices and experiences. No Utopian protocols only specific for India should be prescribed as raising the bar would increase the affordability cost to farmers. Members were also of the view that studies such as proteomics, transcriptomics, etc. are currently only research tools and do not provide any value addition to the biosafety assessment. Dr Bhargava did not agree with the above views and reiterated emphatically that he was not against the technology but in light of the new evidences and experiences available, there is an urgent need for a scientific debate on the additional studies suggested by him. He opined that during the debate, members who do not agree with the requirement may provide scientific basis and evidence on why a particular study is not required. He suggested that during the next meeting, experts such as Prof. Madhav Gadgil, a socio-economic expert and others may be invited for having a wider opinion on the matter. It was clarified that the meeting notice and relevant papers have been circulated to Prof Gadgil but no response has been received. However, the relevant papers would be resent after contacting Prof Gadgil. Dr Bhargava also requested Member Secretary, GEAC to circulate his letter dated September 2, 2010 eliciting the list of 39 studies required for biosafety assessment. It was clarified that the communication has been circulated and would be resent to all the members.

v Representatives of the Department of AYUSH (Ayurveda, Unani and Medicinal

Plant Board) opined that they were participating in this process for the first time and they were enlightened by the discussions and views of the eminent experts. They also informed that discussions with MoEF on concerns pertaining to gene flow and crossability, etc. have been clarified. While the Department was willing to go along with the views of experts regarding the safety of Bt protein, they were of the view that their concern is limited to the fact that brinjals 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 as some of the Solanum species are used in the preparation of classical formulations of Indian medicines used in the treatment of neurological and musculo-skeletal disorders. It was further recommended 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.

vi. In response to the above observations, Dr Sesikaran, Director, NIN requested scientists from AYUSH 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

vii Dr Ram Vishwakarma, Director, Indian Institute of Integrated Medicine, Jammu suggested that International Safety Guidelines with no conflict of interest should be strictly followed. He further suggested that international regulatory data is available on the website and needs to be studied by the GEAC to verify whether the protocols and procedures followed to generate biosafety data with Bt brinjal conforms to international practices/scrutiny.

II Acceptance of company data

All members except Dr P M Bhargava agreed that any data generated in accredited GLP laboratories can be accepted as this practice is being followed internationally for release of all products. Dr. Bhargava opined that there is a need for setting up an independent GMO testing facility devoid of conflict of interest and encompassing all the stakeholders for generation of biosafety data for regulatory purposes and data submitted by the company should not be accepted.

III Suggestions on Way Forward:

The following recommendations of Dr G Padmanabhan were supported by many Experts, however, Dr P M Bhargava categorically opposed it:

1. Limited release of Bt seeds to identified farmers under strict expert supervision should be undertaken to evaluate its performance in public space. This would also help in the assessment of its suitability for cooking purposes and as a food item. If it is considered absolutely necessary, this period can also be used to test a couple of parameters: 1. Analysis of alkaloids 2. Chronic toxicity test for 180 days. He further opined that these two tests are needed only to send the message that GEAC is not averse to go the extra-mile to address even remote issues of safety.

5.0 Joint Secretary (seeds) Ministry of Agriculture, supporting the suggestion for

limited release also stated that Ministry of Agriculture has initiated several developmental programs to improve food security and awareness. For successful implementation of the

promotional programs GM technology is required. He further suggested that the review should be science based and completed in a time bound manner.

6.0 In his concluding remarks, the Chairman opined that the issues involved are very complex and it may not be possible in one meeting or one sitting, to come to an agreed consensus on what needs to be done, etc. On the issue of whether GM technology is needed or not, he informed that the GEAC is guided by the statement made by the Hon'ble Prime Minister at the Indian Science Congress on January 3, 2010 at Thiruvananthapuram wherein he has categorically stated that "we should pursue all possible leads that biotechnology provides that might increase our food security as we go through climate related stress subject to the condition that the question of safety is given full weightage, with appropriate regulatory control based on strictly scientific criteria".

7.0 The Chairman also opined that due consideration should be given to issues raised by the State Governments and such apprehensions have to be addressed in a transparent manner to ensure public acceptability of the technology. He also pointed out that the current regulatory process is going through a transition period as new initiatives such as the Biotechnology Regulatory Authority of India Bill is under active consideration of the Government. During the interim period, the GEAC will continue its dialogue with experts and take necessary action to strengthen the regulatory framework in India. He requested all experts, as a follow-up to today's meeting, to forward a half-page recommendation on the way forward including the need for additional studies within 7 days. With a view to facilitate scientific debate he further suggested, while recommending additional studies, the experts may also indicate the end point for such studies, its applicability in the biosafety assessment, whether such studies are prescribed by other regulatory agencies and if so what the prescribed protocols are.

8.0 Thanking all the members once again for their active participation, he informed that a second consultative meeting will be convened by the GEAC to discuss the recommendations received from experts and other departments on the requirement for additional biosafety studies.

The meeting ended with a vote of thanks to the Chair and Members.

LIST OF POINTS ON THE SUBJECT “CULTIVATION OF GENETICALLY MODIFIED FOOD CROPS – PROSPECTS AND EFFECTS”

1	<p>The role, responsibility and the comments/explanation of UAS, Dharwad & CICR, Nagpur who were involved in the development of the variety and hybrid in question may please be obtained and furnished.</p>	<p><u>Role of UAS, Dharwad</u> A research project was approved under National Agricultural Technology Project (NATP) funding, during 1999-2004, on Bt transgenic cotton. The Lead Centre of this Project was National Research Centre for Plant Biotechnology (NRCPB), Delhi. The University of Agricultural Sciences (UAS), Dharwad and Central Institute for Cotton Research, Nagpur were cooperating centres of the Project. UAS, Dharwad carried out genetic transformation of the cotton variety, <i>Bikaneri Nerma</i> (BN), using cry 1Ac gene construct, that was provided by NRCPB, to develop the Dharwad event (which was later called BNLA 106 event) of BN Bt variety. During 2005, comparative evaluation of all the events, developed under the NATP project was conducted for Cry 1Ac expression and ‘BNLA 106’ Bt event was found comparatively better and hence, this was taken forward for the mandated regulatory evaluations, as RCGM trials.</p> <p><u>Role of CICR</u> CICR was involved in undertaking and coordinating RCGM and GEAC regulatory trials as well as generation of Biosafety data of BN Bt event during 2005 to 2008. BN Bt and Bt. NHH 44 hybrid seeds, that were produced at UAS, Dharwad were sent to CICR in May, 2009 for distribution to state seed agencies.</p>
2.	<p>Similarly, the role, responsibility and the comments/explanation of NRCPB who provided the relevant</p>	<p>National Research Centre for Plant Biotechnology, New Delhi provided a gene construct (cry 1Ac) to UAS, Dharwad in January, 2000 as its part of NATP funded Bt Transgenic cotton. The name of the gene</p>

	gene construct to UAS, Dharwad may also be furnished.	construct was pBinBt3.
3.	The NRCPB may also be asked to explain non-detection of the Mon 531 in BN Bt. Seeds when they confirmed gene integration and copy number by Southern analysis which is a highly sensitive procedure.	The Southern analysis carried out at NRCPB did not detect MON 531 event, in the samples made available in 2003, by UAS, Dharwad.
4.	The work was published in Current Science in 2007. However, the authors of the paper have only been asked after a meeting held on 27 December, 2011 to submit a corrigendum to the Journal to rectify the paper. ICAR may be requested to clarify why this was not done during last four years plus or at least in 2009 when the production of BN Bt. and Bt. NHH 44 seeds was stopped.	During discussions on 27 th December, 2011, an error in the vector map shown in the Current Science paper was noticed. The authors have been asked to rectify this error.
5.	The <u>reported</u> presence of Mon 531 in BN Bt. Seeds was discussed in a meeting convened at New Delhi on 10 December, 2009 under DDG (CS), ICAR. Based on evidence available it was decided that the	In around September-October, 2009, representatives of M/S Mahyco-Monsanto met various officials of ICAR including Deputy Director General (Crop Science), Director, NRCPB, New Delhi and Director, CICR, Nagpur and informed that the BN Bt and Bt NHH 44 hybrid seeds available in the market were found to contain Monsanto gene and event, MON 531. A detailed report was prepared by CICR, Nagpur in October, 2009,

	<p>production and commercial sale of BN Bt. And Bt. NHH 44 seeds be stopped. Another meeting on the subject has been held two years later on 27th December, 2011 when the matter came in press reports. A clarification may be obtained on how the matter was reported and by whom in 2009 and what action apart from discontinuation of seed production was taken by ICAR and other institutions involved as they all public sector entities.</p>	<p>wherein this view of representatives of M/s Mahyco-Monsanto expressing their views has also been recorded. Consequently, a meeting was held in ICAR on 10th December, 2009, wherein the decision to stop further production of BN Bt and Bt NHH 44 seeds was taken.</p> <p>In this meeting of December, 2009, it was felt that the reported presence of MON 531 in the BN Bt and Bt NHH 44 seeds may be on account of some contamination of the seeds at some stage. Therefore, it was decided that production could only be restarted, after complete purification for uniformity and homozygosity of cry 1Ac gene, BNLA 106 original event.</p>
6.	<p>A detailed note on the role and responsibility of M/s Avasthagen who characterized the BN Bt. Event in 2006-07 may be obtained and submitted along with their reports pertaining to the instant case.</p>	<p>BN Bt event was characterized by M/s Avesthagen. This is akin to identifying the unique signature, or footprint, of the gene given to them.</p>
7.	<p>A detailed note on the stance of and the action taken by the private party whose proprietary Cry 1 AC gene Mon 531 event is.</p>	<p>No action has been initiated by the private party.</p>
8.	<p>A detailed note on the question when the presence of Mon 531 was reported in 2009 leading to</p>	<p>When it was noted by ICAR that Mon 531 was reported to be present in BN Bt, the following actions was taken: The seed production for cultivation of BN Bt was suspended.</p>

	<p>discontinuation of production and commercialization of BN Bt. and Bt. NHH 44 seeds why have ICAR chosen to inquire into the matter now after two years that too when it was reported in the media.</p>	<p>The ICAR asked UAS, Dharwad and NRCPB, New Delhi to take up purification, if possible, of BN Bt as explained in (5) above.</p> <p>The progress was reviewed on April, 27, 2011 and process of purification of BN Bt event was reported by UAS, Dharwad and NRCPB, New Delhi to be in progress.</p> <p>A report was submitted on 20th October, 2011 by NRCPB, New Delhi with regard to the molecular analysis of the purified BN Bt event. UAS, Dharwad was asked to provide “purified” sample material to CICR, Nagpur for validation.</p> <p>The ICAR 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.</p>
9.	<p>A detailed note on the role of CICR in the matter because though the project was assigned to UAS, Dharwad, CICR has applied for RCGM permissions and GEAC approvals, submitted application for registration to PPV-FRA, distributed seeds from UAS, Dharwad to seed corporations during May, 2009.</p>	<p>CICR was involved in undertaking the coordination of regulatory field evaluations of the BN Bt Cotton variety and Bt NHH 44 hybrid (RCGM & GEAC trials) and their biosafety evaluation. CICR further undertook the seed distribution of BN Bt and Bt NHH 44 hybrid seeds to state seed agencies and cotton farmers.</p> <p>CICR also submitted an application with Protection of Plant Variety and Farmers Right Authority (PPV & FRA) in May, 2009, as a mandatory requirement for commercialization. However, in the light of the reported presence of MON 531, in BN Bt seeds, on 3rd August, 2011, this application was requested to be withdrawn/cancelled. The leave for withdrawal has since been granted by this Authority on 16th January, 2012.</p>
10.	<p>It also needs to be</p>	<p>The proprietary rights belong to the institutions</p>

clarified as to who had proprietary right over the developed variety and hybrid.

which developed BN Bt cotton variety/Bt NHH44 cotton hybrid.



Annexure - IV

Research Report

(Indian Council of Agricultural Research, New Delhi)

TITLE OF PROPOSAL

***ANIMAL FEEDING TRIAL ON BIO-SAFETY STUDIES
WITH BIOTECHNOLOGICALLY TRANSFORMED BT-
COTTON CROP USING SEED MEAL***

**DIVISION OF ANIMAL NUTRITION
CENTRAL SHEEP & WOOL RESEARCH**



INSTITUTE, AVIKANAGAR - 304 501

INDIA

FUNDED BY:

**Central Institute For Cotton Research
(ICAR)**

**Post Bag No.2, Shankar Nagar
NAGPUR- 440 010, Maharastra**

Research Report of Inter Institution Project

TITLE OF PROPOSAL

***ANIMAL FEEDING TRIAL ON BIO-SAFETY STUDIES WITH
BIOTECHNOLOGICALLY TRANSFORMED
BT-COTTON CROP USING SEED MEAL***

Collaboration Between

**CENTRAL SHEEP & WOOL RESEARCH INSTITUTE,
(ICAR)
AVIKANAGAR - 304 501, INDIA**

&

**Central Institute For Cotton Research
(ICAR)
Post Bag No.2, Shankar Nagar
NAGPUR- 440 010, Maharashtra**

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Title :	Animal feeding trial on bio-safety studies with of Bt-cotton crop using seed meal
Objective:	To asses the bio-safety of feeding genetically modified BT gene containing cottonseed in lamb feeding
Priority research area :	Bio-safety of transgenic crops
Sanction / Fund receipt No. :	AA/2-1/9-07/Trains-crop/10/37; dated: 05-03-07
Proposed start date :	May 1, 2007
Actual date of start :	August 1, 2007
Name and address of Institute/ Organization :	Central Sheep & Wool Research Institute. Avikanagar-304 501, Rajasthan. India
Location of work:	Animal Nutrition Division, Central Sheep & Wool Research Institute, Avikanagar- 304 501, Rajasthan. Tel : 01437-220143 Fax : 01437-220163
Project Leader and associates:	
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Executive Summary

Bt cotton is a transgenic plant, producing an insect controlling protein Cry1A(c), the gene which has been derived from the naturally occurring bacterium, *Bacillus thuringiensis*. The cotton hybrids containing Bt gene produces its own toxin for bollworm attack thus significantly reducing chemical insecticide use and providing a major benefit to cotton growers and the environment. Bt cotton contains the three genes inserted via genetic engineering techniques, wherein, the *Cry1Ac* gene, encodes an insecticidal protein, Cry1Ac, derived from the common soil microbe *Bacillus thuringiensis* which has concern on food and feed safety issues. With this background, a project entitled “**Animal feeding trial on bio-safety studies with of Bt-cotton crop using seed meal**” was initiated at Division of Animal Nutrition, Central Sheep and wool Research Institute (ICAR) Avikanagar, in collaboration with Central Institute For Cotton Research (ICAR), Nagpur. The project aim was to asses the bio-safety of BT-cottonseed in lamb feeding, which was initiated during August 07 and continued for 120 days on weaner lambs at a high plane of nutrition.

Nutrient (OM, CP and fiber fractions) and mineral (Ca, P, Mn, Co and Zn) contents were identical in BT-cotton and non-BT cotton seeds. The growth performance of lambs was similar on control, non- BT cotton seed and BT-cotton seed included diets. The growing lambs consumed 168 g BT-cotton seed per day and did not have apparent adverse effect on dry matter intake, nutrient utilization and nitrogen balance. Similarly BT-cotton seed intake of 0.681 % of body weight or 19.5 % of dry matter intake did not produce deleterious effect on performance and dry matter intake, thus palatability and growth performance was not a problem for BT-cotton seed feeding in lambs even under high plane of nutrition. Rumen fermentation characteristics viz, pH, TVFA and NH₃-N concentrations was not influenced by feeding of GNC, non- BT cotton seed or BT-cotton seed in lamb diets. Heamatological observations did not change due to BT-cotton seed feeding compared to non-BT cottonseed or GNC feeding. Intrestigly feeding of BT-cotton seed increased RBC and decreased WBC in blood. Serum IgG level

did not change due to BT and non-BT cotton seed feeding. Thus feeding of BT-cottonseed to lambs did not alter immunity and allergen status.

Internal organs weights as g per kg empty live weight (ELW) indicated precise effect of BT- cottonseed feeding on internal organ changes. The weights of kidney, spleen, pancrease, heart, lung, penis, kidney fat, cole fat, GI tract, ingest and empty GI tract were not different among BT cotton seed and non-BT cotton seed fed lambs. However BT cotton seed feeding increased liver weight, testicle weight and testicles fat g / kg empty live weight.

Chemical composition of Non-BT and BT-cotton seeds

The chemical composition (% DM basis) of cotton seed is presented in table1. The Non BT cotton seed (N-BT) and BT cotton seed (BT) had 92.76 % and 94.46 % dry matter (DM); 20.35 % and 22.97 % crude protein (CP); 95.1 % and 93.9 % organic matter (OM); 57.22 % and 56.16% NDF; 36.44 % and 29.42 % ADF and 20.77 % and 26.74 % hemicellulose respectively. The CP and hemicellulose contents were higher in BT than N-BT cotton seed. However, the OM, NDF and ADF content showed a reverse trend being high in NBT than BT.

Mineral contents viz. Calcium, Phosphorus, Manganese and Copper were identical in N-BT and BT cottonseed, while Zinc content was higher in BT-cotton seeds by 10 ppm.

Table 1
Chemical Composition of cottonseed

Chemical constituents (g/kg DM)	Type of Cottonseed	
	Non-BT	BT
Dry matter	896.0	908.7
Organic matter	951.4	938.9
Crude protein	203.5	229.7
Neutral detergent fiber	572.2	561.6
Acid detergent fiber	364.4	294.2
Hemicellulose	207.7	267.4
Mineral contents		
Calcium (g %)	0.193	0.144
Phosphorus (mg %)	11.270	12.839
Manganese (ppm)	27.829	28.018
Copper (ppm)	18.517	17.272
Zinc (ppm)	36.544	43.996

Composition of Diets

Diets were prepared to provide adequate essential and non-essential nutrients to support optimum growth of growing lambs as per ICAR recommendations. Ingredient composition and constituents of concentrate are presented in table-2. Bajra Kadbi (Perl Millet Stover) was used as major roughage source. Complete feed mixture (premixes) of total mixed ration (TMR) contained 35 part Bajra Kadbi, 60 parts concentrate mixture and 5 part molasses. Thus TMR had roughage: concentrate ratio of 35: 65. A total of three test diets were prepared. The concentrate mixture was prepared using various grinded concentrate ingredients (Table-2). Diet of control animals contained groundnut cake (GNC), as conventional protein supplement, which was replaced by Non-BT cotton seeds and BT-cotton seed in diets fed to animals allocated in Non-BT and BT group of test diets. Diets were balanced for total protein content with the addition of GNC.

The total mixed rations were iso-nitrogenous that contained crude protein 14.7, 14.6 and 13.9 % respectively in control, N-BT and BT diets. Fiber fractions viz. NDF, ADF, hemicellulose and cellulose were slightly higher in N-BT diet compared to control and BT diets.

Animals and Dietary Treatment

Weaner Malpura lambs (90 ± 5 day of age; 15.5 ± 0.89 kg) were used for the present experiment. The animals were randomly allocated to three dietary treatments, maintaining a sex ratio of 50:50; male and female lambs.

Keeping in view the quantity of BT-cottonseed received three of each male and female lambs were randomly allocated to each treatment II and III, while control group had ten lambs of similar sex ratio.

Treatment I: Control; Groundnut cake was used as major protein supplement

Treatment II: N-BT; Non-BT cottonseed was used to replace groundnut cake (g/g)

Treatment III: BT ; BT cottonseed was used to replace groundnut cake (g/g)

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Table 2

Composition of diet (total mixed ration), concentrate mixture and cottonseed

	Diets		
<i>Ingredient composition (g/kg)</i>	Control	N-BT	BT
<i>Total mixed ration</i>			
Perl millet stover	350	350	350
Concentrate	600	600	600
Molasses	50	50	50
<i>Concentrate mixture</i>			
Maize	250	220	220
Barley	250	210	220
Wheat bran	90	60	70
De-oiled rice bran	80	40	50
Groundnut cake	300	140	110
Cottonseed non-BT	-	300	-
Cottonseed-BT	-	-	300
Common Salt (NaCl)	10	10	10
Mineral mixture	15	15	15
Supplivit-M	5	5	5
<i>Chemical composition (g/kg DM)</i>			
Dry matter	927.6	944.6	941.5
Organic matter	900.0	912.6	890.5
Crude protein	146.7	145.5	139.4
Neutral detergent fiber	515.3	591.0	561.9
Acid detergent fiber	347.2	370.3	389.6
Hemicellulose	168.1	220.7	172.3
Cellulose	264.5	274.7	312.5

Diet and Feeding Regimen

Three test diets were prepared to provide adequate nutrient to support active growth phase of weaner lambs. The total mixed ration contained 60 % concentrate that had 30 % groundnut cake (GNC) fed to control group of lambs, whereas lambs of non- BT (Cottonseed) and BT (BT-Cottonseed) group had 30 % respective cottonseed. Total mixed rations were prepared separately, which had 18 % either of GNC, non-BT Cottonseed and BT-Cottonseed.

Experimental animals were fed individually in separate enclosures, feed offered and residue left were recorded daily to determine daily feed intake. Feed residues were discarded before offering the feed of the day. The feed of the day was offered once in the morning at 10:00 h, to an excess of 10 % of previous days intake. Animals were allowed loitering in an open yard, without vegetation for two hrs daily. Water was available free choice twice in day at 09: 00 h and 16:00 h.

Growth Performance of Lambs

To assess the growth performance lambs, body weight changes were recorded by weighing lambs every week before offering the feed and water for two consecutive days, these means live weights were used to monitor growth profile of the lambs. The growth performance of lambs is presented in table 3. The pattern of live weight change is given in Figure 1.

Initial ($p= 0.228$) and finishing ($p= 0.633$) live weight of lambs were similar, which were respectively 14.3 and 26.9; 15.6 and 25.4; and 16.3 and 27.8 kg of control, N-BT and BT groups. Total live weight gain of 12.6, 10.6 and 12.9 kg; and average daily weight gains were 102; 89 and 111 g were also similar among three groups. Similarly, feed conversion ratio (kg feed/ kg gain) and feed efficiency (%) were also similar among three groups of lamb which ranged from 8.2 to 9.1 kg and

11.1 to 12.3 % respectively.

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Table 3

Growth performance of weaner lambs on diets containing BT or non-BT cottonseed.

	Diets*			SEM	P
	C	N-BT	BT		
Initial live weight (kg)	14.3	15.6	16.3	0.529	0.228
Finishing live weight (kg)	26.9	25.4	27.8	1.008	0.633
Total live weight gain (kg)	12.6	10.9	12.9	0.666	0.496
Average daily gain (g)	102	89	111	5.349	0.270
Total feed intake (kg)	102.5	96.3	108.2	4.298	0.591
Feed conversion ratio (kg feed/ kg gain)	8.2	9.1	8.6	0.230	0.320
Feed conversion efficiency (%)	12.3	11.1	11.8	0.338	0.390

*Diets: Total mixed ration contained roughage, concentrate and molasses in ratio of 60:35:5, concentrate contained groundnut cake (Control-C), non-Bt cottonseed (N-BT) or Bt-cottonseed (BT) as major protein source, which fed to lambs.

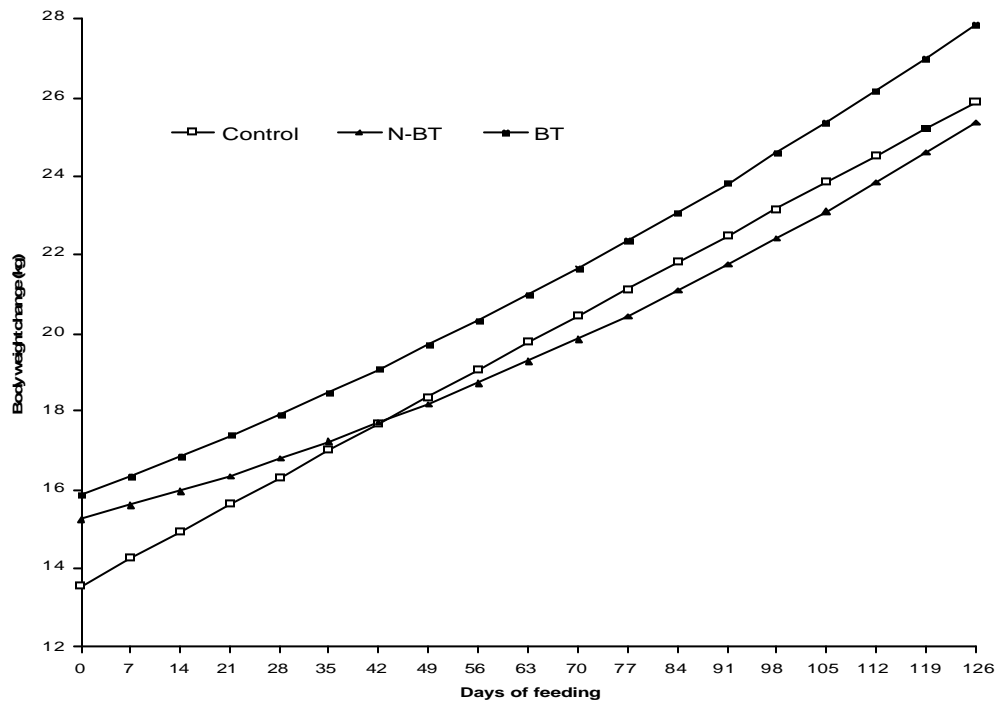


Fig. 1: Body weight (BW) change of lambs fed diets containing groundnut cake (control), BT or Non-BT cotton seed as protein supplement.
 $BW \text{ (kg, Control lambs)} = 13.561 + 0.689X - 0.0003X^2 \text{ (} R^2 = 0.977 \text{)}$

$$\begin{aligned}\text{BW (kg, N-BT lambs)} &= 15.260 + 0.328X + 0.0130X^2 \quad (R^2 = 0.985) \\ \text{BW (kg, BT lambs)} &= 15.860 + 0.470X + 0.0109X^2 \quad (R^2 = 0.970)\end{aligned}$$

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Nutrient Intake, Utilization and Balance

A metabolic trial was carried out toward the end of experiment on all animals of treatment II and III, whereas on six representative animals of treatment I. During metabolic trial animals were allowed three days acclimatizing to metabolic cages followed by seven days collection of faeces and urine voided. Daily records of feed intake, faeces and urine voided were maintained to determine nutrient intake, utilization and balance.

Urine was collected under 10 % sulphuric acid, maintaining a pH between 2-3 to avoid degradation of urinary purine derivatives. Urine purine derivatives estimates the microbial protein synthesis in rumen.

Dry matter intake

Daily dry matter intake varied from 706 g to 861 g among three dietary treatment groups and was not statistically ($p= 0.373$) different. The lambs in present experiment consumed feed dry matter 71, 69, and 78 g/ kg $W^{0.75}$ ($P= 0.383$), and 3.1, 3.2 and 3.5 % of body weight ($P= 0.399$), respectively in control, N-BT and BT group of experimental lambs (Table 4). Similarly intake of roughage, concentrate and protein source (g/day) were also not statistically different among three lamb groups. Apparently, compared to control and N-BT group of lambs, the lambs fed BT-cotton seed had higher dry matter intake in terms of g/day, g/kg $W^{0.75}$ and % of body weight. The growing lambs consumed 168 g BT-cotton per day did not have apparent adverse effect on dry matter intake. Similarly BT-cotton seed intake of 0.681 % of body weight or 19.5 % of dry matter intake did not produce deleterious effect on dry matter intake, thus palatability is not a problem for BT-cotton seed feeding in lambs.

Nutrient intake and digestibility

Intake of organic matter (OM; 711, 647 and 766g), crude protein (CP; 116, 103 and 120 g), NDF (408, 417 and 483 g), ADF (274,261 and 335 g) and

hemicellulose (133, 156 and 148 g), respectively of control, N-BT and BT lamb

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groups, was not statistically different among three feeding regimen, whereas intake of cellulose was higher ($p = 0.053$) in BT group of lambs (269g) compared to N-BT (194g) lamb group, however control and BT- group of lambs had similar cellulose intake.

Digestibility of dry matter, 60.3 57.8 and 58.9 %; OM, 63.2, 62.6 and 62.9 %; CP, 62.2, 59.7 and 60.2 % and NDF 43.5, 49.1 and 46.7 % and were respectively in control, N-BT and BT diet fed lambs, which were similar among the three feeding regimens. However, digestibility of ADF was significantly ($p = 0.022$) lower by 7 % units, while hemicellulose digestibility was higher ($p = 0.047$) by 10 % units in BT lambs compared to N-BT lamb group, whereas cellulose digestibility was similar between BT and Non-BT lambs. Interestingly, the digestibility of DM, OM and CP were slightly higher but NDF, ADF, and cellulose were lower in control lambs.

Nutritive Value of Diet

Three diets prepared using GNC, N-BT cotton seed and BT-cotton seed did not significantly influence nutritive value of diet in terms of digestible crude protein (DCP, g/ kg) and metabolizable energy (ME, MJ/ kg) content of diet. The DCP % was 9.1, 8.7 and 8.4 while ME content was 8.5, 8.6 and 8.4 MJ/ kg diet respectively in control, N-BT and BT diets (Table 5).

Digestible Nutrient and Energy Intake

Intake of digestible nutrient and metabolizable energy were also not different among three dietary treatments. Digestible DM intake (g/ day) was 483, 407 and 509 g; digestible OM intake (g/ day) 456, 403, and 484 g and (g / kg diet) 569, 573 and 560 g; digestible CP intake (g/ day) 72, 61 and 73 g and ME intake (MJ/ day) was 6.8, 6.0 and 7.3, respectively in control, N-BT and BT lamb group.

Table 4

Nutrient intake and utilization of weaner lambs on diets containing BT or non-BT cottonseed.

	Diets*			SEM	P
	C	N-BT	BT		
Body weight (BW, kg)	24.3	22.08	24.52	0.794	0.407
Body weight $W^{0.75}$ (kg)	10.93	10.16	11.00	0.272	0.403
Dry matter intake					
g/day	790.32	705.93	860.53	43.685	0.373
g/kg $W^{0.75}$	71.04	69.25	77.79	2.571	0.383
kg/ 100 kg BW	3.19	3.20	3.50	0.101	0.399
Roughage intake (g/day)	276.61	247.08	301.19	15.290	0.373
Concentrate intake (g/day)	513.70	458.86	559.35	28.395	0.373
Protein source intake					
g/day	154.11	137.66	167.80	8.519	0.373
Kg/100 kg BW	0.623	0.624	0.681	0.197	0.399
Intake and digestibility coefficient					
Dry matter					
Digestibility coefficient	0.603	0.578	0.589	0.006	0.268
Organic matter					
Intake (g/day)	711.28	646.63	766.30	38.701	0.477
Digestibility coefficient	0.632	0.626	0.629	0.006	0.902
Crude protein					
Intake (g/day)	115.94	102.71	119.96	6.192	0.521
Digestibility coefficient	0.622	0.5969	0.6019	0.0145	0.779
Neutral detergent fiber					
Intake (g/day)	407.49	417.21	483.53	23.520	0.379
Digestibility coefficient	0.435	0.491	0.467	0.011	0.104
Acid detergent fiber					
Intake (g/day)	274.40	261.41	335.26	16.700	0.157
Digestibility coefficient	0.338	0.460	0.392	0.019	0.022
Hemi-cellulose					
Intake (g/day)	133.09	155.80	148.27	7.663	0.496
Digestibility coefficient	0.636	0.542	0.637	0.019	0.047
Cellulose					
Intake (g/day)	209.04	193.92	268.92	13.803	0.053
Digestibility coefficient	0.520	0.629	0.598	0.015	0.002

*Diets: Total mixed ration contained roughage, concentrate and molasses in ratio of 60:35:5, concentrate contained groundnut cake (Control-C), non-Bt cottonseed (N-BT) or Bt-cottonseed (BT) as major protein source, which fed to lambs

Table 5

Nutritive value of diets, digestible nutrient intake and N-balance of weaner lambs on diets containing BT or non-BT cottonseed.

	Diets*			SEM	P
	C	N-BT	BT		
Nutritive value of diets					
Digestible crude protein (g/ kg)	91.24	86.85	83.91	2.184	0.411
Metabolizable energy (MJ/ kg)	8.53	8.59	8.40	0.079	0.627
Digestible nutrient and energy intake					
Digestible DM intake (g/ day)	482.55	407.08	509.18	29.634	0.367
Digestible OM intake (g/ day)	455.79	403.40	483.77	27.213	0.501
Digestible OM intake (g/ kg diet)	569.19	573.12	560.26	5.304	0.627
DCP intake (g/ day)	71.72	61.18	72.55	4.079	0.474
ME intake (MJ/ day)	6.83	6.05	7.25	0.408	0.501
DOMR (g/ day)	296.27	262.21	314.45	17.689	0.501
DOMR (g/ kg diet)	369.98	372.52	364.17	3.448	0.627
N-utilization and balance					
N-intake (g/day)	18.55	16.43	19.19	0.991	0.521
N-excretion					
Faeces (g/day)	7.08	5.75	7.59	0.537	0.375
Urine (g/day)	5.19	4.28	5.66	0.326	0.225
Total (g/day)	12.27	10.86	13.24	0.648	0.340
N- balance					
g/day	6.28	5.57	5.95	0.478	0.848
% of intake	33.36	33.58	30.61	1.678	0.748
% of absorbed	53.67	52.41	51.11	2.787	0.939

*Diets: Total mixed ration contained roughage, concentrate and molasses in ration of 60:35:5, concentrate contained groundnut cake (Control-C), non-Bt cottonseed (N-BT) or Bt-cottonseed (BT) as major protein source, which fed to lambs.

Similarly, digestible organic matter apparently fermented in rumen (DOMR; g/ day) and DOMR in term of g/ kg diet were also similar among control, N-BT and BT diets, DOMR (g/ kg diet) was respectively amounting to 369, 372 and 364 g among three dietary regimens (Table 5).

Nitrogen Utilization and Balance

Nitrogen utilization in terms of N-intake, N-excretion in faeces and urine and balance were not statistically different among control, N-BT and BT diets. N- intake was 18.6, 16.4 and 19.2 g; N-excretion in faeces was 7.1, 5.8, 7.6g and in urine was 5.2, 4.3 and 5.7 g and total-N excretion was 12.3, 10.9 and 13.2 g respectively in control, N-BT and BT diets.

Similar to N-utilisation, N-balance was also not different among three dietary treatments. N- balance in term of g/ day was slightly higher (6.3 g) in control lambs compared to N-BT (5.6 g) and BT (6.0 g) diet fed lambs (Table 5). N-balance as percent of intake ranged between 31 to 34 % and as per cent of absorbed 51 to 54 % in control, N-BT and BT diets.

Table 6

Rumen fermentation and microbial protein synthesis of weaner lambs on diets containing BT or non-BT cottonseed.

	Diets*			SEM	<i>P-values</i> **		
	C	N-BT	BT		T	P	T*P
pH	6.68	6.71	6.68	0.0287	0.867	0.001	0.008
TVFA (mEq/l)	80.66	86.94	82.49	2.807	0.638	0.004	0.222
NH ₃ -N (mg/l)	97.54	76.20	88.74	2.145	0.62	0.168	<0.001

*Diets: Total mixed ration contained roughage, concentrate and molasses in ration of 60:35:5, concentrate contained groundnut cake (Control-C), non-Bt cottonseed (N-BT) or

Bt-cottonseed (BT) as major protein source, which fed to lambs.

** Significance level (Diet effect-T, Period effect-P, Interaction T×P).

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Rumen Fermentation Characteristics

Samples of rumen liquor (50 ml) were withdrawn from intact lambs at 0, 4, 8, 12, 18 and 24 h post-feeding using a stomach tube. Each sample was placed in a 100 ml glass jar and the pH determined using a portable pH meter within 4 to 5 min of sampling. After pH measurement rumen fluid was strained with four layer of muslin cloth, a few drops of saturated mercuric chloride were added to stop microbial activity and stored -20°C pending analysis. Rumen fluid samples were also processed to monitor the ciliate protozoa population. A 10 ml rumen fluid was processed to separate cellular and extra cellular fractions to estimate microbial enzymes activity in rumen.

Rumen fermentation characteristics are presented in Table 6. The rumen fluid pH was almost similar in control, N-BT and BT group of lambs, which was respectively 6.68, 6.71 and 6.68. Sampling period had significant ($p<0.001$) influence on rumen fluid pH and was stable between 4 to 18 hr of post feeding (Fig 2). Interactions among post feeding hours and treatment were also significant ($p<0.008$).

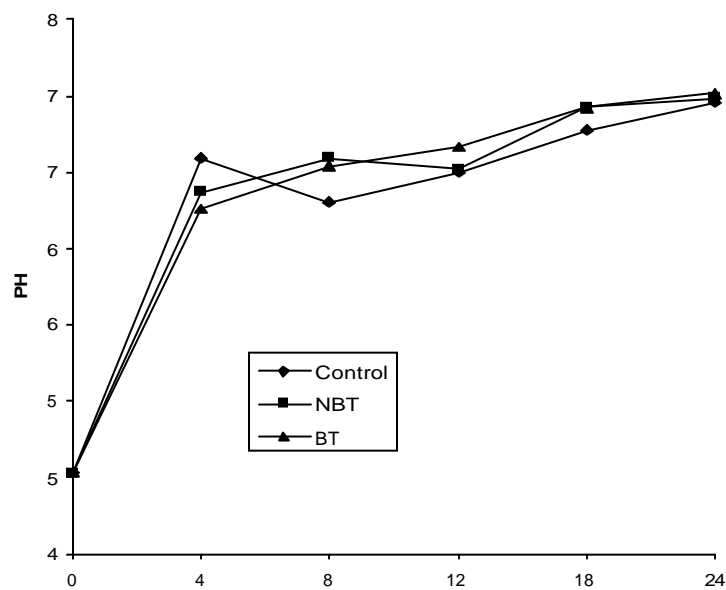


Fig 2: Rumen pH at different post feeding Hours

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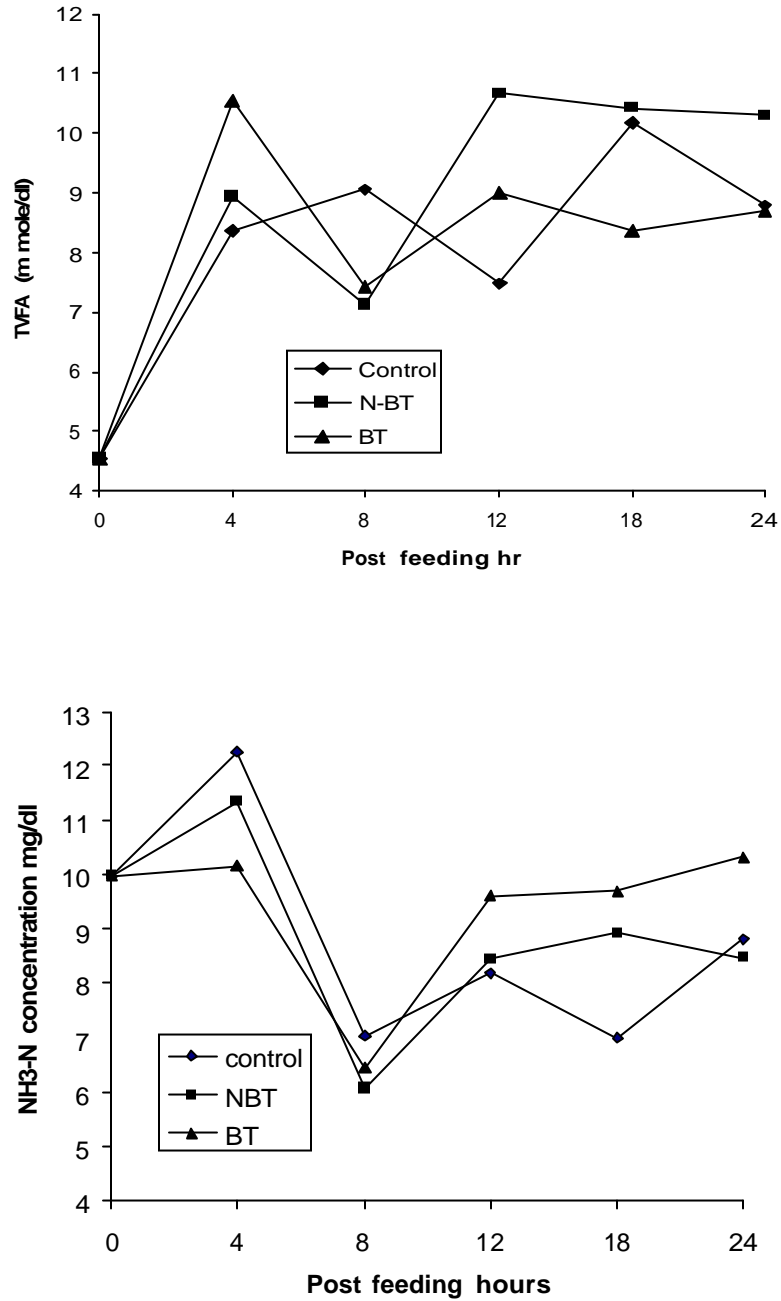


Fig 3: Rumen TVFA and NH₃-N at different post feeding Hours

Rumen TVFA Concentration

The ruminal TVFA (mmol/ l) were also similar in control, N-BT and BT group of lambs, which were respectively 80.7, 86.9 and 82.5 m mol. Sampling period had significant ($p < 0.004$) influence on TVFA concentration, a sharp decline in TVFA concentration was between 48 hr post feeding for BT and N-BT diet fed lambs, where this decline was between 8-12 hrs post feeding in control lambs (Fig 3). Interactions among post feeding hours and treatment were not significant ($p = 0.222$).

Rumen NH₃-N Concentration

The rumen NH₃-N (mg/ l) concentration were similar in control, N-BT and BT group of lambs, which were respectively 97.5, 76.2 and 88.7 mg. Sampling period also did not influence NH₃-N concentration, a sharp decline in NH₃-N concentration was between 4-8 hr post feeding, while it increased till 12 hr post feeding, thereafter established (Fig 3). Interactions among post feeding hours and treatment were significant ($p < 0.001$).

Blood Composition and Hematology attributes

Blood samples were collected through jugular vein puncture at start of the experiment and at every 30th day of the experiment to study blood bio-chemical and hematological changes.

Results of hematology are presented in table 7. Hemoglobin (Hb %) concentration was almost similar (11.1%), whereas packed cell volume (PCV, %) ranged from 11.7 to 12.9 %; ESR at 2 hr ranged from 25.6 to 29.5 and white blood cells ranged from 6.8 to $8.3 \times 10^3/\mu\text{l}$ which were not statistically different among control, N-BT and BT group of lambs. While red blood cells concentration was significantly ($p < 0.001$) higher ($18.41 \times 10^6/\mu\text{l}$) in BT diet fed lambs compared to

control ($15.03 \times 10^6/\mu\text{l}$) and N-BT ($14.85 \times 10^6/\mu\text{l}$) lambs.

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Table 7

Hematology of weaner lambs on diets containing BT or non-BT cottonseed.

	Diet*			SEM	<i>P-values</i> **		
	C	N-BT	BT		T	P	T×P
Haemoglobin (Hb %)	11.17	11.07	11.09	0.119	0.915	0.202	0.016
Packed cell volume (%)	12.92	11.72	11.70	1.561	0.199	<0.001	0.830
ESR 1hr	24.75	25.43	39.82	4.315	0.497	0.042	0.310
ESR 2hr	29.2	25.6	29.5	1.980	0.707	0.009	<0.001
Red blood cells ($\times 10^6/\mu\text{l}$)	15.03 b	14.85 b	18.41 a	0.482	<0.001	0.494	0.986
White blood cells ($\times 10^3/\mu\text{l}$)	6.82	7.8	8.25	0.445	0.220	0.033	0.603
Lymphocytes (%)	58.73	62.00	59.92	0.839	0.347	0.355	0.057
Neutrophils (%)	35.78	33.22	35.80	0.780	0.308	0.269	0.076
Monocytes (%)	3.81	3.56	3.68	0.273	0.943	0.777	0.008
Eosinophils (%)	1.75	1.86	1.18	0.193	0.251	0.093	0.544
Serum IgG (U/dl)	35.10	36.29	37.08	0.533	0.190	0.690	0.420

*Diets: Total mixed ration contained roughage, concentrate and molasses in ration of 60:35:5, concentrate contained groundnut cake (Control-C), non-Bt cottonseed (N-BT) or Bt-cottonseed (BT) as major protein source, which fed to lambs.

** Significance level (Diet effect-T, Period effect-P, Interaction T×P).

Hemoglobin concentration was lower in BT lambs at 60th day of sampling thereafter increased but control lambs shown a steady increase in Hb level with progress of experiment, however N-BT lambs had highest Hb level at 90th day of blood collection (Fig 4). But these differences were not statistically different ($p=0.202$), however interaction between treatment and period of collection were significant ($p = 0.016$).

ESR concentrations increased throughout experiment in control and N-BT lambs, but BT lambs had fluctuation levels, which increased from 0 to 30 and 60 to 120 days of feeding but decreased sharply between 30 to 60 days of sampling (Fig 4), and were significantly ($p = 0.042$) different among the sampling whereas interactions

were not significant.

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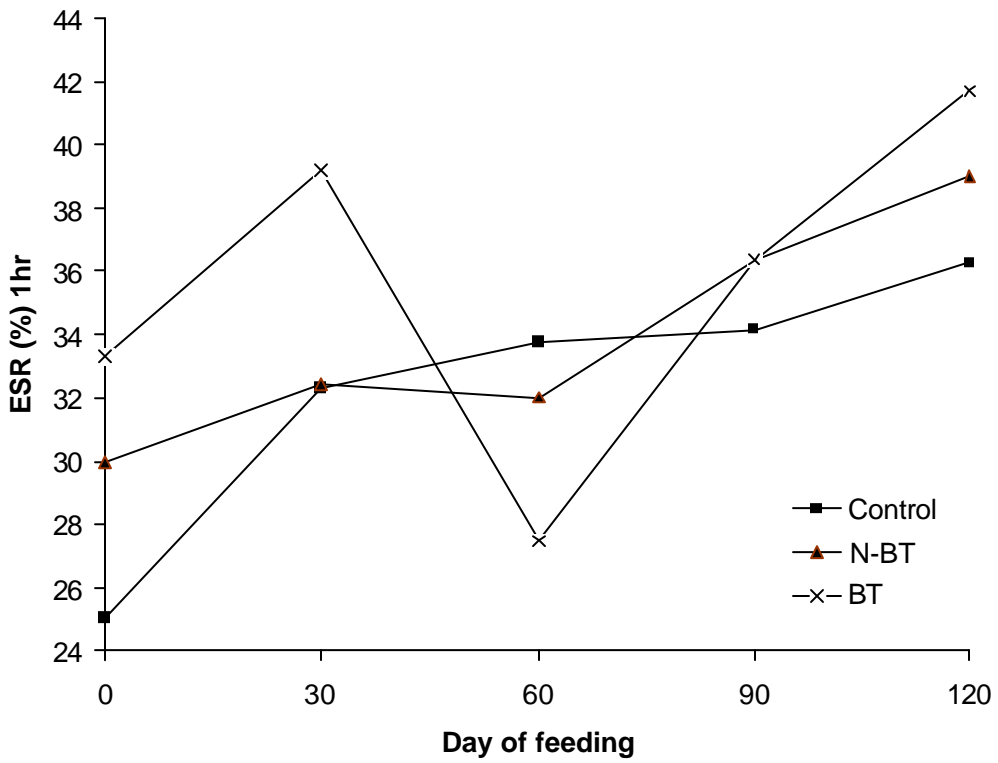
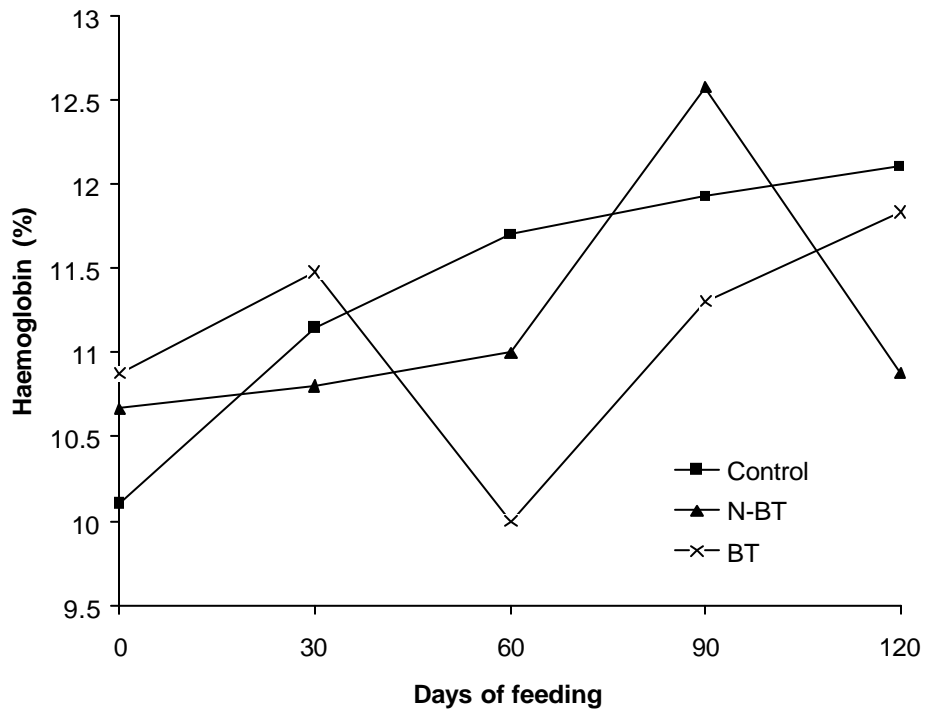


Fig 4: Hemoglobin (%) and ESR (%) concentration of lambs during experimental feeding

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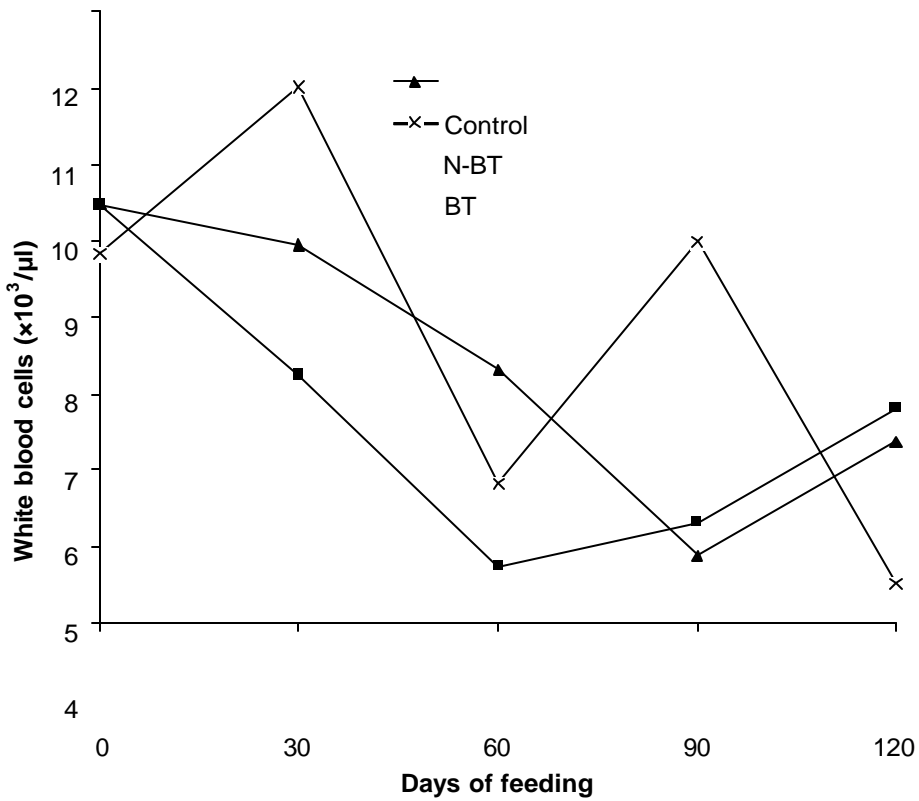
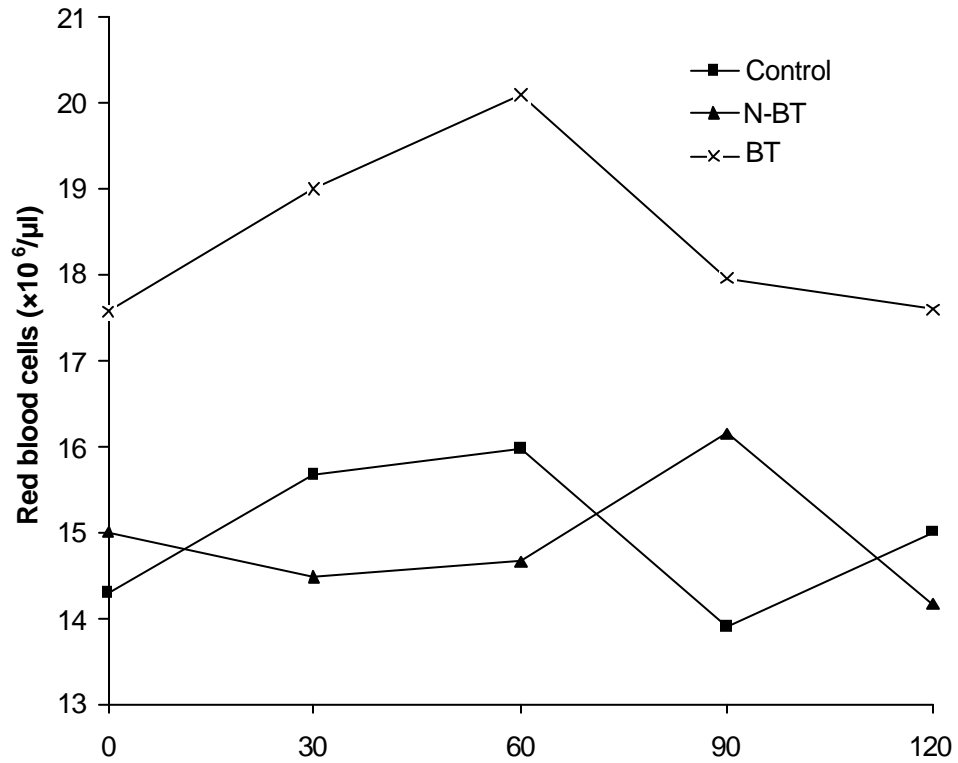


Fig 5: RBC and WBC concentration of lambs during experimental feeding

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Pattern of Red blood cells and white blood cells concentration are presented in fig 5. The RBCs were higher throughout experiment in BT lambs compared to control and N-BT lambs. Neither sampling period nor treatment and period interactions were statistically significant.

White blood cells concentration decreased significantly ($p = 0.033$) with increase in experimental period in three group of lambs. Interactions among treatment and period of sampling were not statistically different.

Serum IgG level

Serum IgG determination assesses the immunity and allergens status of animals. Increased levels are the indicative of immunity depression and induction of allergens. The IgG levels were not different ($p = 0.190$) among in control, N-BT and BT diet fed lamb groups. The pattern of IgG change during experimental feeding of BT and N-BT diet to lambs is presented in Table 7 and Fig. 6. Neither period of blood sampling nor interactions between dietary treatments and period of blood collection had significant influence on IgG level of lambs. Thus feeding of BT-cottonseed to lambs did not alter immunity and allergens status of animals.

Slaughter Study to asses Changes of Internal Organs

Animals were slaughtered using standard procedure under the supervision of institute veterinarian, internal organs were weight and collected for histopathological examinations. Carcass of BT-cotton fed animals were not sold to consumer and disposed off using stands producers.

Internal organs weights as gross and in terms of per kg empty live weight (ELW) were estimated to assess a precise effect of BT- cottonseed feeding on internal organ changes. The gross weights of liver and testicles, gross weight and per kg ELW

of kidney, spleen, pancrease, heart, lung, penis, kidney fat, cole fat, GI tract, ingest and empty GI tract were not different among three feeding regimes.

However, liver weight (g / kg ELW) were different ($p = 0.04$), and were 16.99 g in control lambs, 17.57 g in BT lamb group and 14.95 in N-BT lamb group. The N-BT lamb group had lowest and BT lamb group had highest liver weight, However control and BT lambs had statistically similar liver weights.

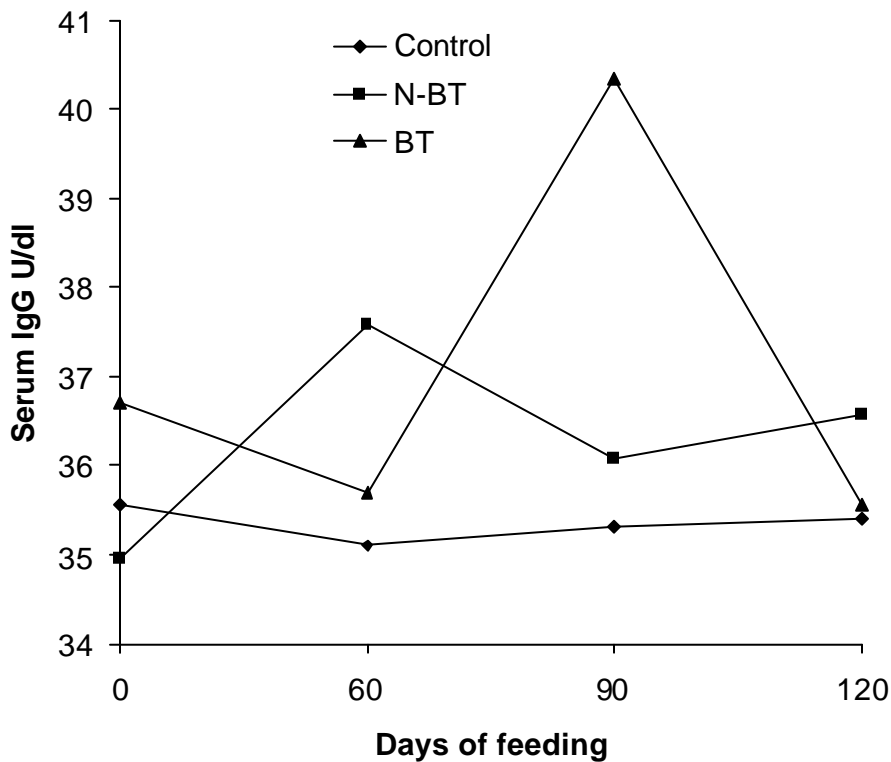


Fig 6: Serum IgG level of lambs during experimental feeding

Table 8

Slaughter study of weaner lambs on diets containing BT or non-BT cottonseed

Attributes	Diets*			SEM	P
	Control	N-BT	BT		
Empty Live weight kg	23.52	25.06	25.48	0.721	0.517
Liver weight g	398.8	375.0	448.3	16.415	0.239
Liver weight g/kg ELW	16.99 b	14.95 a	17.57 b	0.429	0.040
Kidney weight g	60.00	65.00	61.67	2.357	0.770
Kidney weight g/kg ELW	2.56	2.60	2.46	0.131	0.929
Spleen weight g	45.00	45.00	43.33	1.757	0.927
Spleen weight g/kg ELW	1.93	1.79	1.70	0.088	0.566
Lung weight g	515.00	520.00	583.33	20.713	0.360
Lung wt g/ kg ELW	22.02	20.74	22.94	0.763	0.641
Kidney fat g	195.00	360.00	405.00	45.315	0.079
kidney fat g/kg ELW	8.39	14.48	15.83	1.7056	0.114
Cole fat g	316.25	500.00	563.33	57.291	0.138
Cole fat g/ kg ELW	13.56	20.06	21.85	2.066	0.188
Dressing % of ELW	58.17	56.79	55.51	0.789	0.386
Pancreas weight g	37.50	25.00	40.00	4.120	0.433
Pancreas weight g/kg ELW	1.57	0.99	1.56	0.142	0.271
Heart weight g	108.75	110.00	100.00	3.310	0.483
Heart wt g/ kg ELW	4.63	4.38	3.96	0.156	0.177
Testicles weight g	155.0 b	202.5 b	266.7 a	19.041	0.006
Testicles weight g/kg ELW	6.57 b	8.11 ab	10.58 a	0.732	0.023
Testicles fat g	47.50	35.00	43.33	2.357	0.110
Testicles fat g/kg ELW	2.03 a	1.40 b	1.70 ab	0.110	0.049
Penis weight g	52.50	50.00	43.33	3.093	0.486

Penis weight g/kg BW	2.22	2.00	1.69	0.121	0.155
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GI tract weight kg	5.13	5.15	5.69	0.257	0.661
GI tract weight g/kg ELW	217.28	205.11	224.37	8.457	0.762
Empty GIT weight kg	2.14	2.31	2.57	0.101	0.188
Empty GIT weight g/kg ELW	91.10	92.20	100.70	2.573	0.261
Ingesta weight kg	2.99	2.84	3.12	0.213	0.915
Ingesta weight g/kg ELW	126.18	112.91	123.67	8.156	0.856

*Diets: Total mixed ration contained roughage, concentrate and molasses in ration of 60:35:5, concentrate contained groundnut cake (Control-C), non-Bt cottonseed (N-BT) or Bt-cottonseed (BT) as major protein source, which fed to lambs

Gross testicle weight was higher ($p = 0.006$) in BT lambs compared to control and N-BT lambs, similarly testicles weights in terms of g/ kg ELW was also significantly ($p = 0.023$) higher in BT lambs compared to Control lambs but were not statistically different to N-BT lambs. However testicles fat g / kg ELW was lowest in N-BT lambs compared to control and BT-lambs.

Findings of the Project

The CP and hemicellulose contents were higher and ADF content was lower in BT-cotton seed compared to than non-BT cotton seed,

Mineral contents viz. Calcium, Phosphorus, Manganese and Copper were identical in NBT and BT cottonseed, while Zinc content was higher in BT-cotton seeds by 10 ppm,

The growing lambs consumed 168 g BT-cotton seed per day and did not have apparent adverse effect on dry matter intake. Similarly BT-cotton seed intake of 0.681 % of body weight or 19.5 % of dry matter intake did not produce deleterious effect on dry matter intake, thus palatability is not a problem for BT-cotton seed feeding in lambs.

BT-cotton seed feeding @ 20 % of total dry matter intake improved growth, nutrient utilization, rumen fermentation and N balance compared to non-BT cotton seed feeding,

BT-cotton seed feeding did not alter haematological attributes of lambs and were with in the normal range of variations,

BT-cotton seed feeding increased RBC and decreased WBC in blood,

Serum IgG level did not change due to BT and non-BT cotton seed feeding. Thus feeding of BT-cottonseed to lambs did not alter immunity and allergens status,

Internal organs weights as g per kg empty live weight (ELW) estimated precise effect of BT- cottonseed feeding on internal organ changes. The weights of kidney, spleen, pancrease, heart, lung, penis, kidney fat, cole fat, GI tract, ingest and empty GI tract were not different among between BT cotton seed and non-BT cotton seed fed lambs. However BT cotton seed feeding increased liver weight, testicle weight and testicles fat g / kg empty live weight.

Funds Utilization

Total funds received: Rs. 4,45,000=00

Total expenditure incurred: Rs. 4,88,000=00

Deficit of funds due to over expenditure : Rs. 43,000=00

Reasons for over expenditure:

The total emoluments of the Research Fellow have been revised and applicable with effect from 01.04.2007. Hence, fellowship arrears are to be paid to SRF worked under the project.

CERTIFICATE

Institute and investigators of the project in principle agree with the research results reported in present report

Dr. S. A. Karim

Principal Investigator



28.03.2008

Signature with date

Dr M. K. Tripathi

Co- Principal Investigator



28.03.2008

Signature with date



Director

Top 19 items of 2009-10 against the top 20 countries of their export				
S.No.	Desc	Country	Qty	Val(INR)
1	ONIONS, SHALLOTS, GARLIC, LEEKS AND OTHER ALLIACEOUS VEGETABLES, FRESH OR CHILLED	BANGLADESH PR	779090038	11610479700
		MALAYSIA	303442015	4132975401
		SRI LANKA DSR	130880462	1930430941
		U ARAB EMTS	150769531	1790334151
		PAKISTAN IR	106278671	1192524907
		SINGAPORE	25087509	343540462
		PHILIPPINES	15274831	329330478
		NEPAL	38635805	319577485
		OMAN	20409279	234368802
		MAURITIUS	11038022	225112722
		SAUDI ARAB	15948821	197714232
		QATAR	16765928	186250304
		BAHARAIN IS	13640290	172263124
		IRAN	10562778	139933098
		INDONESIA	9749213	135200552
		HONG KONG	8982271	126058096
		KUWAIT	11506064	124245131
		REUNION	4470083	695446296
		VIETNAM SOC REP	3904054	60721670
		2	COCONUTS, BRAZIL NUTS AND CASHEW NUTS, FRESH OR DRIED, WHETHER OR NOT SHELLED OR PEELED	U S A
U ARAB EMTS	33558380			5163114416
NETHERLAND	10594414			2587067818
JAPAN	5935875			1554529136
U K	6432351			1111744677
SAUDI ARAB	4607801			965402211
FRANCE	3779124			951057455
BELGIUM	3701687			793241510
SPAIN	3303113			725973345
GREECE	2288461			597483035
EGYPT A RP	2030334			535571527
GERMANY	1463682			353343136
SINGAPORE	1438467			339808742
TURKEY	1365414			338360179
NORWAY	1361016			316718149
AUSTRALIA	1553903			316004154
JORDAN	1172941			313110935
KUWAIT	1728743			312428525
SYRIA	1071861			283104259
3	DATES, FIGS, PINEAPPLES, AVOCADOS, GUAVAS, MANGOES, AND MANGOSTEENS, FRESH OR DRIED			THAILAND
		KOREA RP	1019045	225876320
		SAUDI ARAB	71563384	2466847935
		U ARAB EMTS	46510087	1781744024
		NETHERLAND	21835288	1153132664
		YEMEN REPUBLC	23827137	697438184
		U K	14393290	677193197
		KUWAIT	13019002	476268336
		BANGLADESH PR	36605927	418609829
		U S A	5968445	450213616
SUDAN	7172833	259924508		
JAPAN	2803401	217319381		
LEBANON	4135300	152796738		

	CANADA	2576854	139472211
	GERMANY	2467306	137752285
	NEPA	9142230	137598275
	FRANCE	1635220	103731573
	MALAYSIA	3110744	873936655
	OMAN	2069053	81655910
	QATAR	1415998	79920516
	BAHARAIN IS	2191866	68650944
	SINGAPORE	1568560	61968768
4 GRAPES, FRESH OR DRIED	NETHERLAND	2907440A	388364885
	U K	14359531	82107258
	U ARAB EMTS	13241415	728565381
	BANGLADESH PR	45576021	627693588
	SAUDI ARAB	5123822	272590575
	BELGIUM	2933708	184056834
	EGYPT A RP	1357628	130845387
	GERMANY	2356453	101044866
	MOROCCO	1040044	36433998
	ALGERIA	970554	84184454
	THAILAND	875642	74116482
	NORWAY	799156	60070709
	RUSSIA	745808	59824302
	MALAYSIA	694746	57802376
	NEPAL	4535936	51435118
	DENMARK	773257	46890148
	SRI LANKA DSR	1506406	46153198
	OMAN	607222	39309711
	KUWAIT	320007	27309775
	SPAIN	236702	24730714
5 COFFEE, WHETHER OR NOT ROASTED OR DACAFFEINATED; COFFEE HUSKS AND SKINS; COFFEE SUBSTITUTES CONTAINING COFFEE	ITALY	44053280	4125348819
	GERMANY	11647299	1299522452
	BELGIUM	6988683	778722846
	JORDAN	5374684	676144614
	SPAIN	5721830	457080553
	KUWAIT	2897858	400577773
	GREECE	4492138	367356506
	AUSTRALIA	3130328	359492930
	SWITZERLAND	2625600	330153899
	CROATIA	4145971	316321184
	SAUDI ARAB	1741051	289421690
	ISRAEL	2952580	284034836
	U ARAB EMTS	1691044	255503177
	EGYPT A RP	2983715	2444773975
	PORTUGAL	2974000	241511605
	SLOVENIA	3117501	231246974
	LIBYA	1743600	202652488
	U S A	1536727	194937137
	SYRIA	1363400	148125782
	FRANCE	1519002	141922426
6 TEA, WHETHER OR NOT FLAVOURED	RUSSIA	37455533	4696001045
	U ARAB EMTS	2340252	3386321129
	U K	24046656	3205729202
	IRAN	12953127	2126075555
	U S A	12861017	1936024749
	KAZAKHSTAN	9226293	1415906839

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	IRAQ	9950096	1233813883
	AUSTRALIA	6787838	1156637709
	GERMANY	4893134	1041727639
	PAKISTAN IR	9024089	909362303
	SAUDI ARAB	6550159	903083758
	SRI LANKA DSR	6551984	898384580
	JAPAN	2827085	634814912
	NETHERLAND	2990457	610933795
	AFGHANISTAN TIS	6918619	554254692
	POLAND	3964698	546537574
	EGYPT A RP	4239959	4674959554
	TUNISIA	4220126	421355373
	CANADA	1874606	260367151
	UKRAINE	1636968	199607871
7 PEPPER OF THE GENUS PIPER; DRIED OR CRUSHED OR GROUND FRUITS OF THE GENUS CAPSICUM OR OF THE GENUS PIMENTA PEPPER	MALAYSIA	49962913	3559175213
	U S A	33869259	2860370816
	SRI LANKA DSR	37316641	2070970239
	BANGLADESH PR	2657537	3303053657
	U K	6174807	620172217
	INDONESIA	10614762	576725792
	THAILAND	8149538	556226118
	VIETNAM SOC REP	4777484	404866800
	U ARAB EMTS	7423700	376454897
	CANADA	2543789	246049849
	SOUTH AFRICA	2757685	211407141
	NETHERLAND	4525368	208882375
	GERMANY	1270417	208151820
	AUSTRALIA	1860567	205990160
	CHINA P RP	2737138	203192842
	EGYPT A RP	2893120	199496332
	MEXICO	2385636	198231503
	ITALY	1478434	178816566
	SINGAPORE	2215343	177598640
	SAUDI ARAB	3265861	157224965
8 SEEDS OF ANISE, BADIAN, FENNEL, CORIANDER, CUMIN OR CARAWAY; JUNIPER BERRIES	U ARAB EMTS	11017857	771698844
	MALAYSIA	31609924	705413077
	U S A	6280437	614114832
	PAKISTAN IR	11628391	586273671
	NETHERLAND	6142705	534418675
	BRAZIL	3846740	405483932
	U K	4078639	330514857
	SAUDI ARAB	5078749	282975382
	EGYPT A RP	2883548	267048651
	BANGLADESH PR	2363527	236787712
	SOUTH AFRICA	2600581	172842416
	UNSPECIFIED	1685373	140223367
	SINGAPORE	2110840	139948155
	PERU	1279000	134630050
	JAPAN	976638	128259209
	YEMEN REPUBLIC	1642495	123739281
	SPAIN	949100	107102462
	EQUADOR	856000	98042704
	INDONESIA	1357380	89288348
	MEXICO	728000	79938894

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9	GINGER, SAFFRON, TURMERIC (CURCUMA), LEAV CURRY AND OTHER SPICES	THYME, BAY U K	13438723	1001717166
		U S A	15623195	986248383
		U ARAB EMTS	13791344	893358339
		SAUDI ARAB	7091499	526958785
		JAPAN	7211984	494107766
		MALAYSIA	5440509	364809599
		BANGLADESH PR	11818532	349777019
		SOUTH AFRICA	4886327	339319689
		IRAN	5063934	337081316
		SRI LANKA DSR	5399992	286649640
		GERMANY	3646798	243236832
		AUSTRALIA	3112264	233211601
		CANADA	3731839	227720867
		NETHERLAND	2848903	208098321
		EGYPT A RP	2956222	157010454
		KUWAIT	2420479	151288212
		VIETNAM SOC REP	11102803	142248298
		NIGERIA	1453748	138512825
		MOROCCO	1874500	137947064
		YEMEN REPUBL	3249974	122747494
10	MAIZE (CORN)	BANGLADESH PR	594914090	5725696891
		VIETNAM SOC REP	597694202	5723956920
		MALAYSIA	550690418	5349470990
		UNSPECIFIED	204001965	1953298094
		INDONESIA	106598125	1062431143
		TAIWAN	110580085	1033806923
		KENYA	77596700	779520041
		U ARAB EMTS	69563314	699172378
		IRAN	45677000	428416102
		SINGAPORE	34771469	344944503
		OMAN	36660230	341229867
		NEPAL	35995612	301813907
		SRI LANKA DSR	21496860	220639292
		SUDAN	19279725	210560468
		YEMEN REPUBL	17709000	188486835
		KOREA DP RP	17730000	176404640
		SOMALIA	17164000	173883020
		THAILAND	2082320	159517320
		PAKISTAN IR	1265074	118283709
		PHILIPPINES	1414046	110753192
11	RICE	SAUDI ARAB	655281701	33465815501
		U ARAB EMTS	628032567	31371322063
		IRAN	466718502	20633224122
		KUWAIT	140051832	10321476375
		YEMEN REPUBL	64001616	3023142597
		U K	37927104	2010184726
		U S A	30879368	1718716493
		UNSPECIFIED	19413339	983503929
		NEPAL	22179988	826492261
		CANADA	10805259	644457400
		SINGAPORE	11323752	578222153
		JORDAN	9345200	506705276
		MALDIVES	22798456	443141375
		IRAQ	10046078	408907174
		MAURITIUS	7358026	402508664
		MALAYSIA	7607009	388624170

		SYRIA	6972000	366836878
		AUSTRALIA	4934355	335685872
		QATAR	6013338	331984452
		OMAN	6248022	329264164
12	GROUND-NUTS, NOT ROASTED OR OTHERWISE WHETHER OR NOT SHELLD OR BROKEN	INDONESIA	136282021	5603518740
		COOKED,		
		MALAYSIA	63837626	2693670509
		PHILIPPINES	61619920	2659787074
		PAKISTAN IR	17291341	643289487
		U ARAB EMTS	9666426	389803113
		THAILAND	8512930	381821770
		UKRAINE	7852258	360184738
		SINGAPORE	5121450	218509314
		U K	3551589	189134837
		CHINA P RP	3400555	156910965
		YEMEN REPUBLIC	2951715	127080544
		SRI LANKA DSR	4256360	123371989
		SAUDI ARAB	2084311	95113541
		NEPAL	2549696	81743616
		IRAN	1698020	73260128
		TAIWAN	1555940	73254970
		UNSPECIFIED	1609000	69606632
		VIETNAM SOC REP	1204785	59340127
		GERMANY	1110948	43027154
		CANADA	846500	28014927
		KOREA RP	29278797	1920748591
13	OTHER OIL SEEDS AND OLEAGINOUS FRUITS, OR NOT BROKEN	U S A	21356547	1567298885
		TAIWAN	20412198	988875766
		GERMANY	10520983	787129668
		NETHERLAND	10581084	771778834
		GREECE	9643906	713735509
		CHINA P RP	11839449	676373885
		TURKEY	8217354	581622119
		VIETNAM SOC REP	10751568	517100003
		ISRAEL	6755870	516488176
		INDONESIA	63851977	460816168
		MALAYSIA	7530289	427028466
		U ARAB EMTS	5794220	411942710
		AUSTRALIA	4944077	398131280
		EGYPT A RP	5432029	377753659
		ITALY	5493087	342198711
		U K	6357986	331713123
		NEPAL	11300584	327047442
		POLAND	4577594	301027049
		BELGIUM	5577714	262208220
		U S A	11378239	1791654553
14	PLNTS & PRTS OF PLNTS INCLD SEEDS & FRUITS PRFUMRY PHRMACY/INSECTICID OR SMLR PURPOSES FRSH/DRID, W/N CUT CRSHD OR POWDRD	PAKISTAN IR	7486751	560974309
		GERMANY	2904154	319591093
		IRELAND	705223	176652243
		VIETNAM SOC REP	3976939	151792326
		U K	890679	151065053
		AUSTRALIA	787887	146036765
		JAPAN	1207484	137139811
		BANGLADESH PR	906882	134414719

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		MALAYSIA	849178	121930383
		MEXICO	903970	113602558
		U ARAB EMTS	1137743	104924823
		CHINA P RP	2016788	82550118
		KOREA RP	460230	79204388
		INDONESIA	619022	76550999
		FRANCE	606493	76348566
		UNSPECIFIED	790479	74294715
		HONG KONG	435823	73181841
		ITALY	479972	72104252
		TAIWAN	1029191	68915248
		CHINA P RP	148143636	8020589712
15	OTHER FIXED VEGETABLE FATS AND OILS (INCLUDING JOJOBA OIL) AND THEIR FRACTIONS, WHETHER OR NOT REFINED, BUT NOT CHEMICALL	NETHERLAND	65587930	3431911441
		U S A	43097167	2295828196
		FRANCE	42009653	2224368657
		JAPAN	16906040	1580388794
		MALAYSIA	6055563	932718351
		THAILAND	15605340	835500790
		U K	8016996	645875197
		BRAZIL	8048342	420638631
		KOREA RP	4603079	278932734
		ITALY	1820235	257192716
		UNSPECIFIED	2577943	172943975
		BELGIUM	2843588	170130294
		MEXICO	1993086	151555973
		GERMANY	2281758	150497348
		TURKEY	2467262	143836144
		TAIWAN	1888690	115997655
		RUSSIA	1777677	109832799
		SOUTH AFRICA	1698965	105302327
		U ARAB EMTS	1354550	102458513
		U K	10008499	1095931829
16	BREAD, PASTRY, CAKES, BISCUITS AND OTHER BAKERS' WARES, WHETHER OR NOT CONTAINING COCOA, COMMUNION WAFERS, EMPTY CACHETS	U S A	7472126	499408103
		NETHERLAND	6349224	430644033
		PAKISTAN IR	9245579	347209391
		ANGOLA	6970496	304498646
		U ARAB EMTS	4002249	265475247
		AUSTRALIA	2672438	214035660
		GHANA	3359236	141535809
		KENYA	3036785	135575343
		MALAYSIA	2037754	124535823
		CANADA	1890875	113459946
		CONGO P REP	2518205	112579138
		SINGAPORE	1780911	101742627
		GUINEA	2004197	92312688
		UGANDA	1923640	86033914
		BENIN	1966815	76441719
		HAITI	1735447	70602396
		TOGO	1552725	66525341
		SAUDI ARAB	1119705	64264607
		OMAN	748033	54047657

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17	VEGETABLES, FRUIT, NUTS AND OTHER EDIBLE PARTS OF PLANTS, PREPARED OR PRESERVED BY VINEGAR OR ACETIC ACID	U S A	43905353	1460366085
		RUSSIA	32571926	788866523
		U K	17847322	70126165
		BELGIUM	18661559	629971705
		CANADA	21711406	604479853
		FRANCE	9031422	782461286
		NETHERLAND	8673540	277495330
		AUSTRALIA	6765951	239352981
		GERMANY	8497678	226556808
		ESTONIA	9162398	201196437
		SPAIN	7606402	191462402
		U ARAB EMTS	3991467	145775784
		IRAC	2273355	98360445
		SAUDI ARAB	2080410	70540140
		CZECH REPUBLIC	2122512	49747337
		NEW ZEALAND	1665894	48992108
		KAZAKHSTAN	1975822	46074165
		JORDAN	1313334	40106598
		KUWAIT	1016393	36563113
		OMAN	874121	31736085
18	EXTRTS ESSNCS & CNCNTRTS OF COFFE TEA/ MATE& THR PRPN,RSTD CHICORY & OTHR RSTD COFFE SUBSTITUTS,EXTRCTS,ESSNCS ETC THROF	RUSSIA	11803215	2878272738
		U S A	2918197	846487642
		FINLAND	3132753	629981307
		UKRAINE	1633412	450689701
		MALAYSIA	1596089	386380386
		TAIWAN	1288737	309085572
		SLOVENIA	1052938	245815279
		IRELAND	362293	233656581
		SINGAPORE	821487	229312303
		SOUTH AFRICA	6155715	191483169
		JAPAN	412119	177405361
		TURKEY	657579	176650786
		LITHUANIA	675243	164818620
		ITALY	997809	158162080
		LATVIA	696441	151310072
		GERMANY	875468	149686169
		POLAND	1453250	133631177
		FRANCE	416537	116577846
		BELGIUM	1164872	113141489
		CHINA P RP	441684	99504227
19	OIL-CAKE AND OTHER-SOLID RESIDUES WHETHER OR NOT GROUND OR IN THE FORM OF PELLETS, RESULTING FROM THE EXTRACTION OF SOYABEAN	VIETNAM SOC REP	866117450	16884751449
		JAPAN	37924222	7865343000
		BANGLADESH PR	372542686	7586781869
		THAILAND	283459950	604278285
		PAKISTAN IR	212062274	4156602954
		INDONESIA	184927900	3700356750
		U ARAB EMTS	126794988	2552763865
		KOREA RP	100959492	2089166435
		SRI LANKA DSR	94181712	2034573728
		CHINA P RP	77646500	1469049451
		IRAN	74655000	1455123905

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		KUWAIT	59917976	1214702955
		PHILIPPINES	45945824	1000028276
		OMAN	3972906	704611135
		NEPAL	38166831	685822719
		SINGAPORE	31178526	619132832
		CROATIA	27445000	500379701
		GREECE	21065000	423541092
		EGYPT A RP	21042600	414826422
		MALAYSIA	19085473	401193286
		CHINA P RP	284085700	3225391760
		KOREA RP	420713150	2965741939
		VIETNAM SOC REP	249278004	2337912965
		BANGLADESH PR	132216530	1497139749
		INDONESIA	109031200	2166810400
		THAILAND	84009500	944139417
		TAIWAN	83664500	615051796
		SINGAPORE	45428409	494250557
		IRAN	15443170	183386089
		JAPAN	15244874	170843520
		UNSPECIFIED	11087000	122803787
		MALAYSIA	8415813	4886994
		U ARAB EMTS	9762560	8598881
		NEPAL	9588640	82564791
		OMAN	4625247	54340188
		FRANCE	4901600	24289625
		YEMEN REPUBLIC	1032000	21948387
		PHILIPPINES	1333000	16996948
		KUWAIT	1341000	16520891
		SRI LANKA DSR	1115000	12520304

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Annexure- VI**Area under Bt. Cotton cultivation (Final), January, 2011****(In hectares)**

States	Kharif- 2002	Kharif- 2003	Kharif- 2004	Kharif- 2005	Kharif- 2006	Kharif, 2007	Kharif, 2008	Kharif, 2009	Kharif, 2010 (Anticipa ted)	Kharif, 2011 (Targ et)
Andhra Pradesh	3762	5400	70400	330000	657435	1001000	1143000	1430000	1706000	1587000
Madhya Pradesh	1470	13200	85119	134639	310000	479980	479980	592700	545156	608870
Gujarat	9031	41200	124463	149317	402977	429000	890000	1825000	1894000	1925000
Maharashtra	12280	21600	159600	488000	1655000	2562000	2880000	3150000	3576000	3576000
Karnataka	2160	3000	33906	27909	74000	146685	225000	262000	370,000	380000
Tamil Nadu	370	7600	11856	17800	40000	46060	75200	78100	50200	112500
Punjab	-	-	-	72000	160000	490000	477000	474000	460000	495000
Haryana	-	-	-	12000	50000	278686	378000	475000	470000	580000
Rajasthan	-	-	-	2281	3775	38730	121000	265000	265000	240000
Total	29073	92000	485344	1233946	3353187	5472141	6669180	8551800	9336356	9504370

Source: DAC

Annexure- VII

Area – Million ha.
Production- Million bales of 170 kgs. each

ALL INDIA AREA AND PRODUCTION OF COTTON

S.No.	Year	Area	Production
1	2000-01	8.53	9.52
2	2001-02	9.13	10.00
3	2002-03	7.67	8.62
4	2003-04	7.60	13.73
5	2004-05	8.79	16.43
6	2005-06	8.68	18.50
7	2006-07	9.14	22.63
8	2007-08	9.41	25.88
9	2008-09	9.41	22.28
10	2009-10*	10.31	23.93
11	2010-11**	11.00	33.50

* Fourth advance estimates as released on 19.7.2010

** First advance estimates as released on 23.9.2010

Source: Directorate of Economics and Statistics, Department of Agriculture and Cooperation.

Options for the Regulation of Genetically Modified Foods in India

A Resource Document Prepared by the
Food Safety and Standards Authority of India

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INTRODUCTION

The Food Safety and Standards Authority of India (FSSAI) is in the process of elaborating a procedure that will allow for the safety assessment and subsequent decision to approve/disapprove foods derived from genetically modified (GM) plants. In order to provide some context for the FSSAI's deliberations, this resource document was prepared to:

- Introduce the concepts and principles of GM food safety assessment;
- Summarize the current regulatory system for GM foods in India;
- Summarize how GM foods are regulated in other countries;
- Provide regulatory options for the FSSAI as regards GM foods; and
- Propose a regulatory model for GM food safety assessment in India that the FSSAI may wish to consider.

2 CONCEPTS AND PRINCIPLES OF GM FOOD SAFETY ASSESSMENT

2.1 INTRODUCTION

Although modern biotechnology¹ broadens the scope of genetic changes that can be introduced into organisms used for food, it does not inherently result in foods that are less safe than those produced by more conventional techniques^{2,3}. This principle has important ramifications for the safety assessment of genetically modified (GM) foods. It means that a new or different standard of safety is not required, and that previously established principles for assessing food safety still apply. Moreover, the inherent precision of molecular biological methods for introducing specific genetic changes should enable a more direct and focused assessment of safety.

While countries may differ in statutory and non-statutory approaches to regulating GM foods, the criteria used to assess the safety of these products is generally consistent from one country to another⁴. This reflects the concerted efforts that have been made internationally to harmonize the risk assessment of foods derived from modern biotechnology (see Table 1). The outcomes of these consultations have contributed significantly to the development of internationally accepted approaches to assessing the safety of GM foods as articulated in two important documents published in 2003 by the Codex Alimentarius Commission (CAC)⁵: “Principles for the Risk Analysis of Foods Derived from Modern Biotechnology”⁶ (hereinafter referred to as “Codex Principles”) and “Guideline for the Conduct of Food Safety

¹ Modern biotechnology means the application of: i) *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or ii) Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection. Source: The Cartagena Protocol on Biosafety, as referenced in Codex' Principles for the Risk Analysis of Foods Derived from Modern Biotechnology.

² OECD. (1993). Safety evaluation of foods derived by modern biotechnology, Concepts and Principles. Organization for Economic Cooperation and Development (OECD), Paris.

³ United States National Academy of Sciences. (2004). Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects. The National Academies Press, Washington, D.C.

⁴ World Bank. (2003). Biosafety regulation: a review of international approaches (Report No. 26028). The World Bank Agriculture and Rural Development Department, Washington, D.C.

⁵ At the same time, the Codex Alimentarius Commission also published a third document, Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms.

⁶ http://www.codexalimentarius.net/download/standards/10007/CXG_044e.pdf

Assessment of Foods Derived from Recombinant-DNA Plants”⁷ (hereinafter referred to as “Codex Plant Guideline”).

The CAC was created in 1963 by FAO and World Health Organization (WHO) to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. The main purposes of this Programme are protecting the health of consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations⁸. The 23rd Session of the CAC agreed to establish the *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology under the following Terms of Reference:

- To elaborate standards, guidelines, or other principles, as appropriate, for foods derived from biotechnology;
- To coordinate and closely collaborate, as necessary, with appropriate Codex Committees within their mandate as related to foods derived from biotechnology; and
- To take full account of existing work carried out by national authorities, FAO, WHO, other international organizations and other relevant international fora.

The Task Force successfully completed its work within the original four year time frame, culminating with the publication of the Codex Principles and Guideline referenced above.

In 2004 the Task Force was re-established and has subsequently developed two annexes to the Codex Plant Guideline which were adopted by the Codex Alimentarius Commission in 2008. The first deals with the food safety assessment of foods derived from GM plants deliberately modified for nutritional or health benefits⁹. The second annex deals with food safety assessment in situations when low levels of GM plant material approved in one country may be present in food in importing countries which have yet to evaluate and approve the GM plant¹⁰. The Task Force also developed a “Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals”¹¹ that addresses safety and nutritional aspects of foods consisting of, or derived from, animals that have a history of safe use as sources of food, and that have been modified by modern biotechnology to exhibit new or altered expression of traits. This guideline was also adopted by the Codex Alimentarius Commission in 2008.

Table 1: Key international consultations addressing the safety assessment of GM foods (1990-present).

Year	Organization	Title and link (where available)
1990	FAO ¹ /WHO ²	Strategies for assessing the safety of foods produced by biotechnology, a joint FAO/WHO consultation, Geneva, Switzerland, 5-10 November 1990 (http://www.who.int/foodsafety/publications/biotech/1990/en/index.html)
1990	IFBC ³	Biotechnologies and food: Assuring the safety of foods produced by genetic modification. Regulatory Toxicology and Pharmacology, 12: S1-S196.

⁷ http://www.codexalimentarius.net/download/standards/10021/CXG_045e.pdf

⁸ http://www.codexalimentarius.net/web/index_en.jsp

⁹ http://www.codexalimentarius.net/download/standards/10021/CXG_045e.pdf

¹⁰ http://www.codexalimentarius.net/download/standards/10021/CXG_045e.pdf

¹¹ http://www.codexalimentarius.net/download/standards/11023/CXG_068e.pdf

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

¹Food and Agriculture Organization of the United Nations

²World Health Organization

³International Food Biotechnology Council

⁴International Life Sciences Institute

⁵Organization for Economic Cooperation and Development

⁶Codex Alimentarius Commission

2.2 THE COMPARATIVE APPROACH FOR SAFETY ASSESSMENT OF GM FOODS

To date, the safety assessment of GM foods has been based on the principle that these products can be compared with traditional foods that have an established history of safe use. The objective is to determine if the GM food presents any new or altered hazard in comparison with its traditional counterpart, or whether it can be used interchangeably with its traditional counterpart without affecting the health or nutritional status of consumers. The goal is not to establish an absolute level of safety, but rather the relative safety of the new product such that there is a reasonable certainty that no harm will result from intended uses under the anticipated conditions of processing and consumption.

Accounting for processing and consumption patterns is important even for traditional foods. A number of plants consumed by humans are acutely toxic in their raw state, but are accepted as food because processing methods alter or eliminate this toxicity. For example, the cassava root is quite toxic, but proper processing converts it into a nutritious and widely consumed food. Soybeans and Lima beans, among other crops, contain antinutrients (*e.g.*, soybean trypsin inhibitor and lectins) and require proper processing. Potatoes and tomatoes can contain toxic levels of the glycoalkaloids solanine and alpha-tomatine, respectively. Thus, the presence of a toxicant in a plant variety does not necessarily eliminate its use as a food source. In considering the safety of the GM food, it is therefore important to examine the range of possible toxicants, critical nutrients or other relevant factors, as well as its processing, intended use and exposure.

This comparative approach has been embodied in the concept of substantial equivalence; a concept which was developed before GM foods came to the market. It was first described in an OECD publication in 1993¹². This document was the product of some 60 experts from 19 OECD countries, who spent more than two years discussing how to assess the safety of GM foods. The concept of substantial equivalence was further endorsed by an FAO/WHO joint expert consultation in 1996. It recognized that the establishment of substantial equivalence is not a safety assessment *per se*, but that establishing the characteristics and composition of the GM food as equivalent to those of a familiar, conventional food with a history of safe consumption means that the new product will be no less safe under similar consumption patterns and processing practices.

One important benefit of the concept of substantial equivalence is that it provides flexibility that can be useful in food safety assessment. It is a tool that helps identify any difference, intended or unintended, which might be the focus of further safety evaluation. Because it is a comparative process for evaluating safety, the concept of substantial equivalence can be applied at several points along the food chain (*e.g.*, at the level of the harvested or

unprocessed food product, individual processed fractions, or the final food product or ingredient) allowing the safety assessment to be targeted to the most appropriate level based upon the nature of the product under consideration.

The most recent FAO/WHO joint expert consultation on foods from biotechnology¹³ re-examined the concept of substantial equivalence and concluded that the safety assessment requires an integrated and stepwise, case-by-case approach, which can be aided by a structured series of questions. They reaffirmed that the concept of substantial equivalence, which focuses on the determination of similarities and differences between a GM food and its conventional counterpart, aids in the identification of potential safety and nutritional issues, and that this comparative approach is the most appropriate strategy for evaluating the safety and nutritional quality of GM foods. They further clarified that the concept of substantial equivalence is not a safety assessment in itself as it does not characterize hazard; rather it should be used to structure the safety assessment of a GM food relative to its conventional

¹² OECD. (1993). Safety evaluation of foods derived by modern biotechnology, Concepts and Principles. Organization for Economic Cooperation and Development (OECD), Paris.

¹³ FAO/WHO. (2000). Safety aspects of genetically modified foods of plant origin, FAO/WHO consultation 29 May – 2 June 2000. Food and Agriculture Organization (FAO), Rome and World Health Organization (WHO), Geneva. http://www.who.int/foodsafety/publications/biotech/ec_june2000/en/index.html

counterpart (comparator). The Consultation was satisfied with the approach used to assess the safety of GM foods that have been approved for commercial use. Safety assessments based on the concept of substantial equivalence have been the most practical approach to addressing the safety of foods and food ingredients developed through modern biotechnology. In fact, there are presently no alternative strategies providing a better assurance of safety¹⁴.

The Codex Guideline includes the following reference to substantial equivalence (paragraph 13).

13. The concept of substantial equivalence is a key step in the safety assessment process. However, it is not a safety assessment in itself; rather it represents the starting point which is used to structure the safety assessment of a new food relative to its conventional counterpart. This concept is used to identify similarities and differences between the new food and its conventional counterpart². It aids in the identification of potential safety and nutritional issues and is considered the most appropriate strategy to date for safety assessment of foods derived from recombinant-DNA plants. The safety assessment carried out in this way does not imply absolute safety of the new product; rather, it focuses on assessing the safety of any identified differences so that the safety of the new product can be considered relative to its conventional counterpart.

Applying the concept of substantial equivalence requires that sufficient analytical data be available in the literature, or be generated through analysis, to allow effective comparison between the GM food and its traditional counterpart. This suggests a basic limitation of the substantial equivalence concept: dependence on a comparator and on the information that is

available or can be generated for the comparator, means safety assurance is relative to the components assessed for the particular comparator. The choice of comparator is therefore crucial to effective application of the concept of substantial equivalence in establishing the safety of a GM food. An appropriate comparator must have a well-documented history of use. If adverse effects have been associated with the particular food type, specific components considered to cause these effects should be described and well characterized to permit effective comparison.

Without exception, all of the GM foods approved to date have been the result of incorporating (or selecting for) one or two rather simple single-gene traits into plants. Except for canola and soybean varieties with modified oil composition (*e.g.*, high lauric acid; high oleic acid), delayed softening tomatoes for improved shelf-life and maize (*e.g.*, high lysine for livestock feed; modified amylase for ethanol production¹⁵), all of these traits have been targeted toward reducing agricultural inputs by conferring resistance to insects and/or viruses, or tolerance to environmentally friendly broad-spectrum herbicides. Since these products were

¹⁴ FAO/WHO. (2000). Safety aspects of genetically modified foods of plant origin, FAO/WHO consultation 29 May – 2 June 2000. Food and Agriculture Organization (FAO), Rome and World Health Organization (WHO), Geneva. http://www.who.int/foodsafety/publications/biotech/ec_june2000/en/index.html

¹⁵ Although SYN-E3272-5 (Event 3272), developed for production of maize grain primarily for industrial ethanol, and REN-ØØØ38-3 (LY038), developed for production of maize grain for livestock feed, are not intended for food consumption, they were submitted for food safety assessment and approval by the appropriate regulatory authorities because of the possibility that the products may enter into the food value chain (<http://www.agbios.com/dbase.php?action=ShowProd&data=Event+3272&format=LONG> and <http://www.agbios.com/dbase.php?action=ShowProd&data=LY038>).

the result of rather simple modifications and did not result in the introduction of new components into the food supply, the application of the concept of substantial equivalence to structure the safety assessment was straightforward.

The next generation of products will be much more complex and will include new products with intentionally altered nutritional profiles¹⁶, nutraceuticals, edible vaccines, and biopharmaceuticals produced in plants and animals. For these products, it will be more challenging to find appropriate comparators due to the larger and often deliberate differences expected from the traditional counterparts. This will make the application of the concept of substantial equivalence more difficult and the safety assessment of these products will likely require more sophisticated testing strategies.

3 THE REGULATION OF GM FOODS IN INDIA

3.1 Legislation

In India, the regulation of all activities related to GMOs and products derived from GMOs was initiated with the notification of *Rules for the Manufacture/Use/Import/Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells, 1989* (commonly referred to as *Rules, 1989*) under the provisions of the *Environment (Protection) Act, 1986* through the Ministry of Environment and Forests (MoEF). The *Rules, 1989* which created six competent authorities, are primarily implemented by MoEF and the Department

of Biotechnology (DBT), Ministry of Science and Technology. The competent authorities created under the *Rules, 1989* are: the Recombinant DNA Advisory Committee (RDAC); the Review Committee on Genetic Manipulation (RCGM); the Genetic Engineering Approval Committee (GEAC); Institutional Biosafety Committees (IBSC); State Biosafety Coordination Committees (SBCC); District Level Committees (DLC).

The *Rules, 1989* are very broad in scope and essentially capture all activities, products and processes related to or derived from biotechnology. They include reference to foods derived from biotechnology in Rule 11, Permission and Approval for Food Stuffs which states:

Food stuffs, ingredients in food stuffs and additives including processing aids containing or consisting of genetically engineered organisms or cells, shall not be produced, sold, imported or used except with the approval of the Genetic Engineering Approval Committee.

Until recently, this meant that GEAC was the competent authority to approve or disapprove the release of GM foods in the marketplace. However, this changed with the enactment of the *Food Safety and Standards Act, 2006*¹⁷ which includes genetically modified foods within the definition of food under the *Food Safety and Standards Act*¹⁸ (see section 2.2 below).

¹⁶ A framework for the safety and nutritional assessment of foods and feeds nutritionally enhanced through biotechnology has been published : ILSI. (2004). Nutritional and safety assessment of foods and feeds nutritionally improved through biotechnology. Comprehensive Reviews in Food Science and Food Safety 3: 38-104.

¹⁷ The Food Standards and Safety Act, 2006 “consolidates the laws relating to food and to establish the Food Safety and Standards Authority of India for laying down science based standards for articles of food and to regulate their

3.2 Guidance

In 1998, DBT published “Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts” which, until 2008, was the only guidance that explicitly addressed the safety assessment of GM foods in India. As there were no internationally accepted guidelines for the safety assessment of GM foods at that time, DBT’s 1998 guidelines referenced a number of OECD test standards developed for chemicals which, in many cases, were either not appropriate for whole food analyses or were not suitably modified so that the test provided meaningful safety related information about a GM food or the novel protein(s) expressed in that food.

In 2005, the Indian Council of Medical Research (ICMR) as the scientific and technical advisory body to the Ministry of Health and Family Welfare (at that time the nodal agency responsible for ensuring the safety of food in India) convened a multi-stakeholder consultation to address the issue of GM food safety assessment. The outcome of the consultation was consensus that the Codex Alimentarius’ “Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants” should form the basis of the Government of India’s own regulatory guidance for the safety assessment of foods derived from genetically modified plants. ICMR established a drafting committee which subsequently prepared “Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants”. These Guidelines, which were adopted by RCGM and GEAC in 2008, establish the criteria for undertaking the safety assessment of GM foods in India. The 2008 GE Food Guidelines are complemented by a series of five protocols: (1) Acute Oral Safety Limit Study in Rats and Mice; (2) Sub-chronic Feeding Study in Rodents; (3) Protein Thermal Stability; (4) Pepsin Digestibility Assay; and, (5) Livestock Feeding Study. Two additional protocols on bioinformatics analyses and specific serum testing are currently under development.

In 2006, the Ministry of Environment and Forests published “Procedure for Clearance by GEAC for Import of GM Products”¹⁹. This document lists import procedures for three categories of GM foods:

***i. LMOs²⁰ for food, feed and processing** (e.g., maize, corn, soybean, potato): For import of LMO as FFP detailed environmental clearance of GEAC needs to be obtained for which detailed biosafety and food safety studies need to be furnished. The GEAC may stipulate additional studies taking into consideration the*

manufacture, storage, distribution, sale and import, to ensure availability of safe and wholesome food for human consumption and for matters connected therewith or incidental thereto.” (MoLJ, 2006)

¹⁸ “Food means any substance whether processed, partially processed or unprocessed, which is intended for human consumption and includes primary food to the extent defined in clause (zk), genetically modified or engineered food or food containing such ingredients, infant food, packaged drinking water, alcoholic drink, chewing gum, and any substance, including water used into the food during its manufacture, preparation or treatment but does not include any animal feed, live animals unless they are prepared or processed for placing on the market for human consumption, plants prior to harvesting, drugs and medicinal products, cosmetic, narcotic or psychotropic substance.” (MoLJ, 2006)

¹⁹ http://www.envfor.nic.in/divisions/csurv/geac/gmo_lmo.htm

²⁰ LMO is the acronym for “Living Modified Organism” terminology from the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. “Living modified organism” means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

environmental risk in case of accidental release. The importer would also require compliance as per the provisions of Biosafety Protocol.

ii. GM processed food derived from LMOs (e.g., corn flour, soymeal, potato chips): *In case of GM processed food, the GEAC follows an “event based approval” in a given crop. The importer is required to obtain one time approval of GEAC for which the following information may be furnished:*

- *List of gene/events approved in the crop species for commercial production in the country of export/ country of origin.*
- *Whether the product has been approved for consumption in countries other than producing countries*
- *Food safety study conducted in the country of origin.*
- *Analytical / compositional report from the country of export/ origin.*
- *Whether further processing is envisaged after import. If so details of the same.*
- *Whether the gene/events from which the product has been derived has been approved and is in commercial production, marketing, use for food/feed in the country of origin/export.*

iii. Processed food containing ingredients derived from LMO (e.g., bread containing from non-GM flour but containing enzymes derived from GMO/LMO for increasing shelf life / non GM potato fried in GM soybean oil etc): *If the processed food contains any ingredient derived from category i and ii mentioned above, and if the LMO / product thereof has been approved by the GEAC, no further approval is required except for declaration at the port of entry. In case it does not have the approval of GEAC, the procedure mentioned at ii above may be complied.*

It is not clear how effective the “Procedure for Clearance by GEAC for Import of GM Products”, has been in clarifying the process for obtaining GM food approvals. For example, GEAC has yet to adopt an event-based approval system even though this is indicated in category ii above.

3.3 THE FOOD SAFETY AND STANDARDS ACT, 2006

The Food Safety and Standards Act, 2006 established the FSSAI as the statutory body for “laying down science based standards for articles of food and regulating manufacturing, processing, distribution, sale and import of food so as to ensure safe and wholesome food for human consumption”²¹. The *Act, 2006* has a significant impact on the regulation of GM foods in India as it:

- Provides the FSSAI with the authority to regulate GM foods through the inclusion of “genetically modified or engineered food or food containing such ingredients” within the definition of food;
- Effectively removes GM foods from the remit of GEAC. Section 89 of the *Act, 2006* overrides all other food related laws and states “The provisions of this Act shall have

²¹ www.fssai.gov.in

effect notwithstanding anything inconsistent therewith contained in any other law for the time being in force or in any instrument having effect by virtue of any law other than this Act.”

Specific to the regulation of GM foods the *Act, 2006* states:

22. Save as otherwise provided under this Act and regulations made thereunder, no person shall manufacture, distribute, sell or import any novel food, genetically modified articles of food, irradiated food, organic foods, foods for special dietary uses, functional foods, nutraceuticals, health supplements, proprietary foods and such other articles of food which the Central Government may notify in this behalf.

and

(2) "genetically engineered or modified food" means food and food ingredients composed of or containing genetically modified or engineered organisms obtained through modern biotechnology, or food and food ingredients produced from but not containing genetically modified or engineered organisms obtained through modern biotechnology;

The *Act, 2006* also empowers the FSSAI to establish a Scientific Panel on Genetically Modified Organisms and Foods whose members are to be independent scientific experts. The FSSAI recently announced the membership of the inaugural panel²². To date no implementing rules or regulations for GM foods have been notified by the FSSAI.

3.4 INTERIM REGULATION OF GM FOOD STUFFS BY GEAC

In response to the promulgation of the *Food Safety and Standards Act, 2006* and the establishment of the FSSAI, the Ministry of Environment and Forests published Notification S.O. 1519(E) in the Gazette of India on 23 August 2007 that exempted Rule 11 from the Rules, 1989. Rule 11 states:

Food stuffs, ingredients in food stuffs and additives including processing aids containing or consisting of genetically engineered organisms or cells, shall not be produced, sold, imported or used except with the approval of the Genetic Engineering Approval Committee.

However, because the FSSAI had yet to publish rules that describe how GM food stuffs (*i.e.*, processed foods containing one or more ingredients derived from a genetically modified organism) will be regulated under the *Food Safety and Standards Act, 2006* at the time Rule 11 was rescinded, the Ministry of Health and Family Welfare submitted a request to GEAC to continue to regulate of GM food stuffs under *Rules, 1989* as an interim measure²³. To this end a series of three supplemental notifications were published in the Gazette of India on 25 February 2008, 3 October 2008 and 17 March 2009. The latest notice states:

²² <http://www.fssai.gov.in/ViewContentDetails.aspx?ContentId=9&CategoryId=4>

²³ Decisions taken at the 80th meeting of the Genetic Engineering Approval Committee held on 1.10.2007. <http://www.envfor.nic.in/divisions/csurv/geac/decision-nov-82.htm>

S.O. 880(E). Notification No. S.O. 1519(E) dated 23-8-2007 is kept in abeyance till 30-09-2009 or until issue of further notification by the Ministry of Health and Family Welfare regarding regulation of GM processed foods by the Food Safety and Standards Authority, whichever is earlier.

GEAC has interpreted the *Food Safety and Standards Act, 2006* to mean that FSSAI's regulatory mandate *vis. GM foods* extends only to processed foods that contain GM ingredients and that "GM food/seeds which can propagate in the environment would require prior approval of GEAC²⁴". This is not consistent with the definition of genetically modified food in the *Act, 2006* which includes "food and food ingredients composed of or containing genetically modified or engineered organisms obtained through modern biotechnology". This definition arguably applies to foods that are viable (*e.g.*, grain, seeds, tubers and fruit) as well as non-viable or processed food products, meaning that all GM foods should be regulated by the FSSAI.

3.5 THE BIOTECHNOLOGY REGULATORY AUTHORITY OF INDIA

In 2007 the Government of India approved the National Biotechnology Development Strategy which promoted the establishment of a national biotechnology regulatory authority that would act as an "independent, autonomous and professionally led body to provide a single window mechanism for biosafety clearance of genetically modified products and processes"²⁵. DBT has been given the responsibility to establish and operationalize this new regulatory authority, the Biotechnology Regulatory Authority of India²⁶ (BRAI). Biotechnology regulation will continue under the existing regulatory framework until the BRAI is fully functional.

In order to establish and empower the BRAI, the "Biotechnology Regulatory Authority of India Bill, 2009" was prepared by an expert committee convened by DBT under the Chairmanship of Professor M.S. Swaminathan. A review of the Bill and the associated Establishment Plan for the BRAI are beyond the scope of this paper but preliminary versions of both were made available for public review and comment in 2008 and can still be viewed at http://dbtindia.nic.in/uniquepage.asp?id_pk=668. Note that both the Establishment Plan and Bill have undergone revisions since these versions were published but the essential elements of the Establishment Plan and Bill remain largely the same.

Specific to the regulation of GM foods, the Establishment Plan for the BRAI recommended coordination of safety assessments between the FSSAI and BRAI and provided for three options to do so:

1. The Risk Assessment Unit²⁷ (RAU) of the BRAI could undertake all or part of the safety assessment of GM foods on behalf of the FSSAI and submit its report to the Chairperson, FSSAI for product approval;

²⁴ Decisions taken at the 80th meeting of the Genetic Engineering Approval Committee held on 1.10.2007. <http://www.envfor.nic.in/divisions/csurv/geac/decision-nov-82.htm>

²⁵ <http://dbtindia.nic.in/biotechstrategy/National%20Biotechnology%20Development%20Strategy.pdf>

²⁶ Until very recently the new authority was popularly referred to as the National Biotechnology Regulatory Authority (NBRA) however the name was changed to the Biotechnology Regulatory Authority of India during the review of the associated draft bill by the Ministry of Law and Justice. Documentation about the BRAI on DBT's website still refers to the authority as the NBRA.

²⁷ The Risk assessment Unit will undertake the case-by-case assessment of products and processes regulated by the BRAI. It will be a permanently staffed unit of the BRAI with a multi-disciplinary team of scientists responsible for undertaking science-based risk assessments, including but not limited to those required to approve: import of regulated organisms and products; inter-state transport of regulated organisms;

2. GM food safety assessment could remain the exclusive purview of the FSSAI; and
3. The regulation of GM foods could be removed entirely from the mandate of the FSSAI and vested with the NBRA. All other rules and regulations that pertain to food would still apply to GM foods as regulated by the FSSAI and any other authority in India.

Schedule I of the BRAI Bill, 2009 identifies the categories of biotechnology derived products that will be regulated under the Bill. Part I(1)(b) of Schedule I states “Any genetically engineered plant, animal, micro-organism, virus or other animate organism used as food” will be regulated by the Agriculture, Fisheries and Forestry Division of the BRAI. This may be

interpreted to mean that Option 3 above will become the working modality unless additional revisions to Schedule I are made before the BRAI Bill is promulgated. It is anticipated that the Bill will be laid before Parliament this year.

The Regulation of GM Foods in Other Countries

There is no uniform model for regulation GM foods that has been applied internationally as regulatory systems must necessarily reflect national priorities, which differ between countries and also within a country over time. Nevertheless, it is instructive to compare how countries with established and functional regulatory systems have addressed the key programmatic and operational issues. This chapter reviews the regulatory systems for GM foods of Australia and New Zealand, Canada, the European Union, Japan and the United States and then provides a comparative summary that highlights how fundamental issues related to the implementation of their respective regulatory systems have been addressed.

Australia & New Zealand

Authority for regulating food in Australia is derived from the *Food Standards Australia New Zealand Act 1991*²⁸ which is administered by the bi-national Food Standards Australia New Zealand (FSANZ) and enforced by the State/Territory Health Departments within Australia and New Zealand. There is a general prohibition on the sale and use of food produced using gene technology unless the food is listed in Standard 1.5.2 of the Food Standards Code.²⁹ Importers or producers apply to FSANZ to have a new GM food included on the list of approved foods.³⁰ FSANZ completes a safety assessment of the GM food for which the applicant provides the data although information from other sources may also be used by FSANZ. Approvals are listed in Standard 1.5.2 and the amendment to the Standard is then published³¹. Any special conditions on the sale and use of a GM food are also listed in the amended Standard.

FSANZ carries out safety assessments on a case-by-case basis, which means each new genetic modification (event) is assessed individually for its potential impact on the safety of the food. FSANZ compares the GM food with a similar, commonly eaten conventional food from a

field trials of regulated organisms, clinical trials of regulated organisms and products for pharmaceutical production; manufacture of regulated organisms and products; and pre-market safety assessment of regulated organisms and products.

²⁸ [http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/0/34FDA538E7B40ACFCA256F71004DA6FE/\\$file/FoodStandANZ91.pdf](http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/0/34FDA538E7B40ACFCA256F71004DA6FE/$file/FoodStandANZ91.pdf)

²⁹ http://www.foodstandards.gov.au/_srcfiles/FSC_1_5_2_GM_v85.pdf

³⁰ http://www.foodstandards.gov.au/_srcfiles/GM_Guidelines_Nov_05.pdf,

[http://www.foodstandards.gov.au/_srcfiles/Application Format - GM June 05.doc](http://www.foodstandards.gov.au/_srcfiles/Application_Format_-_GM_June_05.doc)

³¹ <http://www.foodstandards.gov.au/thecode/foodstandardscode/standard152foodprodu4248.cfm>

molecular, toxicological, nutritional and compositional point of view. The aim is to find out if there are any differences between the GM food and its conventional counterpart, which is already known to be safe to eat.

Canada

Health Canada is responsible for the safety assessment of all food products, including novel food products under the *Novel Food Regulations* of the *Food and Drugs Act*, which were

promulgated in October 1999.³² Under these regulations, a manufacturer or importer of a novel food³³ (which includes GM foods) must notify Health Canada 45 days prior to the sale or advertising for sale of these products. The department undertakes to respond within 45 days should additional safety information of a scientific nature be required, and will notify the manufacturer within 90 days of receipt of such information as to whether it is sufficient. Until the *Novel Food Regulations* came into force in 1999, the safety assessment of novel foods was based on voluntary compliance with the Guidelines for the Safety Assessment of Novel Foods.³⁴

Risks to be assessed relate to major changes brought about by the application of processes to the particular food product which may, based on the manufacturer's experience or generally accepted theory, adversely impact: the composition, structure or nutritional value of the food or its generally recognized physiological effects; the manner in which the food is metabolized in the body; or the microbiological safety, the chemical safety or the safe use of the food.

Safety considerations for foods produced from genetic engineering are of the same nature as those that arise from other means of altering the genome, such as conventional breeding. Each safety assessment considers a range of both direct and indirect consequences. The former includes the nutritional, toxic or allergenic effects resulting from the presence of new gene products, as well as intentionally altered levels of existing gene products. Indirect consequences would include altered levels of existing gene products or changes in plant metabolism resulting in the production of new components, or altered levels of existing components. The consequences of mutations due to the genetic modification, such as interruption of coding or control sequences or activation of latent genes, leading to new components or altered levels of existing components are also investigated.

Health Canada has published "Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms" which provide guidance in classifying a product as 'novel' and contain specifications to product developers regarding the data they must provide to regulatory authorities in order to demonstrate the safety of their product. Novel foods that are products of modern biotechnology are evaluated on an event specific basis and, according to Health Canada's Guidelines:

³² Health Canada. (1999). Schedule No. 948: Novel Foods Regulations. http://www.hc-sc.gc.ca/food-aliment/english/subjects/novel_foods_and_ingredient/sch948e.pdf

³³ Novel food" means (a) a substance, including a microorganism, that does not have a history of safe use as a food; (b) a food that has been manufactured, prepared, preserved or packaged by a process that (i) has not been previously applied to that food, and (ii) causes the food to undergo a major change; and (c) a food that is derived from a plant, animal or microorganism that has been genetically modified such that (i) the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism, (ii) the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or (iii) one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism.

³⁴ Health Canada. (1994). Guidelines for the Safety Assessment of Novel Foods. (http://www.hc-sc.gc.ca/food-aliment/english/subjects/novel_foods_and_ingredient/novele.pdf)

Data should be provided for the raw food, in other words, the edible part of the plant in its unprocessed state. Data may also be required for the food prepared for human consumption by conventional means to examine the effects, where applicable, of

processing, storage and cooking to look , for example, at the effectiveness of cooking to destroy anti-nutrients in cases where anti-nutrients normally destroyed by cooking are present.

Novel food decisions are published by Health Canada³⁵.

4.3 Japan

The Ministry of Health, Labour and Welfare (MHLW) is responsible for food safety approvals of GM plants under the *Food Sanitation Law*.³⁶ Food safety is reviewed by the Food Safety Commission (FSC), an independent risk assessment body under the Cabinet Office.³⁷ The Genetically Modified Foods Expert Committee of the FSC, consisting of plant biotechnology scientists from universities and public research institutes, undertakes the actual scientific review. Upon completion, the FSC provides its safety assessment conclusions to MHLW.

The safety assessment is based on comparison of the GM food with its conventional counterpart where there is a history of the safe use of the conventional counterpart as a food or food ingredient.³⁸ All intended and unintended effects of the inserted DNA should be covered from both a toxicological and a nutritional standpoint, including the effect on endogenous genes, identified by the sequence analysis of flanking regions, which may have been modified by the inserted DNA. The effects of processing on any novel traits should be considered as should any potential for the accumulation of toxic metabolites. Where safety cannot be confirmed on the basis of the data presented, further testing maybe required. The list of approved events for food is available from MHLW³⁹.

4.4 European Union

Within the European Union (EU), all GMOs and derived products must be evaluated by the European Food Safety Authority (EFSA) before they can be authorised in the EU. To obtain such an authorization, a product developer must submit an application that is consistent with EU legislation which provides for two different regulatory frameworks: Regulation (EC) No 1829/2003 on genetically modified food and feed and Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms (GMOs).

The framework used is chosen by the applicant and depends on the nature and the purpose of the GMO in question. GM foods (and feeds) are handled under Regulation (EC) No 1829/2003 whereas GMOs intended for deliberate release into the environment are dealt with under Directive 2001/18/EC. In both cases, EFSA is responsible for conducting scientific risk assessments of GMOs and for the provision of science advice to the European Commission

³⁵ <http://www.hc-sc.gc.ca/fn-an/gmf-agm/appro/index-eng.php>

³⁶ <http://www.jetro.go.jp/jpn/regulations/guidebook/pdf/free/food2004nov-e.pdf>

³⁷ <http://www.fsc.go.jp/english/index.html>

³⁸ http://www.fsc.go.jp/senmon/idensi/gm_kijun_english.pdf

³⁹ <http://www.mhlw.go.jp/english/topics/food/pdf/sec01.pdf>

and the Member States. While EFSA provides the scientific basis for EU decisions on GMOs, the Authority is not involved in the decision-making process which is the responsibility of the European Commission and Member States.

Regulation (EC) No 1829/2003 EFSA provides for a centralized risk assessment procedure that assesses the human, livestock and environmental safety of a GMO. The steps in this procedure are as follows⁴⁰:

- The GMO application is submitted by the product developer to a Member State that immediately forwards it to EFSA who must work to deliver an Opinion within six months.
- All Member States have full access to the application and to full studies and data presented by the applicant via EFSA's dedicated extranet.
- Member States have the possibility of raising objections and commenting on the application, including on the full data and studies presented by the applicant.
- If the application includes the cultivation of a GMO, one of the Member States is delegated to perform the environmental risk assessment.
- EFSA finalises the full scientific risk assessment of the GMO (within six months unless additional data are requested from the applicant) in its Scientific Opinion.
- EFSA forwards the Scientific Opinion to the European Commission along with all other information required under Regulation (EC) No 1829/2003.
- The overall opinion is published on the websites of both EFSA and the European Commission.
- The European Commission consults the public on the overall opinion during a 30 day period.
- Based on the overall Opinion, the European Commission and Member States are then responsible for taking a decision on the applicant's request.

Under Directive 2001/18/EC, the risk assessment is decentralized in that it is completed first by a Member State and, if necessary, independent scientific advice may be sought from EFSA. The steps in this procedure include⁴¹:

- The GMO notification is sent by the applicant to a Member State and the risk assessment of the GMO is carried out by that Member State.
- The Member State's risk assessment is sent to the European Commission which then forwards it to all Member States for their comments and input on the risk assessment (the so-called "Community period").

⁴⁰ http://www.efsa.europa.eu/cs/BlobServer/Non_Scientific_Document/Factsheet_GMO_frameworkv4,3.pdf?ssbinary=true

⁴¹ http://www.efsa.europa.eu/cs/BlobServer/Non_Scientific_Document/Factsheet_GMO_frameworkv4,3.pdf?ssbinary=true

- If objections are raised by Member States and cannot be resolved amongst Member States, EFSA is asked to provide an Opinion (within 90 days) focusing particularly on the points of scientific divergence between Member States.
- Based on EFSA's Opinion, the European Commission and Member States are then responsible for taking a decision on the applicant's request.

Risk assessments and scientific opinions⁴² prepared by EFSA are completed by EFSA's Scientific Panel on GMOs. The panel is comprised of leading experts selected from the EU and is multidisciplinary in nature. Membership on the Panel is for three years and it works independently on behalf of EFSA. Membership on the Panel can be extended to non-EU scientists if warranted.

4.5 United States

In 1992, the FDA published in the Federal Registry a Statement of Policy on its approach to the regulation of foods derived from GM plants. The purpose of this policy was to provide a risk-based "decision tree" to guide plant breeders and food manufacturers through issues critical to ensuring the safety, nutritional value, and wholesomeness of new foods.⁴³ Under this "standard of care", which applies equally to new foods produced through traditional breeding as well as biotechnology, FDA also provided guidance on regulatory issues such as when an introduced substance is not generally recognized as safe and would require pre-market approval as a food additive, and when special labelling would be required under *Federal Food Drug and Cosmetics Act* (FFDCA). Food producers are not required to seek FDA pre-market approval or apply a special label for a new variety of food if it is substantially equivalent to existing varieties already on the market. Guidance documents⁴⁴ on the consultation procedures have been issued and updated and a draft rule on Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use has also been published.⁴⁵

The "Guidance on Consultation Procedures: Foods Derived from New Plant Varieties" details the system the FDA has established to manage the consultation process:

The Office of Food Additive Safety of the Center for Food Safety and Applied Nutrition (CFSAN) and the Office of Surveillance and Compliance of the Center for Veterinary Medicine established the Biotechnology Evaluation Team (BET) to facilitate and ensure consistency in the process by which developers consult under the 1992 policy and inform FDA regarding the marketing of foods and food ingredients derived from new plant varieties including those developed using rDNA techniques. The BET oversees the consultation

*process, identifies regulatory and scientific issues that need to be addressed, and once all relevant issues have been adequately addressed, brings the consultation to closure.*⁴⁶

⁴² Scientific opinions prepared by the Scientific Panel on GMOs can be viewed at http://www.efsa.europa.eu/EFSA/ScientificPanels/GMO/efsa_locale-1178620753812_GMOOpinions455.htm

⁴³ <http://www.cfsan.fda.gov/~dms/bioprgui.html>

⁴⁴ <http://www.cfsan.fda.gov/~lrd/consulpr.html>

⁴⁵ <http://www.cfsan.fda.gov/~dms/bioprgui.html>

⁴⁶ <http://www.cfsan.fda.gov/~lrd/consulpr.html>

There are no formal requirements for the data to be submitted for an approval from the FDA; during the product development process, in consultation with the BET, the developer will accumulate the information that it believes is adequate to ensure that the product is safe and complies with the relevant provisions of the FFDCA. At this stage, FDA recommends that the developer submit a summary of the safety and nutritional assessment that has been conducted and meet with FDA scientists to discuss the scientific data and information that support the summary of the safety and nutritional assessment. This meeting allows the developer and FDA to discuss and clarify the data and information provided in the summary document. Summaries of completed consultations are published by CFSAN⁴⁷.

If the introduced trait is a “plant incorporated protectant” (*e.g.*, an insecticidal protein) a registration and exemption from food tolerance must be obtained from the EPA under the *Federal Insecticide, Fungicide, and Rodenticide Act*. Regulations are contained in 40CFR152⁴⁸, 40CFR172⁴⁹ and 40CFR174.⁵⁰

4.6 POINTS OF CONSENSUS

As exemplified by the descriptions in Sections 3.1-3.5, it is apparent that while countries have different legal and regulatory frameworks for addressing the safety assessment and authorization of GM foods (see also Table 2) there are important commonalities that reflect international consensus on key programmatic and operational issues. Three of these issues that are critical to the regulation of GM foods in India are discussed below.

4.6.1 Regulatory Authority

In the five countries reviewed above (and in other countries with functional biotechnology regulatory systems), the regulatory authority for GM foods is the same authority that is responsible for administering food safety law(s). **This recognises that the safety assessment of GM foods is part of, and not separate from, programs that address the broader context of ensuring the safety of the foods that the public consumes.** The “GM nature” of a food derived from a GM crop or other GM organism is not (and should not be) the solely defining characteristic of that food as regards safety. Other, and arguably more important, food safety and food quality considerations⁵¹ and associated laws, regulations, standards and guidance apply to GM and non-GM foods alike which is typically why GM food safety

assessment is positioned within ministries of health and their associated food safety and standards agencies.

⁴⁷ <http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=bioListing>

⁴⁸ http://www.access.gpo.gov/nara/cfr/waisidx_05/40cfr152_05.html

⁴⁹ http://www.access.gpo.gov/nara/cfr/waisidx_05/40cfr172_05.html

⁵⁰ http://www.access.gpo.gov/nara/cfr/waisidx_05/40cfr174_05.html

⁵¹ In 2002, the World Health Organization published a list of potential hazards associated with food (in descending order of importance): microbial pathogens; zoonotic diseases; parasitic organisms; physical contaminants and adulterants; naturally-occurring toxicants; agro-chemical and veterinary drug residues; prions; persistent organic pollutants; heavy metals; GMOs that may contain allergens or toxins that are not found in conventional foods. WHO (2002). Food Safety and Food-Borne Illness. World Health Organisation, Geneva.

4.62.2 Subject of the Safety Assessment

In all but one country where GM plants, foods and feeds have been submitted for regulatory authorization, the safety assessment and subsequent regulatory decision is applied not to a variety or a hybrid but to an “event” *i.e.*, a genotype produced from the transformation of a single plant species using a specific genetic construct⁵². **This means that the GM food safety assessment and approval of an event applies to the event as well as any other hybrids or varieties bred from that event using conventional plant breeding techniques and their derived food products.** These approvals typically do not apply to a subsequent transformation of the same plant species using the same construct that was used to transform the approved event – instead this would be considered a new event as it would result in a different genotype⁵³. The exception to event-specific approvals occurs in India. For example, GM cotton continues to be regulated and approved on a hybrid-by-hybrid basis even though the safety assessment of parental event, MON 531, has been accepted by GEAC. There is every indication that RCGM and GEAC will continue to regulate other GM crops in this same way⁵⁴.

The rationale behind approving an event vs. a variety or hybrid is scientifically defensible as it builds on decades of knowledge and experience with stability of trait expression gained through genotypic and phenotypic evaluation and selection which, as with conventional plant breeding, is an integral part of the development of a GM plant. It also affords an acceptable assurance of safety within realistic financial, human resource and institutional resource allocations.

4.6.3 Processed Food Products

To date, 22 countries have approved GM foods for human consumption. In all cases the pre-market safety assessment was of the primary or whole food product harvested from the GM crop (*e.g.*, potato tubers from potato, whole kernel from maize, seed from soybean etc.). The subsequent food approval is applicable to the whole food and any other food product derived from the approved whole food (*e.g.*, corn starch and corn syrup from an approved GM corn event are also considered safe and are not independently evaluated). **There are no examples of a processed food product containing an ingredient derived from a GM plant (*e.g.*, a biscuit containing cornstarch derived from GM corn or a potato chip derived from a GM potato or soy oil derived from a GM soybean) being assessed for safety as a stand-alone “GM food”.** This approach to determining the safety of the primary or whole food is analogous to the safety assessment of food additives, whereby the additive is evaluated from a safety perspective and, when determined to be safe, can be used in any number of food products. The food products with the additive are not, themselves, subject to an additional safety assessment.

Table 2: Summary of regulatory authorities, laws and regulations applicable to GM foods in selected countries.

⁵² For example, two lines of the same plant species transformed with the same or different constructs constitutes two events.

⁵³ In Canada and the U.S. retransformations of the same plant species with the same construct as an approved event can be evaluated using a subset of the typical information and data requirements, effectively providing for an expedited review process.

⁵⁴ RCGM and GEAC have publicly stated that they have adopted an event-specific approval process, but recent decisions taken by both regulatory committees indicate this is not the case.

Country	Regulatory Authority	Law	Regulation(s)	Guideline(s)
India	Food Safety and Standards Authority	Food Safety and Standards Acts, 2006	None to date.	
Australia & New Zealand	Food Standards Australia New Zealand	Food Standards Australia New Zealand Act 1991	Food Standards Code	Guidelines for the Safety Assessment of Genetically Modified Foods
Canada	Health Canada	Food and Drugs Act	Novel Food Regulations	
European Union	European Food Safety Authority		Regulation (EC) No 1829/2003 on genetically modified food and feed Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms	Guidance document for the risk assessment of genetically modified plants and derived food and feed by the Scientific Panel on Genetically Modified Organisms (GMO) - including draft document updated in 2008
Japan	Ministry of Health, Labour and Welfare	Law 55 of 2003 - Food Sanitation Law	Food Sanitation Law Enforcement Regulations	Standards for the Safety Assessment of Genetically Modified Foods (Seed Plants)
United States	EPA, FDA	Federal Food Drug and Cosmetics Act; Federal Insecticide, Fungicide and Rodenticide Act Toxic Substances Control Act	40CFR152 - Pesticide registration and classification procedures; 40CFR17- Procedures and requirements for plant-incorporated protectants; 40CFR172 - Experimental use permits	

4.7 RELEVANT INTERNATIONAL AGREEMENTS

India is a signatory to, or has ratified, a number of multilateral agreements and conventions that are potentially relevant to the regulation of GM foods. The most significant of these in the context of this document are introduced below.

4.7.1 World Trade Organization

The World Trade Organisation (WTO) administers rules governing trade between its members (over 150 countries) according to approximately 30 agreements.⁵⁵ Two of these agreements are relevant to national policies on biotechnology: the Agreement on the

⁵⁵ http://www.wto.org/english/docs_e/legal_e/ursum_e.htm

Application of Sanitary and Phytosanitary Measures (SPS),⁵⁶ which controls the mechanisms and procedures for countries to impose barriers on the movement of plants and animals into and within a country; and the Agreement on Technical Barriers to Trade (TBT),⁵⁷ which considers the application of technical standards and labelling regimes to determine if they present an unwarranted barrier to the trade in certain goods. Because they were negotiated prior to the commercialization of any genetically modified (GM) organisms, the SPS and the TBT agreements do not contain provisions that are GMO-specific and so apply to all products of agricultural, forest or aquatic biotechnology.

SPS Agreement

Sanitary and phytosanitary measures are defined as measures taken to prevent damage to human, animal or plant health from risks arising from the entry, establishment or spread of pests and diseases. Included in this are measures to control organisms which carry diseases and any additives, contaminants or toxins of foods, beverages or feedstuffs which can cause damage or disease. Countries have a national right to protect their territories from such damage and the agreement seeks to establish methods to implement measures so that they do not unfairly discriminate between different countries where similar conditions prevail and become a barrier to trade.

The SPS Agreement sets out the basic rules for food safety and animal and plant health standards. Although it allows individual countries to set their own standards, it requires that regulations be based on science, and that they should be applied only to the extent necessary to protect human, animal, or plant life and health. Under the SPS Agreement, nations are encouraged to adopt international standards⁵⁸ where they exist, but may define even higher standards provided they are based on a sound scientific risk assessment, and do not discriminate against imports. Recognizing that a complete risk assessment may not be possible in the short term because of scientific uncertainty or the lack of sufficient evidence, Article 5.7 of the SPS Agreement allows countries to temporarily adopt restrictive measures. In such cases, countries are expected to seek the additional information required to complete a full risk assessment within a reasonable period. Maintaining restrictive measures indeterminately in the absence of scientific evidence of risk solely for “precautionary” reasons are not allowed.

TBT Agreement

It is recognised that technical standards, and procedures to ensure conformity with such standards, are important in the smooth functioning of international trade, but that where these are differentially applied they can also be a barrier to entry. The TBT Agreement seeks to ensure that technical negotiations and standards, as well as testing and certification procedures, do not create unnecessary obstacles to trade. Countries retain the right to

⁵⁶ http://www.wto.org/english/docs_e/legal_e/15-sps.pdf

⁵⁷ http://www.wto.org/english/docs_e/legal_e/17-tbt.pdf

⁵⁸ These standards are developed by the Codex Alimentarius Commission, the International Office of Epizootics and the International Plant Protection Convention (IPPC).

establish protection at levels they consider appropriate and should not be prevented from taking measures necessary to ensure those levels of protection are met. The Agreement therefore encourages countries to use international standards where these are appropriate, but it does not require them to change their levels of protection as a result of standardization.

The articles of the TBT Agreement focus on the procedures for setting and implementing standards and the assessment of conformity with these standards. In a similar manner to the SPS measures, countries are encouraged to participate in standard setting through international bodies as much as possible. No particular types of technical barriers are mentioned in the Agreement, but one area that is considered important to trade in GM organisms is the imposition of labelling regimes for products based on their method of manufacture as opposed to their composition. The issue of labelling for products of GM organisms is a complex topic that should be addressed outside of discussions relevant to safety assessment and so is beyond the remit of this document.

4.7.2 Cartagena Protocol on Biosafety

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity is the only international environmental agreement that is concerned exclusively with the transboundary movement (*i.e.*, trade) of products of modern biotechnology that are living modified organisms⁵⁹. It applies to the “transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health⁶⁰”. GM foods are considered only if they are LMOs that may be subject to transboundary movement for direct use as food, feed or for processing (FFPs)⁶¹ and then only in the restricted context of their potential impact on the environment. The Protocol does not apply to processed food products nor does it address the food safety of LMOs that are FFPs.

⁵⁹ A Living Modified Organism (LMO) is defined in the Cartagena Protocol on Biosafety as any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology. The Protocol also defines the terms 'living organism' and 'modern biotechnology' (see Article 3).

⁶⁰ Article 4 (<http://www.cbd.int/biosafety/articles.shtml?a=cpb-04>)

⁶¹ Article 11, Article 18(a) and Annex II (<http://www.cbd.int/biosafety/articles.shtml?a=cpb-11>; <http://www.cbd.int/biosafety/articles.shtml?a=cpb-18>; <http://www.cbd.int/biosafety/articles.shtml?a=cpb-42>).