



**PARLIAMENT OF INDIA  
RAJYA SABHA**

**DEPARTMENT-RELATED PARLIAMENTARY STANDING COMMITTEE  
ON SCIENCE & TECHNOLOGY, ENVIRONMENT & FORESTS**

**THREE HUNDRED FIRST REPORT**

**“GENETICALLY MODIFIED CROPS AND ITS IMPACT ON ENVIRONMENT ”**

**(PRESENTED TO HON'BLE CHAIRMAN, RAJYA SABHA ON THE 25<sup>TH</sup> AUGUST, 2017)  
(FORWARDED TO HON'BLE SPEAKER, LOK SABHA ON THE 25<sup>TH</sup> AUGUST, 2017)**

**(PRESENTED TO THE RAJYA SABHA ON 18<sup>TH</sup> DECEMBER, 2017)  
(LAID ON THE TABLE OF LOK SABHA ON 18<sup>TH</sup> DECEMBER , 2017)**



**Rajya Sabha Secretariat, New Delhi  
December, 2017/ Agrahayana, 1939 (Saka)**

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\*To be appended at printing stage

**COMPOSITION OF THE COMMITTEE**

**(2016-17)**

**(Constituted on 1<sup>st</sup> September, 2016)**

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- 1. Shrimati Renuka Chowdhury — Chairperson**

**RAJYA SABHA**

2. Shri Prasanna Acharya
3. Shri S.R. Balasubramoniyam
4. Shrimati Vandana Chavan
5. Shri C.P. Narayanan
6. Shri Parimal Nathwani
7. Shri Rangasayee Ramakrishna
8. Dr. T. Subbarami Reddy
9. Shri Ronald Sapa Tlau
10. Shri Ch. Sukhram Singh Yadav

**LOK SABHA**

11. Shri Badruddin Ajmal
12. Shri Muzaffar Hussain Baig
13. Shri E.T. Mohammed Basheer
14. Shri Prabhatsinh Chauhan
15. Shri Pankaj Chowdhary
16. Kum. Sushmita Dev
17. Shri Ninong Ering
18. Shri Laxman Giluwa
19. Dr. K. Gopal
20. Shri Daddan Mishra
21. Shri Chirag Paswan
22. Shri Shivaji A. Patil
23. Shri Nanabhau Falgunrao Patole
24. Shri Nagendra Kumar Pradhan
25. Shri Harinarayan Rajbhar
26. Shrimati Sandhya Roy
27. Shri Kirti Vardhan Singh
28. Shri Nagendra Singh
29. Shri Vikram Usendi
30. Shrimati M.Vasanthi
31. Shri Prabhubhai N. Vasava

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**SECRETARIAT**

Shri M.K. Khan, Joint Secretary

Shri T.N. Pandey, Director

Shri Rajiv Saxena, Under Secretary

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# COMPOSITION OF THE COMMITTEE

(2017-18)

(Constituted on 1<sup>st</sup> September, 2017)

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1. Shri Anand Sharma — **Chairman**

## **RAJYA SABHA**

2. Shri Prasanna Acharya
3. Shri S.R. Balasubramoniyam
4. Shrimati Renuka Chowdhury
5. Shri Rajkumar Dhoot
6. Shri C.P. Narayanan
7. Shri Parimal Nathwani
8. Shri Sharad Pawar
9. Dr. T. Subbarami Reddy
10. Shri Bhupender Yadav

## **LOK SABHA**

11. Maulana Badruddin Ajmal
12. Shri Muzaffar Hussain Baig
13. Shri E.T. Mohammed Basheer
14. Shri Pankaj Chaudhary
15. Shri P.P. Chauhan
16. Kumari Sushmita Dev
17. Shri Ninong Ering
18. Shri Laxman Giluwa
19. Dr. K. Gopal
20. Shrimati Vasanthi M.
21. Shri Daddan Mishra
22. Shri Prabhubhai Nagarbhai Vasava
23. Shri Chirag Paswan
24. Shri Shivaji A. Patil
25. Shri Nana Patole
26. Shri Harinarayan Rajbhar
27. Shrimati Sandhya Roy
28. Shri Kirti Vardhan Singh
29. Shri Nagendra Singh
30. Shri Vikram Usendi
- <sup>1</sup>31. Vacant

## **SECRETARIAT**

Shri M.K. Khan, Joint Secretary

Shri T.N. Pandey, Director

Shri Mohd. Salamuddin, Additional Director

Shri Rajiv Saxena, Under Secretary

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<sup>1</sup> Due to change of nomination of Shri Nagendra Kumar Pradhan from the Committee w.e.f. 12<sup>th</sup> December, 2017

## INTRODUCTION

I, the Chairperson of the Department-related Parliamentary Standing Committee on Science & Technology, Environment & Forests, having been authorized by the Committee to present the Report on its behalf, present this Three Hundred and First Report on "Genetically Modified Crops and its Impact on Environment".

2. In its meeting held on the 23<sup>rd</sup> December, 2016, 5<sup>th</sup> January, 2017, 8<sup>th</sup>, 27<sup>th</sup> and 28<sup>th</sup> February, 2017, 24<sup>th</sup> April, 2017, 24<sup>th</sup> and 25<sup>th</sup> May, 2017 and 5<sup>th</sup> July, 2017, the Committee heard the views of the representatives of Ministries of Health and Family Welfare and Environment, Forest & Climate Change and Departments of Biotechnology; Agricultural Research & Education; Animal Husbandry, Dairying and Fisheries and some Members of Civil Society and Experts on the subject. During its study visit to Chennai in May, 2017, the Committee also heard the views of the Members of Civil Society and local representatives on the subject.

3. The Committee expresses its thanks to the representatives of the concerned Ministries/Departments, Members of Civil Society and Experts for placing before the Committee the required material and replying to the clarifications sought by the Members on the subject.

4. In its meetings held on 8<sup>th</sup> and 21<sup>st</sup> August, 2017, the Committee considered the draft report and adopted the draft report on 21<sup>st</sup> August, 2017.

New Delhi:  
August 25, 2017  
3, Bhadra, 1939

**(RENUKA CHOWDHURY)**  
*Chairperson,  
Department-related Parliamentary Standing Committee on  
Science & Technology, Environment & Forests,  
Rajya Sabha.*

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# REPORT

India, the second most populous country in the world, is soon likely to be the world's most populous country, considering our rate of increase in the population. The requirement of foodgrains has also been keeping pace with the increasing population. In order to meet our ever increasing demand for foodgrains and keeping in mind the limited land and water resources, high input cost, worsening soil health, dependence on rain, increasing indebtedness, stagnated productivity, and climatic changes, innovative scientific and technological efforts are the need of the hour to give fillip to our agricultural production so as to ensure food security of the country on a sustainable basis.

2. On the one hand we have the ever increasing demand for food and on the other hand, we have to be equally cautious to strike a fine balance between technological and scientific interventions and their impact on our environment, bio-diversity, bio-safety, human health and health of livestock and animals. To address these issues, it is claimed that the genetically modified crops have been developed worldwide for a variety of purposes and reasons such as enhancing agricultural productivity, reducing dependence on the use of pesticides, improving the agronomic performance of crop plants; enhancing the nutritional value of foods and feeds; increasing tolerance to biotic (insect pests, fungal, bacterial and viral diseases) and abiotic stresses (drought, high and low temperature), elevated levels of carbon dioxide (major global warming gas); providing cost effectiveness and sustainable industrial products, cleaning of soils contaminated with heavy metal pollutants including bio-energy (biofuels) crops to produce clean energy.

3. There have been major controversial debates in the country since the introduction of genetically modified crops in India. On the one hand, it has been argued that genetically modified crops can provide a potential solution to many of our malnutrition problems and food security and also help in preserving and protecting the environment by way of minimising dependence on chemical herbicides and pesticides, and increasing crop yield whereas and on the other hand, there have been widespread apprehensions from various sections of the society on the safety of genetically modified crops especially in the area of human and animal health and environmental degradation.

4. In this backdrop and in its endeavour to understand the whole gamut of genetically modified crops and its impact on environment as well as the human and animal health, the Committee selected the subject "Genetically Modified crops and its impact on environment" for examination.

## INTRODUCTION

5. Genetically modified organisms (GMOs) can be defined as organisms i.e. plants, animals or microorganisms in which the genetic material i.e. DNA has been altered in a way that does not occur naturally by mating and/or natural recombination. The technology is often called "modern biotechnology" or "gene technology", sometimes also "recombinant DNA technology" or "genetic engineering".

6. Genetic engineering techniques have enabled development of GM crops that could address several biotic and abiotic stresses as well for enhancing agricultural productivity. This technique allows individual genes to be transferred from one organism into another, also between non-related species. Plants produced from genetic engineering techniques are called GM crops/Transgenic plants.

7. Traditionally, a plant breeder tries to exchange genes between two plants to produce offspring that have desired traits. This is done by transferring the male (pollen) of one plant to the female organ of another. This cross breeding, however, is limited to exchanges between the same or very closely related species. It can also take a long time to achieve desired results.

8. GM technology enables plant breeders to bring together in one plant useful genes from a wide range of living sources, not just from within the crop species or from closely related plants.

This powerful tool allows plant breeders to do faster what they have been doing for years and generate superior plant varieties.

9. The Committee was given to understand that since biotechnology/genetic engineering techniques are new and novel and their effects/consequences are not known properly, several regulations/guidelines and manuals have been put in place from time to time at national and international level. As a party to several International Conventions, India ensures the safe usage of GM crops through the "Precautionary Approach" from time to time. In line with the same, India ratified International Protocols like Convention on Biological Diversity (CBD), Cartagena Protocol on Biosafety (CPB) and Nagoya Kuala Lumpur Supplementary Protocol on Liability and Redress (NKSPLR).

10. The Committee was informed by the Ministry of Environment, Forest and Climate Change that genetic modification of plants using conventional selection and plant breeding principles have been carried out for centuries. The modern techniques of rDNA technology can obtain the same results by directly identifying the genes responsible for the desired character/trait from various source organisms and transferring these into a variety of crop plants and other organisms with high degree of precision.

11. The Committee was informed that genetic engineering differs from other plant-breeding techniques by enabling specific and predictable changes in the transgenic plant. The risks, if any, therefore, associated with the introduction of GM crops should be the same as those with conventionally modified hybrid crops and organisms except the new trait introduced. However, the main difference between the classical selection methods and rDNA technology is that the latter goes beyond the species barrier, i.e., a gene(s) can be transferred across microorganisms, plants and animals.

12. The Department of Biotechnology in its background note on the subject submitted for the consideration of the Committee informed that the process for the GM crop development is very long in which during R&D phase several independent transgenic lines are generated in a variety which is amenable to genetic engineering for obtaining a stable and effective final "Event". Such events are then mobilised into desired cultivated variety or hybrid through backcross breeding methods. Once the final event in a defined genetic background is established, it requires that prior to the environmental release of GM plants, these undergo a case-by-case risk assessment to evaluate any potential for adverse environmental impacts. Statutory Committees (IBSC, RCGM and GEAC) examine each case through a step by step process from research to product development to generate data on food and environmental safety.

13. The Committee was further informed that in the laboratory and contained conditions, the parameters to be examined include description of the host plant; center of origin of the host plant; geographical distribution of the host plant in the country; source and sequence of transgene(s); cloning strategy; characteristics of expression vector(s); characteristics of inserted genes with detailed sequence homology searches; characteristics of gene regulator elements; site of target gene integration into host plant genome; genetic analysis including copy number of inserts, genetic stability over the generations, level of expression of transgene(s) in various tissues, characterization of expressed gene product; mode of action of gene product; compositional analysis; rationale for the development of GM plants in terms of agronomic, nutritional and other benefits.

14. The Committee notes that the Government follows a policy of case by case approval of GM crops. The Ministry of Environment, Forest and Climate Change informed the Committee that as per various guidelines and protocols updated from time to time, the applicant is required to complete several health and environmental safety studies for ensuring the safety of GM products. The environmental safety assessment studies includes (i) weediness potential wherein seed germination & speed of seed germination; seedling vigour & seed size; long continuous seed production; and pod shattering are being booked into, (ii) crossability and gene flow under which extent of cross pollination with related species; extent of cross pollination with other plant species; alteration in pollen viability; and alteration in pollen production are being studied, (iii)

effect on soil microflora to study the alteration in abundance (cfu/gm) and alteration in predominant species in the region, and (iv) effect on pests, diseases and beneficial insects wherein change in the susceptibility for insects and diseases; change in predator abundance; change in receptibility towards honeybees & any toxicity to honey bees are to be studied. The health safety assessment studies include allergenicity & toxicological potential and compositional analysis wherein various related studies such as bioinformatics analysis of proteins, pepsin digestibility, thermal stability, expression levels of introduced protein, acute oral toxicity of purified protein, sub-chronic toxicity with edible parts, alteration in nutrient composition of leaf and seed, and alteration in toxin/anti-nutrient composition in leaf and seed are to be conducted.

## **REGULATORY FRAMEWORK**

15. In India, the manufacture, import, use, research and release of Genetically Modified Organisms as well as products made thereof by the use of rDNA technology are governed by the Rules 1989 of the Environment (Protection) Act, 1986 (EPA) administered by the Ministry of Environment, Forest and Climate Change, Government of India. These rules and regulations are commonly referred to as 'Rules 1989' and are available at the Ministry of Environment, Forest and Climate Change website and cover the areas of research as well as large-scale applications of GM organisms and products made thereof. The regulatory agencies responsible for implementation of the Rules 1989 are the Ministry of Environment, Forest and Climate Change and Department of Biotechnology through the following six competent authorities:-

**(i) Recombinant DNA Advisory Committee (RDAC)**

The RDAC is involved in reviewing the developments in biotechnology both at national as well as international levels and recommend safety regulations as per the indigenous requirements of our country in recombinant research, use and applications from time to time. The RDAC functions are of advisory nature.

**(ii) 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. IBSC is the authority for regulating GH or Lab experiments.

**(iii) Review Committee on Genetic Manipulation (RCGM)**

RCGM is established under the Department of Biotechnology and is mandated to monitor the safety related aspects in respect of on-going research projects and activities 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. RCGM is the authority for Biosafety Research Level I (BRL I) trials.

**(iv) Genetic Engineering Appraisal Committee (GEAC)**

GEAC is established under the Ministry of Environment, Forest and Climate Change. It 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 perspective. 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 II known as BRL-II). Minimum of three seasons/years BRL trials are required for approval of event by GEAC.

**(v) State Biotechnology Co-ordination Committees (SBCC's)**

SBC plays a major role in monitoring and has the powers to inspect, investigate and take punitive action in case of violations of statutory provisions.

**(vi) District Level Committee (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.

16. Rules 1989 are also supported by several Acts and Guidelines put in place from time to time for ensuring the safety of products derived from Living Modified Organisms (LMOs) viz.:-

- The Environment (Protection )Act, 1986;
- Recombinant DNA Safety Guidelines, 1990;
- Recombinant DNA Safety Guidelines and Regulations, 1994;
- Revised Guidelines for research in transgenic plants & Guidelines for toxicity and allergenicity evaluation of transgenic seeds, plants and plant part, 1998;
- Guidelines for generating Pre-clinical and clinical data for rDNA Vaccines, Diagnostics and other Biologicals, 1999;
- The Biological Diversity Act, 2002;
- Plant Quarantine (Regulation of Import into India) Order, 2003;
- Food Safety and Standards Act, 2006;
- Industries (Development & Regulation) Act, 1951 - New Industrial Policy & Procedures, 1991;
- Seeds Act, 1966; Seeds Rules, 1968; Seeds (Control) Order, 1983; Seeds Policy 1988 & 2002;
- Protection of Plant Varieties and Farmers' Rights Act 2001, PPV & FR Regulations 2006;
- Guidelines & Standard Operating Procedures (SOPs) for Confined Field Trials of Regulated, GE Plants, 2008;
- Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants, 2008-ICMR; and
- Protocols for Food and Feed Safety Assessment of GE Crops, 2008

17. The role of various Ministries/Departments related to the GM crops is as detailed below:-

Ministry of Environment, Forest & Climate Change	<ul style="list-style-type: none"> <li>• Primarily responsible for conservation and protection of environment, ensuring environmental and human health safety before release of LMOs</li> </ul>
Department of Biotechnology (Ministry of Science & Technology)	<ul style="list-style-type: none"> <li>• Promotion of biotechnology.</li> <li>• Provide services in areas of research, infrastructure, and generation of human resources.</li> </ul>
Ministry of Agriculture	<ul style="list-style-type: none"> <li>• Policies aimed at agriculture growth.</li> <li>• ICAR responsible for monitoring agronomic benefits of GM technology.</li> <li>• Post release performance of GM crops.</li> </ul>
Ministry of Health and Family Welfare	<ul style="list-style-type: none"> <li>• Policies aimed at protecting and monitoring human health.</li> </ul>
Ministry of Commerce and Industries Department of Customs	<ul style="list-style-type: none"> <li>• Enhance trade with other countries through export/import policies.</li> <li>• Enforcement at point of entry.</li> </ul>

18. The Committee notes that several international organisations such as Organization for Economic Cooperation and Development (OECD); CODEX Alimentaries (FAO-WHO food Code); and Cartagena Protocol on Biosafety (CPB) under Convention on Biological Diversity (CBD) and many functional regulatory systems such as USA Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and the Environmental Protection Agency (EPA); European Union European Food Safety Authority; Brazil; Japan and Australia-Office of the Gene Technology Regulator have published several global consensus documents, protocols and data requirements for food/feed and environmental safety assessment of GM crops.

19. The Committee heard the views of Ministry of Environment, Forest & Climate Change on the subject on 5<sup>th</sup> January, 2017. During his deposition before the Committee, the Secretary, on the issue of regulatory mechanism available with the Ministry, submitted the following:-

*"India has been one of the early movers in the development of regulatory system to ensure bio-safety evaluation and its application and use. The role of the Ministry of*

*Environment, Forest and Climate Change is conservation of environment, protection of environment and ensuring environmental health and human health safety, before release of LMOs.*

*In 1989, the bio-safety rules were framed to cover use, import, export, storage of hazardous microorganisms and genetically engineered organisms. The Environment Ministry takes care of the regulatory mechanism and the Department of Biotechnology is responsible for the scientific support in implementation of bio-safety regulations. We get collaborative support also from the Ministry of Agriculture, ICAR, the Ministry of Health and Family Welfare, the Ministry of Commerce and Industry, the Central Board of Excise and Customs. All of them play a very useful role in the regulatory mechanism that goes behind regulating the genetically engineered organisms.*

*There are at least six stages of scrutiny involved in the entire process. And, each stage has several iterations within it. On an average, a proposal from the lab stage to the point of decision-making on clearance takes, at least, ten years, if not more".*

20. Contrary to the views of the Ministry of Environment, Forest & Climate Change on the issue of regulatory mechanism available with the Government, the Committee in its meeting held on 5<sup>th</sup> January, 2017, was informed by one of the non-official witnesses as under:-

*"RCGM (Review Committee on Genetic Manipulation) is purely a lab committee, an institutional committee. So, there are three levels. There is a lab and RCGM takes care of lab procedures being right, and not escaping into the "grain-drain" and the antibiotic resistance is not escaping into the environment. The next one is, whether the designs for the lab work appropriate? That is the role of Department of Biotechnology. The Department of Biotechnology under the rules is the only legal body. They did try and I sued them for ultra vires. They started to write guidelines. Now, the trials of the Bt cotton, after the planting of that season of 1998, when we broke the case, they immediately ran to RCGM which then sent hand approvals to the people carrying out the trials. It is the wrong body. The statutory approval on environmental safety and bio-safety in terms of a deliberate release into the environment is only to be given by GEAC. This is now recognized by a Supreme Court Order that RCGM, the Biotechnology Department is a promoter Department. It promotes bio-technology and in that technology, it does work out the institutional parameters of a good research. But, anything in the environment is called a deliberate release, once it is out and even with the small trial one bee can pick up the pollen and contaminate. I remember the Biotechnology Department put in submissions that had to be counted by us where they said that they change the language. The language in the rules is that large scale manufacture with hazardous micro-organisms in the contained environment and open-field trials. They mixed up the two and said, 'Large scale open field trials.' Because even a one-by-one plot in the open environment will affect the soil; will affect the pollinator and that is why, all those tests have to be done under contained conditions of green houses. You can find now what is happening to soil in a green house. You can find out what is happening to the toxicity and health through lab research. This is never done in the field. So, when they say that they need to do the open releases for research is very, very false. Not a single health safety test is done in the field. It is done in the lab by feeding trials and they have done no human feeding trials and they have done no animal feeding trials".*

21. **The Committee takes note of the divergent views on the efficacy of existing regulatory mechanism. On the one hand, the Government claims that a very stringent regulatory mechanism has been put in place leaving no scope for any non-adherence whatsoever by the technology developer whereas on the contrary, the Committee has been given to understand by some representatives of the civil society that the existing regulatory**

mechanism is stringent on paper only and the whole process of regulation depends upon the data made available to the regulators by the technology developers. The Committee is surprised to know that none of the Committees referred to in the preceding paragraphs conduct the closed field trials on their own but are solely dependent on the data provided to them by the technology developer. The Committee feels that this leaves a scope for the technology developers to fudge the data to suit their own requirements. The existing regulatory system is, therefore, susceptible to manipulations. The Committee, therefore, recommends that the Central Government should, in consultation with the State Governments and Administrations of Union Territories ensure that the whole process of field trials should be done in closed environment keeping bio-safety and health safety in mind and in collaboration with the agricultural universities so as to minimise the scope of fudging the primary data.

22. The Committee is further perturbed to note that despite having GEAC which consists of experts from various relevant fields, the Government failed to put in place the desired protocols as late as till 2011. The Committee fails to understand as to why the Ministry did not feel the necessity to frame these protocols from the introduction of GM crops in 2002. The Committee takes a serious view of the lackadaisical approach of the Ministry of Environment, Forest and Climate Change as well as GEAC in this matter. The Committee is of the opinion that the casual approach of Ministry and GEAC is indicative of the indifference of these agencies towards the environmental safety and health hazards of human and animals. The Committee feels that the Ministry of Environment, Forest and Climate Change and GEAC should shrug this complacency and be more focused in their approach in the matter.

23. The constitution of GEAC also came up for discussion during the meeting of the Committee held on 25<sup>th</sup> May, 2017 with the representatives of Ministry of Environment, Forest and Climate Change and Department of Biotechnology. The Committee was informed that the GEAC was first constituted on 28.05.1990 and it was last re-constituted on 11.03.2013 for a period of three years. Subsequently, with the approval of the Competent Authority, the tenure of the committee has been extended till re-constitution of the new committee. The Committee expressed its concerns about the *ad hocism* in the constitution of the Committee and also about the criteria adopted by the Ministry for selection of the members of GEAC, their credentials, etc. The Committee also noted that two of the top three positions of GEAC are held by the bureaucrats of the Ministry of Environment, Forest and Climate Change. The Committee is also of the view that there is a conflict of interest in the appointment of some of the members of GEAC. The Committee is also of the opinion that it would be in fitness of things if GEAC is headed by an expert from the field of Biotechnology given the understanding of scientific data and analysis of research and its implication before coming to a conclusion in the matter.

24. The Committee further notes that there is no mention of GEAC in Rules 1989, and later the term has been used just for administrative convenience. The Committee further notes that Members of GEAC are mostly from the Government and Government-aided institutions and there is hardly any representation of civil society on the board. The Committee is equally surprised to note that there is hardly any representation from the States particularly where Bt Cotton has been introduced. The Committee is of the view that the functioning and activities of GEAC call for more transparency. The Committee recommends that the Ministry of Environment, Forest and Climate Change should review the functioning of GEAC along with the organisational set up of GEAC and take necessary corrective measures to make the whole process of assessment and approval more transparent so as to ensure environmental safety, bio-diversity safety, bio-safety, health safety, food and feed safety of our country. The Committee also feels that Acts & guidelines must reflect their concerns in the final consideration.

25. The Committee also feels that the presence of District Level Committee (DLC), which is one of the most important committees to regulate GM crop at the ground level, is hardly felt in any of the States/Union Territories and the functioning of these Committees also create suspicion in the minds of the stakeholders further weakening the confidence level of our farmers, civil societies, environmentalists, etc.

26. Further, Members of Parliament are representatives of the people of that constituency and the absence of their representation in the DLC is surprising. The Committee, therefore, is of the view that Members of Parliament should be nominated as members in the District Level Committees so that the activities of these Committees are also shared with the public.

#### **STATUS OF GM CROPS**

27. As per the Background Note submitted by the Department of Biotechnology, the experience of the first 20 years from 1996 to 2015 of commercialisation of the GM crops, has confirmed that the early promise of crop biotechnology has been fulfilled. Biotech crops have delivered substantial agronomic, environmental, economic, health and social benefits to farmers and, increasingly, to society at large. The rapid adoption of biotech crops, during the initial 20 years of commercialisation, reflects the substantial multiple benefits realized by both large and small farmers in industrial and developing countries, which have grown biotech crops commercially. From the initial planting of 1.7 million hectares in 1996 to 179.7 million hectares in 2015, GM crops achieved a remarkable 100-fold increase. A record 181.5 million hectares of biotech crops were grown globally in 2014. In 2015, approximately 18 million farmers planted biotech crops in 28 countries, including 20 developing countries, of which 97.1 million hectares (over 54%) were planted by small and resource-poor farmers from developing countries. Biotech crops were grown commercially in all six continents of the world. Of the 28 countries planting biotech crops in 2015, 19 countries planted 50,000 hectares or more of biotech crops. These mega-countries include the USA, Brazil, Argentina, India, Canada, China, Paraguay, Pakistan, South Africa, Uruguay, Bolivia, Philippines, Australia, Burkina Faso, Myanmar, Mexico, Spain, Colombia and Sudan. India is occupying the 4<sup>th</sup> position with 11.6 million hectares of GM crop during 2014 and 2015. The top ten countries with GM Crop cultivation in 2015 are as under:-

<b>Country</b>	<b>Crop</b>	<b>Area (million ha)</b>
USA	Maize, soybean, cotton, canola, sugar beet, alfalfa, papaya and squash	70.9
Brazil	Soybean, maize, cotton	44.2
Argentina	Soybean, maize, cotton	24.5
<b>India</b>	<b>Cotton</b>	<b>11.6</b>
Canada	Canola, maize, soybean and sugar beet	3.70
China	Cotton, papaya, poplar, tomato, sweet pepper	11.0
Paraguay	Soybean	3.60
Pakistan	Cotton	2.90
South Africa	Maize, soybean, cotton	2.30
Uruguay	Soybean and maize	1.40

28. The Committee notes that the currently, twenty years after their introduction in 1996, only 6 countries continue to account for over 90% of all GM crop area globally (USA 40%, Brazil 23%, Argentina 14%, India 6%, Canada 6%, China 2%). The Committee was informed by the members of civil society during the deliberation on the subject that there was a decline in GM crop area in 2015. The Committee notes with surprise that inspite of the fact that GM technology is being propagated as the most advanced agricultural technology, 17 of the 20 most developed countries (HDI) do not grow it which includes most of Europe, Japan, Russia, Israel etc. The Committee opines that there is increasing evidence about the lack of safety of GM crops and little or no benefits to justify the risks, most countries in the world do not grow GM crops. The Committee also feels that the

policy makers of these countries, as custodians for both present and future generations, have seen that GM organisms spread rapidly, that the impacts have been unpredictable, potentially hazardous, uncontrollable and irreversible, assessed the benefits and risks, taken note of emerging evidence of harm, and therefore do not permit GM crops. The non acceptance of the most advanced agricultural technology, GM technology, by the most developed countries raises doubts about the efficacy of the technology. The Committee, therefore, feels that the Government of India should conduct a comparative study to examine the reasons for not accepting this technology by these developed countries *viz-a-viz* the reasons led to its acceptance.

#### **GM STATUS IN INDIA**

29. Bt cotton is the only transgenic crop approved for cultivation in India subsequent to extensive evaluation and regulatory process. Bt cotton was introduced primarily for bollworm control. Yields of cotton which was 189 kg lint per ha in 2001 increased to 504 kg lint/ha in 2015. Prior to the introduction of Bt cotton, in 2001 about 13,176 tonnes of insecticides were used for cotton pest control in India in an area of 86 lakh hectares at 1.53 kg insecticide per hectare. In 2013, the insecticide usage was 0.96 kg/ha at a total usage of 11,598 tonnes used in 127.5 lakh hectares.

30. The Committee was informed by the Department of Agricultural Research & Education, Ministry of Agriculture and Farmers Welfare that Bt cotton has been under cultivation for more than ten years and there has been no report of adverse impact on health and environment due to Bt cotton cultivation in India. It was brought to the notice of the Committee that comprehensive bio-safety studies were carried out by ICAR institutions with Bt cotton to study its effects on lab animals such as rabbit, rat and guinea pigs; on broiler chickens for feeding of Bt cotton seed meal (by Central Avian Research Institute, Izatnagar); on fishes (by CIFE, Mumbai) and large animals like cow and sheep (by Central Sheep & Wool Research Institute (ICAR), Avikanagar). Safety of Bt Cry protein on various studies such as primary skin irritation test, irritation to mucous membrane, acute oral toxicity study and skin sensitization study showed that Bt-Cotton did not induce any treatment related observable toxic effects when compared with non-Bt cotton seeds. Studies on skin sensitization revealed that the repeated application of Bt cottonseed extract did not induce dermal sensitization (allergies) to the skin of any tested animals.

31. The Committee was informed by Department of Agricultural Research & Education that a study entitled "Impact evaluation of Bt cotton in Maharashtra" was conducted by ICAR- CICR during 2012-13 funded by Government of Maharashtra for which the data was collected from 2700 cotton farmers belonging to 18 major cotton growing districts of Maharashtra. The analyzed result for overall 18 sample districts indicated that most of the cotton producers adopted Bt cotton during 2005-08. It was found that the incidence of bollworms reduced drastically as a result of introduction of Bt genes. Number of insecticidal sprays decreased after the adoption of Bt cotton from 7-8 application to 4 applications. Presently, there are more than 300 Bt cotton hybrids in the market. The farmers were selecting hybrids based on the advice of the seed dealers or neighbours, however they are not getting expected yield. Only 55% respondents had sown non Bt seeds on border rows or as intercrop of red gram seeds as refugia. After introduction of Bt cotton, about 30% of the respondents used weedicides and 21% used growth regulators in Bt cotton cultivation. Average cotton yield increase from 10 q/ha to 20.8 q/ha after the adoption of Bt cotton. Most of the respondents felt that crop failures are not responsible for the suicides of the farmers and there were no incidences of death of animals due to Bt cotton. 95% of respondents opined that there are no health hazards due to cultivation of Bt cotton. On average Bt cotton farmers got a gross net return of Rs.36831.05/ha.

32. **The Committee notes the growth and success of Bt cotton since its introduction in India. The relevant data furnished by the government agencies for the consideration of the Committee speaks volume about the success of Bt cotton in the country. On the contrary, the members of the civil society informed the Committee that the production of cotton in the country has increased largely due to increase in area under cotton, significant increase**

in irrigation, fertile groundnut areas shifting to cotton, etc. The Committee, therefore, feels that the Government agencies have made attempts to portray a rosy picture with regard to the success of Bt Cotton in the country which actually is not the case.

33. The Committee also notes that the data provided by the government agencies speak only about the production and not the average yield in area which the Committee believes would be the true assessment of the potential of GM technology to find out as to what has been the increase in yield of cotton since the introduction of Bt cotton in the country. The Committee further learns that India's cotton yields increased by 69% in the 5 years (2000-2005) when Bt cotton was less than 6% of total cotton area, but by only 10% in the ten years from 2005 to 2015 when Bt cotton grew to 94% of total cotton area. The Committee is of the considered view that this duality of the claims about the increase in the yield of cotton after its commercialisation in the country needs further examination and clarification. The Committee, accordingly, recommends that the Ministry of Environment, Forest and Climate Change should undertake a comprehensive study to bring out clarity in the matter.

34. The representatives of some NGOs appearing before the Committee also brought out that the production output of GM crops was reducing with successive generation of crops i.e. the productivity of third generation GM crops was much less than the first generation GM crops. As such, the long term benefits of GM crops were under a doubt. In this context, in its meeting held on 25<sup>th</sup> May, 2017, the Committee drew the attention of the representatives of Ministry of Environment, Forest & Climate Change and Department of Biotechnology to a news item stating that in Global Rajasthan Agri-Tech meeting platform, one Minister in the State Government of Rajasthan had categorically stated that Rajasthan already produces 28 to 30 quintals per hectare from normal seed whereas GM mustard is said to be producing only 16 quintal per hectare. The oil content in their mustard was 40 to 42 per cent, which was the highest in the Country.

35. In view of the above, the Committee is at a loss to understand as to why the Government is pushing for GM crops without even having thoroughly assessed its environmental impacts, even when the desired result of increased productivity could be achieved through our own traditional methods of farming and the long term benefits of GM crops were under a doubt.

36. The Committee observes that one of the promising facts about the benefits of GM technology as being promoted by the Government has been that the technology will help in conservation and protection of environment by way of minimising dependence on chemical herbicides and pesticides whereas the Committee in its various interactions with the members of civil society in and outside Delhi was given to understand that the use of insecticides for sucking pests has, on the contrary, increased steeply both in value and quantity because sucking pests became a menace, replacing the bollworm, when Bt cotton grew from 12% of total cotton area in 2012 to 95% of total cotton area 2015. The Committee was further informed that the pesticide use on cotton had begun to decline and was 0.5 kg per ha by 2006 when Bt cotton was only 12% of total cotton area and after the advent of Bt cotton, the insecticide use on bollworm decreased sharply as the bollworm was controlled, but sucking pests took over the ecological niche vacated by the bollworm and the per ha insecticide use had almost doubled to 0.97 kg/ha by 2013 even though Bt cotton had increased to 93% of total cotton. The Committee was also informed that in Maharashtra the annual consumption of pesticides (insecticides, weedicides and fungicides) has gone up drastically from 2800 lakh tonnes in 2002-03 to 11502 lakh tonnes in 2015-16 registering an increase of 311%. The Committee, therefore, recommends that the Ministry of Environment, Forest and Climate Change should before proceeding further in the matter, obtain the results of scientific study by Ministry of Agriculture and then come up with a view in this regard. The Ministry should also come up with a comprehensive note containing the year-wise details of increase in area cultivated under Bt cotton in the

country, usages of pesticides details be compiled State-wise so as to give a clear picture as to whether the usages of pesticides has gone down or up, etc.

37. The Committee brought to the notice of Ministry of Environment, Forest & Climate Change that resistance by the pink bollworm to Bollgard II (BG-II) has been escalated sharply from 2012. The reduction in insecticides used for bollworm and the increase in insecticide for curbing the growing menace of secondary pests after the advent of Bt cotton has increased and sought the views of the Ministry thereon. In response, the Ministry informed the Committee that the matter is being looked into more scientifically and critically by Ministry of Agriculture.

38. The Committee expresses its serious concerns over the problem of sucking pest which is turning out to be a big menace. The Committee also observes that consumption of pesticides has gone down in case of American Bollworm, however, the total usages of pesticide in the areas under cultivation of Bt cotton has not gone down. The Ministry of Environment, Forest & Climate Change has not been able to respond to the facts brought to the notice of the Ministry by the Committee, and has merely stated that the matter is being looked into more scientifically and critically by the Ministry of Agriculture.

39. The Committee takes a serious view on the casual attitude of the Ministry and expresses its concerns as the issue raised by the Committee deserves diligent and immediate analysis with a view to arrive at a conclusion best suited for the country. The Committee further feels that farmers who were using GM seeds had lost sovereignty over the seeds since they had to purchase seeds from the seed selling companies every time even if they were not getting the fair price for their produce.

#### **ASSESSMENT OF FOOD/FEED AND ENVIRONMENTAL SAFETY (AFES) OF GM PLANTS**

40. The Department of Biotechnology in its submission before the Committee stated that Indian law and the Cartagena Protocol on Biosafety, to which India is a signatory, require that a risk assessment be performed prior to the environmental release of a GM plant in India. The purpose of the risk assessment is to identify risks to the health and safety of people and the environment from the cultivation of the GM plant, when compared with the cultivation of the non GM version of the plant, and to characterise the risks on the basis of severity and likelihood.

41. The Committee was given to understand that the Risk Analysis Framework describes the principles of risk analysis used by the Regulatory Agencies to protect human health and safety, and the environment, in accordance with the Environment (Protection) Act, 1986. This Risk analysis approach followed in India is also in agreement with recently published report by National Academy of Science, USA (2016) and an article by Gregory et al. (2016). Risk analysis integrates the assessment, management and communication of risks posed by GM plants. The risk context defines the parameters within which risk is assessed, managed and communicated.

42. The Department apprised the Committee that risk assessment process for GM plants described is based on a comprehensive, transparent, and science based framework by which regulators can identify potential harms that might be caused by GM plants, collect relevant scientific data pertaining to the likelihood and severity of any harms, and consistently evaluate the level of risk posed by the use of GM plants. This framework uses a conventional approach to risk assessment similar to ones used in many other areas of risk assessment, and it incorporates a case by case approach that takes into account a variety of sources of information.

43. The Committee was further informed that using Problem Formulation, regulators identify protection goals, formulate risk hypotheses that explore causal relationships between the cultivation of GM plants and the identified goals, and then determine which relevant data are needed to test the hypotheses. Using these data, regulators will assess the severity and likelihood of harms and ultimately evaluate the level of risk that would result from cultivating the GM plant. This process is performed for each risk hypothesis generated through Problem Formulation. More recently (2016), the Ministry of Environment, Forest and Climate Change has brought out an elaborate and updated Environmental Risk Assessment (ERA) guidance document after a

through process of stake holder's consultation process. The ERA is consensus document which is in line with the ERA guidelines followed by all major functional regulatory agencies across the globe.

44. Risk assessments method used for the environmental release of a GM plant are performed using the below mentioned fundamental principles:

- Risk assessments must be carried out in a scientifically sound manner.
- Risk assessments should be comparative. For example, according to the Cartagena Protocol on Biosafety, "Risks associated with living modified organisms.....should be considered in the context of the risks posed by the non modified recipients or parental organisms in the likely potential receiving environment."
- Risk assessments should be carried out on a case by case basis, taking into account the specific circumstances or context for each individual application.

45. It was submitted that the Risk Hypothesis is based on a comparison between the GM plant and the non GM version of the plant, typically, the host variety or a near isogenic parental line, and so the data collection process must first collect sufficient information to fully characterise the biology of the non GM version of the plant. This information establishes a background of long standing familiarity with the crop and with the breeding of novel varieties using traditional methods.

46. The Committee was also informed that relevant data should focus on characteristics that could likely have environmental implications, such as the plant's reproductive biology, whether the plant is known to have weedy or invasive properties, and whether the plant is known to produce toxic or allergenic substances. The goal is to identify specific ways, including both intentional changes and unintended ones, in which the GM plant is significantly different from the non GM version and how those differences could impact the environmental resource in question. Useful data would be taken from a variety of sources: published scientific literature, applications submitted for confined field trial permits, past environmental risk assessments of GM plants with the same phenotype, including risk assessments from other countries, and professional experience of the risk assessors. Following such due diligence through scientific appraisal process and consultations, the GEAC may determine that organism or product regulated under this Rules 1989 of Environmental (Protection) Act 1986 as safe for intended purpose or environmental release with post release risk management conditions, if any. Finally, the Ministry of Environment, Forests and Climate Change, Government of India through approval process provides authorisation for intended use. However, such authorization shall also be subject to all other laws, rules and regulations made thereof in the Central and State Governments relevant at that time.

**47. The Committee notes the existing mechanism available in the country for the assessment of Food/Feed and Environmental Safety (AFES) of GM crop. The Committee finds it very surprising that despite having so many levels of scrutiny in place, none of these levels of scrutiny is directly involved in the process of Environmental Impact Assessment and the regulators are predominantly relying upon the data made available by the applicant himself. The Committee is of the view that inspite of claiming to have the most stringent assessment process, we are lacking on the very basis of the same. The Committee, therefore, recommends that the whole process of evaluation should be carried out by an independent agency consisting of the people of impeccable credentials in the relevant field to ensure that there is no violation of the existing regulations in this regard.**

48. During its interaction with the various members of the civil society the Committee learnt that there are numerous concerns and apprehensions in the minds of the stakeholders about the whole assessment process which is largely found to be non-transparent and non-participatory. It was also brought to the notice of the Committee that ICAR - Directorate of Rapeseed - Mustard Research has informed in response to an RTI application that DRMP has not conducted any trial and the data received from the technology developer was passed to DRMR for onward transmission to GEAC.

49. The Committee further notes that the very purpose of the risk assessment process for GM plants which is based on a comprehensive, transparent, and science based framework by which regulators can identify potential harms that might be caused by GM plants, collect relevant scientific data pertaining to the likelihood and severity of any harms, and consistently evaluate the level of risk posed by the use of GM plants gets defeated in the absence of any long term scientific study to further corroborate the claims of the Government in the matter. Throughout its examination of the subject, the Committee raised the issue with all the concerned government agencies that without having any long term scientific studies how the government has arrived at this conclusion that GM crops would not have any adverse impact on human as well as animal health. It is surprising that the Government has also failed to come up with even a single study assessing the impact of Bt cotton on our environment, bio-diversity, bio-safety, ecosystem, etc. The Committee takes serious note of this apathy of the concerned government agencies. The Committee strongly believes that given the complexity and uncertainty of the GM technology, its evaluation should be done after taking into account the long term impact on our environmental safety, bio-diversity safety, bio-safety, health safety, food and feed safety of our country.

50. The Committee further notes that risk analysis integrates the assessment, management and communication of risks posed by GM plants and the risk context defines the parameters within which risk is assessed, managed and communicated. In this regard, the Committee is of the considered view that the whole issue of GM technology and its usage has not been communicated to the society to the desired level. None of the government agencies involved in the matter seems to have taken it to the public thus creating a suspicion in the minds of public about the efficacy of this technology. The Committee, therefore, recommends that all the concerned Ministries/Departments should take necessary corrective measure in the matter and put every piece of information pertaining to the subject for the public scrutiny which the Committee feels in turn would make the whole process more participatory and transparent and also help clearing the doubts that seem to have been deepened in minds of our public.

#### **GM CROPS - IMPACT ON ENVIRONMENT**

51. The Ministry of Environment, Forest and Climate Change through its background note submitted that the safety of GM crops is crucial for their adoption and has been the object of intense research work. The literature produced over the years of GM crop safety is large. However, GM crop safety literature is still often ignored in the public debate hence, a publicly accessible database were created with the aim of improving visibility and regulatory agencies have funded research programs with the intent to gain new scientific evidence addressing the public concern on the safety of GM crops. Various parameters considered for assessing potential impacts of the introduction of genetically engineered crops relates to crop diversity, biodiversity of wild relatives, non-target soil organism, weeds, land use, non-target above-ground organisms, and area-wise pest suppression.

52. The Ministry informed the Committee that biodiversity preservation is unanimously considered a priority by the scientific community and society at large. A risk may exist if a GM plant possesses an introduced trait having the potential to adversely impact individual species, ecosystems, or biodiversity and these potential risks must be evaluated before the GM plant may be authorised for widespread planting. It was submitted that risk assessors use scientific data regarding potential hazards and exposure to assess the likelihood of adverse impacts on populations of organisms as well as on communities of organisms and their diversity. The Committee was apprised that the potential impact of GM crops on biodiversity can be investigated at different levels (crop, farm and landscape) and different organisms or microorganisms (target and non-target) can be considered.

53. The Committee was apprised that if we consider the effect of GM crops on the target species, weeds or pests, a reduction of biodiversity is obviously expected and necessary for the

success of the crop. On the other hand, higher reductions on biodiversity is generally expected with non-GM crops and herbicide/insecticide applications, because the chemicals used are often more toxic and persistent in the environment. In a systematic study of 20 years conducted pre- and post adoption of Bt cotton in China at 36 sites, it was seen that marked increase in abundance of generalist arthropod predators and a decreased abundance of aphid pests associated with widespread adoption of Bt cotton and reduced insecticide sprays in the crop. Evidence showed that the predators might provide additional bio control services spilling over from Bt cotton fields onto neighboring crops (maize, peanut and soybean), thereby proving that Bt crops can promote bio-control services in agricultural landscape.

54. In its meeting with the representatives of the Department of Agricultural Research & Education, Ministry of Agriculture and Farmers Welfare, the Committee desired to know the views of the Department on the environmental impacts, biosafety and risk management of GM crops. In response, the Department of Agricultural Research & Education informed the Committee that with the development of transgenics, the issues of bio-safety, food safety, the environmental impact and their risk assessment have become one of the great concerns of researchers, consumers and policy makers around the world. Therefore, it is of crucial importance that transparent and science based approaches are used to adopt to conduct safety assessments on GM crops before their commercialisation so that the public at large should be informed about the benefits and risks, if any, of the GM foods. Environmental risk assessment and food/feed safety need to be carried out as a strict scientific basis including economic analyses of benefits and costs to determine the socio economic feasibility of implementing specific biotechnology application. Biosafety legislations and regulatory institutions to implement them have been put in place by many countries including India both for research and trade of GM crops and food.

55. On the issue of gene flow and potential of the introduced genes to outcross to weedy relatives of crop plant, the Department of Agricultural Research & Education informed the Committee that this is a major environmental concern associated with GM crops and has the potential to create new super weeds. It was brought to the notice of the Committee that a herbicide tolerant gene may escape through pollen into nearby farms and fields, to another GM or non-GM cultivars or to a wild and weedy relative. It was also informed that the possibility of these escaped genes seems very unlikely, and is being regulated through extant monitoring system.

56. On the same issue of gene flow, the Ministry of Environment, Forest and Climate Change and Department of Biotechnology submitted before the Committee that in an agricultural context, the gene flow between cultivated and wild species and its impact on biodiversity is an issue that exists independently of GM crops. However, in the absence of any selection pressure this gene flow does not lead to any advantage to the receiving plant. Horizontal gene transfer (HGT) to soil bacteria is also studied and the results indicate that soil bacteria can uptake exogenous DNA at very low frequency ( $10^{-4}$  to  $10^{-8}$ ) in laboratory experiments whereas experiments in the field did not show any evidence of HGT. Apprising the Committee about the gene flow in Mexico for commercial use of GM corn, it was brought to the notice of the Committee that particular concerns have been raised about the potential impact of GM crops on diversity of crop landraces and wild relatives in centers of origin. The Committee was informed that any gene from commercial varieties, whether from GM varieties or not, may introgress into landraces. However, the potential impact of such introgression would depend on consequences, that is, whether or not the additional genetic material confers any fitness advantage or disadvantage.

57. The issue of contamination and cross pollination with non-GM and creation of super weed was deliberated by the Committee in its meetings with the members of civil society. The Committee was informed that there are numerous instances of even open air field trials of GM crops leading to contamination of non-GM crop. It was submitted that such cross pollination with non-GM could also be in the context of related and wild species (not just intra-specific contamination), which gives rise to the possibility of a selection advantage being conferred on the

new contaminated species. This has a risk of erosion of native diversity and genetic purity being affected. The Committee was given to understand that contamination has an immediate regulatory implication for organic farmers, of their organic status being withdrawn. The Committee was further informed that in USA, farmers have faced a nightmare with a particularly tenacious species of glyphosate-resistant weed called Palmer amaranth, or pigweed, which can grow about three inches a day and reach seven feet or more, choking out crops; it is so sturdy that it can damage harvesting equipment and in an attempt to kill the pest before it becomes that big, farmers in the US began plugging their fields and mixing herbicides into the soil. It was also submitted that the increase in the number of glyphosate-resistant weeds worldwide has been steep from the time of large scale adoption of GM crops. It was informed that more than 50% of farms surveyed for a study were infested with glyphosate resistant weeds in 2013 in the USA. In southeastern USA, a reported 92% of cotton and soybean fields are infested with superweeds as a result of Roundup Ready HT crops.

58. **The Committee notes the issues highlighted by the representatives of Civil Society regarding contamination and cross pollination with non-GM and creation of super weed. The Committee feels that these issues are of vital importance from the perspective of long term impact of GM crops on our environment since cross pollination and contamination of non-GM crop have the potential of destroying our traditional crops as well as organic farming. It is noteworthy that the Department of Agricultural Research & Education, Ministry of Agriculture and Farmers Welfare has accepted that an herbicide tolerant gene may escape through pollen into nearby farms and fields, to another GM or non-GM cultivars or to a wild and weedy relative. The Committee is therefore, of the view that if GM crops are allowed in the midst of other indigenous farming, there is no way contamination can be stopped. India, being endowed with various types of naturally available organic form of nutrients in different parts of the country, has a competitive advantage in the global market due to low production cost and diverse climates to grow a large number of crops all through the year. The Committee, accordingly, recommends that the Ministry of Environment, Forest and Climate Change, in consultation with the Department of Agricultural Research & Education, Ministry of Agriculture and Farmers Welfare, should study the matter threadbare scientifically and take the desired measures in the matter.**

59. The Committee desired to know from representatives of the Ministry of Environment, Forest & Climate Change regarding the development of insect resistance to GM crops. In response, the representative of the Ministry informed the Committee that one of the major concerns of GM crops with insect resistance is that in long run, the insects develop tolerance and can no more be managed. Such reports to Bt cotton in terms of laboratory and field studies have been reported. It was submitted that it is important to have a management strategy so that the genes and their products in GM crop continue to be effective for as long as possible. As part of a resistance management strategy, refuges of a non-insecticidal crop or non-GM cotton lines are grown alongside Bt transgenic crops in order to dilute resistance in populations of *H. armigera* moths which may survive the Bt toxin. The Committee was informed that in Bt cotton cropping systems, the refuge is usually composed of Pigeon pea or non-Bt cotton. Poor management of refuges, (in particular the farmer do not grow non-GM cotton for economic reasons) and insufficient irrigation are the greatest barriers and to deal with the issue, a new technique called Refugia in Bag with five percent non-Bt cotton is advised to overcome the situation.

60. The Department of Agricultural Research & Education, Ministry of Agriculture and Farmers Welfare in its submission on the issue informed the Committee that one of the concerns with Bt crops is that it may lead to the development of insect resistance to Bt crop. In this context, strategies like pyramiding of insecticidal genes with divergent mode of action along with additional resistance management practice have been initiated. It was further informed that commercialisation of transgenic crops may lead to erosion of biodiversity and contaminate gene pools of endangered plant species and many endangered plant species are threatened by habitat

loss or hybridization with cultivated plants. The potential transfer of a transgene to local flora and its any possible subsequent impact on specific plant species is thus an issue that needs to keep in view before commercial release of specific transgene.

61. The Committee was informed by the representatives of civil society that genetically modified seeds that are engineered to resist pests, such as Bt crops, express the pesticide in every cell of the plant from root to fruit and involve constant exposure to the pesticide, unlike sprayed pesticides which are applied primarily during pest attacks. The Committee notes that the amount of Bt toxins produced by GM Bt crops can be much greater than the reduction in chemicals sprayed. The Committee feels that such heavy and continuous exposure induces the target pest to develop resistance far more rapidly than would occur with intermittent exposure to sprayed insecticides. Such rapid development of resistance has been found in India too for Bt cotton. Bollgard I was released in 2002, and Bollgard II was released in 2006-7, when it was found that the pink bollworm was showing resistance. However resistance by the pink bollworm to Bollgard II was reported by 2012 - and has escalated sharply thereafter.

**62. In view of the facts brought out above, the Committee is, therefore, of the view that given the small farm holdings of our farmers it seems to be a bit difficult to create refugia to combat resistance as suggested by the Ministry of Environment, Forest and Climate Change. The Committee, therefore, is of the opinion that the matter needs to be examined thoroughly and directs the Ministry of Environment, Forest and Climate Change to take necessary action in this regard.**

63. The Committee while sharing the concern expressed about GM genotypes becoming the dominant cultivars, sought the response of the Ministry of Environment, Forest and Climate Change thereon. The Ministry, accordingly, informed the Committee that one of the apprehensions about the adoption of GM technology is the likelihood of one or a few GM genotypes becoming the dominant cultivars thus leading to reduction of crop diversity in farmers' fields. However, GM crops may actually increase crop diversity by enhancing underutilised alternative crops, making them more suitable for widespread domestication. One example is that the introduction of Bt cotton in India led to more Bt varieties becoming available over time. Concern over Area-wise pest suppression has also been studied in detail. The results shows that pest suppression not only reduces losses to adopters of the GM Bt crop technology, but may also benefit non-adopters and growers of other crops by reducing crops losses and/or the need to use pest control measures such as insecticides.

64. The Ministry of Environment, Forest and Climate Change also informed the Committee that the pest management traits that are embodied in currently commercialised GM crops have led to changes in the use of pesticides that may have impacts on biodiversity. It was brought to the notice of the Committee that if the planting of GM pest-resistant crop varieties eliminates the need for broad-spectrum insecticidal control of primary pests, naturally occurring control agents are more likely to suppress secondary pest populations, maintaining a diversity and abundance of prey for birds, rodents and amphibians.

**65. The Committee notes the explanation of the Ministry of Environment, Forest and Climate Change that the pest management traits that are embodied in currently commercialised GM crops have led to changes in the use of pesticides that may have impacts on biodiversity.**

**66. The Committee while noting the changes in pest and disease ecology also observes that insects are a vital part of agricultural, horticultural and forest ecosystems and vitally ensure food security as pollinators and natural pest controllers. The Committee learns that heavy and continuous exposure induces the target pest to develop resistance and there are several studies pointing out as to how insect resistance Bt crops in particular have led to changes in pest and disease ecology. The Committee observes that in India, this has been experienced firsthand in the case of Bt cotton where secondary pests have become major pests. The Committee notes that Bollgard I was released in 2002 and Bollgard II was released in 2006-07 when it was found that the pink bollworm was showing resistance. The**

Committee further notes with concern that the incidence of white fly, mirid bugs and other such pests in Bt cotton crop has led to increased use of chemical insecticides with the result that at the end of 15 years of Bt cotton cultivation and expansion (to nearly 95% of the cotton cultivation area), India's pesticide use on cotton has only increased and not decreased. The Committee is of the view that such usage of pesticides will have their own environmental impacts in terms of contamination of resources and impact on unintended organisms. The Committee, therefore, recommends that the Ministry should make a scientific study to examine the impact of pesticides on the environment in general and ecology in particular of the areas under cultivation of Bt cotton and submit the findings of the study for the consideration of the Committee. The Committee is also of the view that the impact of GM crops on insect biology further needs to be studied.

67. On the issue of pest resistance build up, the Committee notes that insect resistant GM crops are based on faulty pest management science, where a target pest is sought to be killed through the use of an externally sprayed pesticides, or in-planta toxin production wherein if the target pest eats the Bt plant, it gets killed. The Committee was informed by some representatives of civil society that in this kind of pest management, through simple natural principles of evolution and mutations, pests develop resistance as has been seen in the case of pink bollworm in India's Bt cotton where the GM crop is unable to control the pest anymore forcing our farmers to resort to higher use of chemicals since this has been found as an unsustainable pest management strategy/science.

68. The Committee takes note of all the submissions of the Ministries/Departments referred to in the preceding paragraphs, which make us believe that the environmental impact of GM crops is not a matter of serious concern at all and all these agencies have no doubt that there would be any negative impact of these crops on our environment, bio-diversity, ecology, etc. In view of the concerns raised by the Committee in the earlier paras in the report, the Committee is of the opinion that either all these agencies have turned a blind eye to the negative impact of GM crops on our environment or are indifferent to the threat to our environment due to these GM crops. The Committee also feels that all the government agencies seem to have relied blindly upon the finding of the studies conducted in different parts of the world to justify their views. The Committee is of the considered view that given the topography of our country and its diversity, it is imperative that the government agencies should come up with indigenous studies to substantiate their claim that there is no threat posed to our environment on account of GM crops.

69. The Committee further feels that at an environmental level, the enormous complexity of living organisms and their web of inter-relationships has evolved over millennia and sudden, lab-based, insertion of genes, often across species, results in unpredictability of environmental impacts at multiple levels. It is noteworthy that currently 99% of GM crops are modified to express only 2 traits 'Herbicide Tolerance' and 'Insect Resistance or Pesticide Producing' and both these traits constitute major interventions in living agro-ecosystems, natural ecosystems and human diets. The Committee also feels that Bt crops continuously express a pesticide which can adversely affect non target organisms like soil microbes, insects, birds or even mammals and also rapid development of resistance in the target insect.

70. The Committee further notes the impact of GM technology on the microbes, soil and water. The Committee was informed that Bt toxin produced in genetically modified Bt Crops is present in every part of the plant, so when the parts that have not been harvested decompose, a considerable amount of the toxin may reach the soil. The Committee also observes that the use of herbicides also impacts soil micro organisms, which are the foundation for both agricultural and wild ecosystems, and affects water sources for all species including humans. The Committee strongly feels that before we allow any commercialisation of GM crops in the country, the Ministry owns a responsibility to inform the nation that GM crops are not going to have any negative impact on the microbes, soil

and water. The Committee, therefore, recommends that the Ministry should examine the matter threadbare in the light of the points raised by the Committee.

71. The Committee also understands that GM crops do impact unintended organisms including beneficial organisms like bees and butterflies along with predators which are also impacted. The Committee notes that the impact is related to both the genetic engineering process as well as by accompanying agricultural practices in terms of use of pesticides and herbicides on GM crops and GM seeds. The Committee feels that the Ministry of Environment, Forest and Climate Change should study the impact of GM crops on the unintended organisms including beneficial organisms like bees and butterflies. The Committee further desires that a study be made to examine the impact of GM crops on monarch butterflies, honeybees, earthworms, etc. which were shown to have been impacted in various studies.

72. One member of the Civil Society, who also happened to be former Secretary, Department of Biotechnology, Government of India informed the Committee that hardly any research or study on the impact of GM crops was funded by Department of Biotechnology and majority of the research was supported by seed and insecticide companies which cannot be relied upon. **The Committee is, therefore, of the considered view that any scientific research/study to assess the impact of GM on environment should be funded by the Department of Biotechnology for its sheer credibility.**

### **IMPACT OF GENETICALLY MODIFIED CROPS ON HUMAN HEALTH**

73. In its endeavour to apprise itself of the views of the Government on the concerns and apprehensions expressed on account of impact of GM crops on human health, the Committee heard the views of the Secretary, Department of Health Research in its meeting held on 24<sup>th</sup> May, 2017. In the Background Note of the Department of Health Research, submitted as under:-

“The genetically modified products that are currently on the international market have all passed safety assessments conducted by national authorities. These different assessments in general follow the same basic principles, including an assessment of environmental and human health risk. So far, no serious health problem in humans has been shown as a result of the consumption of such foods by the general population in the countries where they have been approved.

The safety assessment of GM foods generally focuses on: (a) direct health effects (toxicity), (b) potential to provoke allergic reaction (allergenicity); (c) specific components through to have nutritional or toxic properties; (d) the stability of the inserted gene; (e) nutritional effects associated with genetic modification; and (f) any unintended effects which could result from the gene insertion. According to World Health Organisation the three main possible issues concerning human health are the potential to provoke allergic reaction (allergenicity), gene transfer and outcrossing.

A study carried out on Genetically modified cotton and farmers health in China indicated that the adoption of Bt cotton can substantially reduce the risk and the incidence of pesticides poisonings (Hosain et al, 2004). Another study carried out in Taiwan reported that no differences were observed on allergenicity between GM broccoli and non-GM broccoli (Liao et al, 2013). A study carried out by Netherwood et al (2004) in United Kingdom to assess the survival of transgenic plant DNA in the human gastrointestinal tract reported that gene transfer did not occur during the feeding experiment. A study carried out by Council of Scientific Industrial Research in India on allergenicity response in humans reported that GM mustard may be as safe as its native counterpart with reference to allergenic responses (Misra et al, 2012).

However, few studies published a decade ago reported that an allergen from a food known to be allergenic can be transferred into another food by genetic engineering (Nordlee et al, 1996). Another study carried out in United Kingdom to assess degradation of transgenic DNA from genetically modified soya and maize in human intestinal simulations

indicated that some transgenes in GM foods may survive passage through the small intestine (Martin-Orue, 2002).

A review based on 24 studies on laboratory animals published in 2012 in Food & Chemical Toxicology did not suggest any health hazards and in general there were no statistically significant differences with parameters observed. The studies reviewed present evidence to show that GM plants are nutritionally equivalent to their non-GM counterparts and can be safely used in food and feed (Snell et al, 2012)

Three studies published from India on GM mustered between 2006 and 2014 on allergenicity in mice demonstrate substantially equivalent allergic responses against GM as well as its native counterpart. Therefore, the GM mustard may be as safe as its native counterpart with reference to allergenic responses.

A recent study published in 2017 in Food and Chemical Toxicology carried out on rats in China to assess safety of genetically modified milk revealed that there was no difference in the nutritional composition of genetically modified and conventional milk. Furthermore, body weight, food consumption, blood biochemistry, relative organ weight and histopathology were normal in rats from both groups. No adverse effects were observed between groups that could be attributed to varying diets (Chen et al, 2017)

A recent study published in 2016 in British Poultry Sciences on Japanese quail fed diets containing genetically modified plant ingredients over 10 generations did not indicate the existence of any pathological changes caused by pathogens, nutritional factors or environmental nature. According to the obtained results, it was concluded that there was no negative effect of the use of GM soya or maize with regard to bird health status or to the presence of transgenic DNA in the final consumable product (Kossakowska et al, 2016).

A critical review published (2014) in Environment International demonstrates an incomplete picture regarding the toxicity (and safety) of GM products consumed by human and animals (Zdziarski et al, 2014). Therefore, each GM product should be assessed on merit, with appropriate studies performed to indicate the level of safety associated with them.

The review of available literature indicates that genetically modified crops available in the market that are intended for human consumption are generally safe and their consumption is not associated with serious health problems. However, as different GM organisms include different genes inserted in different ways, individual GM foods and their safety should be assessed on a case-by-case basis”.

74. The Committee enquired about the scientific studies undertaken to assess the impact of GM food on human health. Responding to the query of the Committee, Secretary, Department of Health Research stated about the scientific studies done to assess the impact on human health submitted the following:-

*“In terms of food, it would be very difficult to design a study where you tell one group of people that you have to take only this GM food and, then, you tell another group of people to not take that GM. Then, you have to follow them for many years. So, this type of study has not been done anywhere in the world. It has not been done in India also”.*

75. The Committee in its meeting held on 5<sup>th</sup> July, 2017 with the Secretary, Department of Health further desired to know the views of the Department in the matter of impact of GM crops on human health. Sharing the views of the Department of Health about the scientific studies done on humans, the Secretary submitted that no study till date has been carried out on humans. He further submitted that scientists in ICMR feel that doing this kind of a test on human beings right now does not seem to be practical as it is very difficult to feed one person GM alone to test its impact. He also submitted the following:-

*“We have requested WHO also to give us some backup material on this as to which way we should be acting, collective evidence from the globe. One of the issues in this is that you did mention that one should take preparatory measures. The basic issue arises out of the FSSAI Section 22, which talks about the Genetically Modified food.*

*The essential work on this was being carried out by the Genetic Engineering Appraisal Committee which falls under the Ministry of Environment and Forests but that, unfortunately, did not lead anywhere. It got, in a way, aborted in 2016 when no further action was taken on that. FSSAI, meanwhile, instead of duplicating this effort that has already been made by GEAC moved away to what you call making the consumers aware through labelling, in fact, trying to say that this food does have Genetically Modified element so the harm should be well-known to them. That is a provision in Section 13. A scientific panel for the Genetically Modified organism in food was formed in the FSSAI. They have come to a conclusion. They have said that they recommended to FSSAI that the labelling should be mandatory and designated food products have been defined. Any food product having GE ingredient 5 per cent or more shall be labelled is what they have said. This has gone to their panel and to the authority which will take a view on this and we hope to get a decision on the labelling aspect very soon. A lot of work has already been done on it and the scientific panel has collected all the evidence. Based on that, they have put it across to the authority. Once the authority does the labelling work then the enforcement will become a little easier and this is going to happen quite soon. We are moving in that direction. Once the labelling comes into force, some of the imported items -- where we are still not very clear what the elements of the Genetically Modified food are -- is something they are still working on. Standard setting is not something that the FSSAI is doing right at the moment. They are concentrating on labelling. So, I thought I should bring these facts before the hon. Committee. Apart from Sections 22 and 13, the evidence, once it comes to us, I mean, the Department of Health, as you advised, would rather be pro-active than be reactive once a disease sets in. We are looking for evidence and ICMR has promised that they will give us some lead on this very soon so that, at least, advisories can go out because no food product has really been approved so far. There are certain Genetically Modified food which we are told is coming in as a mixed form in some of the imports that is happening”.*

76. **The Committee notes with surprise that the Department of Health Research has not taken any action with regard to examination of impact of GM crops on human health except narrating the studies done in other countries growing GM crops. Equally surprising to note is that there has been no in house scientific study carried out till date to study the impact of GM crops on human health. The Committee fails to understand as to how the Department of Health Research gave its approval for the commercialisation of GM crops in India even without having the matter studied thoroughly on its part. The Committee, therefore, finds the approach of the Department of Health Research very casual and it is disheartening to note that the Department till date did not bother to collaborate with any of the countries which are growing GM crops for in depth research. The Committee is of the firm opinion that the Department of Health Research should have taken an initiative instead of sitting idle on the matter and approving the commercialisation of GM crops without making any scientific study for the purpose. It is all the more painful to note that only acute and sub-chronic studies have been done and chronic, i.e., long term effects have not been studied on the human health anywhere in the world. The Committee also feels that the Departments concerned with the subject have this approach and indifferent attitude toward the issue which if not dealt scientifically may turn out to be a disaster not only for us but for the generations to come also. The Committee is also of the strong opinion that if there has been no threat attached to the GM crops either to human health or environment as being claimed by our government agencies, the whole world would have by now adopted this technology.**

77. **The Committee is also at a loss to understand the haste being made for the commercialisation of GM crops in the country. The Committee is of the considered view that without having been scientifically proven that GM crops would have no adverse**

**impact on human health and solely relying on the studies which have not been done here in India and on our own population as well as in the context of our climate and environment negating any adverse impact on human health, the Government should reconsider its decision to commercialise GM crops in the country.**

78. It was also brought to the notice of the Committee that GM products being sold in the country had no such indication. The Committee feels that it is every citizen's right in the country to be aware of the type of food being bought by him/her and therefore, proper labeling is imperative of all the GM products being sold in the country. **The Committee though appreciates that process to label GM products has been started. The Committee feels that it is very late in the day for FSSAI to take a decision to label GM foods imported into the country. However, the Committee strongly recommends that labeling on GM foods must be done with immediate effect.**

#### **IMPACT OF GENETICALLY MODIFIED FOOD ON ANIMALS**

79. In its meeting held on 5<sup>th</sup> July, 2017, the Committee heard the views of the Secretary, Department of Animal Husbandry, Dairying & Fisheries, Ministry of Agriculture and Farmers Welfare to examine the impact of GM food on animal health.

80. Secretary, Department of Animal Husbandry, Dairying & Fisheries informed that various trials were conducted by the Indian Council of Agricultural Research (ICAR) to study the impact of genetically modified food/feed items on animals in various institutes. The institute-wise information, as shared by the Department of Animal Husbandry, Dairying & Fisheries, is as follows:

**ICAR-Central Avian Research Institute, Izatnagar, Bareilly (U.P.)** has conducted series of feeding trials on transgenic crops (*Bt* cotton, *Bt* brinjal, transgenic corn and *Bt* rice) in broiler chickens (0-42 days of age) during the years 2003-2011. The results in terms of body weight gain, feed intake, feed conversion efficiency, immune response, carcass attributes and organs yield indicated that genetically modified crops provided similar response to that of their respective non-*Bt* counterparts or commercial check crops in broiler chickens.

**ICAR-Central Sheep and Wool Research Institute (CSWRI), Avikanagar (Rajasthan)** conducted 120 days trial in weaner lambs (at a high plane of nutrition) in the year 2007 to study the bio-safety of *Bt* cotton seed in lamb feeding. The study was conducted in collaboration with ICAR-Central Institute for Cotton Research (CICR), Nagpur. Nutrient (organic matter i.e. OM, crude protein i.e. CP and fibre fractions) and mineral (Ca, P, Mn, Co and Zn) contents were identical in *Bt*-cotton and non-*Bt* cotton seeds. The study revealed that 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.

81. Similarly, Rumen fermentation characteristics viz., pH, TVFA and NH<sub>3</sub>-N concentrations were not influenced by feeding of GNC, non- *BT* cotton seed or *BT*-cotton seed in lamb diets. Feeding of *Bt*-cotton seed increased RBC and decreased WBC in blood. The serum IgG levels did not change due to *Bt* and non-*Bt* cotton seed feeding indicating that feeding of *BT* cotton seed did not alter immunity and allergen status. Internal organs weights as g per kg empty live weight (ELW) indicated precise effect of *Bt* cotton seed feeding on internal organ changes. The weights of kidney, spleen, pancreases, heart, lung, penis, kidney fat, caul 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.

**ICAR-Indian Veterinary Research Institute (IVRI), Izatnagar, Bareilly (U.P.)** conducted 90 days feeding trials with concentrate mixtures @ 250g/day/animal of which 12.5 % was cottonseed (non *Bt* version of JKC 738 or *Bt*. JKC 738 *Bt* trait) on 36 Barbari goats of 1 year of

age. The study indicated no significant effect on organ biometry as compared to Indian Cotton and Control groups. On postmortem examination none of the goats belonging to Bt Cotton or Indian Cotton groups showed lesions of toxicity. There was no variation in the haematological (haemoglobin, WBC and DLC), biochemical (total serum protein, glucose, blood urea nitrogen, bilirubin, GOT, GPT, alkaline phosphates, LDH) and serum mineral status (Calcium, Phosphorus, Magnesium, Potassium, Sodium, Iron, Copper, Zinc and Manganese). It was concluded that on the basis of results obtained, there was no toxicity of any kind in the goats fed concentrate mixture having crushed Bt cotton seeds (12.5%) and concentrate mixture @25% of total feed intake for 90 days.

**ICAR-National Dairy Research Institute, Karnal (Haryana)** conducted a study for four weeks on cows. Sixteen crossbred (KS and KF) multiparous cows were adapted to test by feeding Bt cottonseed based diet. Mainly the Bt Cry protein side effect and absorption in the milk was tested. Milk yield and voluntary feed intake were recorded daily while milk samples were collected at the start of experimental feeding and thereafter at weekly intervals during the four week experimental period for the analysis of milk composition and to test for the presence of Bt protein. At the end, a blood sample from each cow was collected and plasma was separated to test for the presence of Cry 1Ac protein. Cry 1Ac protein in cottonseed, milk and blood samples was measured by ELISA method. The amount of Cry 1Ac protein in Bt cottonseed was 195.04 ng/g on fresh basis. Corresponding value in Bt concentrate mixture was 78 ng/g on fresh basis. Cows in both the groups improved their body weight during the study period and body weight gain in both groups was similar. Average milk yield during 28 days of experimental period in Non Bt (13.53 kg/day) and Bt (13.12 kg/day) groups did not vary significantly. During the experimental period the milk composition in terms of fat, protein, lactose, SNF and total solids content in Bt and Non-Bt were similar. Cry 1Ac protein was not detected in milk samples, drawn at 0, 7, 14, 21 and 28 day of feeding the experimental diet, as well as in plasma samples drawn on day 28 from the cows fed the Bt cottonseed based ration. Lactating dairy cows of both the groups did not show symptoms of any disease, maintained their health and performed in a similar fashion when fed with Non Bt and Bt cottonseed as a source of energy and protein supplement during the four week long experimental period. The present study results revealed that the Cry1Ac proteins were neither detected in the milk nor in blood of cows that were fed with Bt cottonseed during the four week trial. Further, there was no effect of Bt cottonseed containing Cry protein on milking cows. Hence, feeding of Bt cottonseed as a source of protein and energy in the ration of crossbred cows was considered to be safe and as nutritious as Non Bt cottonseed.

**ICAR- Central Institute for Cotton Research, Nagpur** also carried out a field study involving a team of scientists led by a scientist of the Krishi Vigyan Kendra, for two years (2007-2009) by tethering six goats in one hectare of Bt cotton and one hectare of conventional cotton. The goats were fed on the crop continuously for four months and there were no differences in any biological aspects of the two sets of animals. The biochemical and health results clearly showed that Bt cotton was safe to goats.

**ICAR-Central Institute of Fisheries Education, Mumbai** conducted a systematic study with Bt cotton seed meal as a feed for Fish Common Carp and the side effects if any were tested in the fish food chain. This study was conducted in a 60-day feeding trial on common carp fry. Bt cotton seed cake was included in the diet of common carp at 3 – levels (10, 20, 30%) and compared with its non-Bt counterpart along with control group comprising of no cotton seed cake. Growth rate of Bt cotton seed cake fed group was comparable ( $P < 0.05$ ) with that of control group and with non-Bt counterpart as well. No mortality was found after feeding the Bt cotton cake, suggesting no adverse effect of Bt cotton seed cake. Studies were also conducted on large animals such as Cow and Sheep to assess the bio-safety of Bt cotton seed.

82. The Committee was given to understand that based on the available literature, the ICAR has drawn the following conclusions with regard to impact of GM crops on Animal Health:

- i. GM crops are assessed thoroughly and rigorously before their approval as food and feed to animals. More than two decades of proven history indicates safe use of GM crops as feed to animals.
  - ii. Scientific methods used for the assessment of the safety of GM crops as food and feed are harmonized globally over the years, Bt-cotton, Bt-brinjal and GM-mustard assessed by Indian regulators also proved to be safe as feed to animals.
  - iii. No deleterious effect of GM plants approved for animal feed has been described.
  - iv. Gene constructs used for creating insect resistant and herbicide tolerant plants tested by appropriate bio-molecular methods are safe for animal feeds.
  - v. Methods used for the safety assessment and recommendations of new plants for use as animal feed are appropriate for detection of any ill effect on the animals health and performance.
  - vi. The absence of recombinant DNA, either as whole gene or gene fragment, in animal products, milk, meat and eggs was confirmed in the results of 12 publications, based on several hundred samples.
83. Sharing views of the Department of Animal Husbandry, Dairying and Fisheries with the Committee, the Secretary further informed as under:-
- i. Although ICAR has undertaken feeding trials of Bt Cotton on Broiler chicken, Sheep (Lamb), Goats, Crossbred multiparous cows karanswiss and Karanfresien (KS & KF) species but these trials are of short duration. Hence, long term feeding trials in all the species of livestock including fish must to be undertaken.
  - ii. Once the suggested long term feeding trials about the safety of Bt cotton on Animal Health prove to be positive then the technology can be recommended to the farmers through package of practices.
84. **The Committee notes that feeding trials of Bt Cotton on some animals have been of very short duration. The Committee is not at all convinced with the duration and the manner in which ICAR has conducted its trials to study the impact of GM crops on animal health. It is also surprising to note that these trials have been conducted on a very limited number of animals whereas the Committee feels that these trials should have been conducted on a large number of animals and for atleast 2-3 generations. The Committee is also wary of the methodology opted by the ICAR for conducting these trials. The Committee, therefore, is of the considered view that the Department of Animal Husbandry, Dairying and Fisheries should chalk out guidelines for the purpose and then conduct these trials under its supervision so that the veracity of these claims can be established in the light of these studies.**
85. **The Committee is further a little bewildered to note that even after about 15 years of introduction of GM crop in India, the Department of Animal Husbandry, Dairying and Fisheries could not scientifically prove whether GM crops has any adverse impact on the health of an animal. The Committee, accordingly, is at a loss to understand that when the Department itself feels that long term feeding trials in all the species of livestock including fish must be undertaken then how come it should give a conclusive view that GM crop has no impact on animal health. The Committee, therefore, recommends that the Department should get the desired scientific study done to give its conclusive recommendations in the matter.**
86. **The Committee observes that there are several animal studies indicating serious health risks associated with GM food including infertility, immune problems, accelerated aging, insulin regulation, and changes in major organs and the gastrointestinal system which should also be examined thoroughly before arriving this conclusion that there lies no negative impact on animal health on account of GM crops. The Committee, accordingly, recommends that necessary action in the matter may be taken by the Ministry of Environment, Forest and Climate Change in consultation with ICAR and Department of Animal Husbandry, Dairying and Fisheries.**

87. The Committee, further, learns that GEAC has given its approval for commercialisation of GM mustard inspite of the fact that the matter is pending for decision in the Hon'ble Supreme Court of India. The Committee has been given to understand that GM mustard being a herbicide tolerant GMO, there is clear evidence on the adverse impacts of such GMOs from elsewhere in the world. In the case of GM mustard, from what one can gather from different quarters, there are serious unanswered questions. The Committee has also come to know that many State Governments in the country are opposed to its entry even in the form of field trials, leave alone commercial cultivation. The Committee strongly believes that unless the bio-safety and socio-economic desirability, taking into consideration long run effects, is evaluated by a participatory, independent and transparent process and a retrieval and accountability regime is put in place, no GM crop should be introduced in the country. The Committee, accordingly, recommends that the Ministry of Environment, Forest and Climate Change should examine the impact of GM crops on environment thoroughly, in consultation with the concerned Government agencies, experts, environmentalists, civil society, and other stakeholders so that the nation is very clear about all its probable impacts before taking a call in the matter.

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