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A CRITICAL ANALYSIS OF THE BIOSAFETY REGULATIONS ON GENETICALLY MODIFIED ORGANISMS (GMOs) IN INDIA

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Abstract

Genetically Modified Organisms (GMOs) or Living Modified Organism (LMOs) is an organism in which hereditary material has been manipulated by the means of bioengineering technology. Bioengineering or genetic engineering technology is a technique of modern biotechnology. By using this technology, we can create or design any kind of novel organisms. Human Insulin, Human Growth Hormones, Bt Cotton, Bt Brinjal, Golden Rice, Transgenic Mouse, Transgenic Mosquito are some example of GMOs or LMOs. GMOs and products thereof are more useful in modern society. But many unpredicted risks and concerns are associated with GMOs and products thereof. In India, all activities related to GMOs are regulated by *Biosafety Rules, 1989*. Without prior approval of the GEAC, GMOs and products thereof can not be utilised by any persons. This research article discusses the in depth legal analysis of the biosafety laws on genetically modified organisms (GMOs) in India.

Key Words - Genetically modified organisms (GMOs), Living Modified Organism (LMOs), GM Technology, Biosafety Rules, 1989 etc.

1. An Introduction to the Genetically Modified Organisms (GMOs)

According to World Health Organization, "Genetically modified organisms (GMOs) can be defined as organisms (i.e. microorganisms, plants or animals) in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating and/or natural recombination" [1]. According to Monsanto Company, "A genetically modified organism (GMO) is any organism the genetics of which have been altered through the use of modern biotechnology to create a novel combination of genetic material. GMOs may be the source of genetically modified food ingredients and are also widely used in scientific research and to produce

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goods other than food" [2]. In simple word we say that bioengineered organisms are organisms wherein hereditary materials i.e. DNA have been manipulated by the tools and techniques of modern biotechnologies.

Cartagena Protocol on Biosafety to the Convention on Biological Diversity, 2000 are used a word "*Living Modified Organism (LMOs)*" instead of GMOs. According to the article3 (g) of the convention, "Living modified organism means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology" [3]. As per convention "Living organism means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses" [4]. Point to be noted that the expression GMOs includes both LMOs and other 'dead' organisms which are not capable of replicating. Whereas the LMOs includes those genetically modified organisms that are still alive, in other words, all GM entities which are able to transfer, replication of hereditary material [5].

2. Classification of the Genetically Modified Organisms (GMOs)

GM Technology based organisms can be classified into the following three broad categories:

1. **Genetically Modified Microorganisms (GMMs)** – Presently, GMMs is widely used in the production of drugs, enzymes, proteins, vitamins, hormones and other useful industrial chemicals. Most of industrial products are manufactured with the aid of genetically modified microorganisms (GMMs). In 1982, the "US Food and Drug Administration (USFDA)" allow the foremost GM Technology based medicine "***Genentech's Humulin***, ***a form of human insulin***" makes by recombinant microorganism *E. coli*. It is a first commercial product developed by GMMs.
2. **Genetically Modified Plants (GMPs)** - Transgenic plants are mainly utilised in the production of biotic and abiotic resistance plants. In 1994, the US Department of Agriculture approves the first GM Technology based crop "***Calgene's Flavr Savr Tomato***". It is a first commercial product developed by GMPs. Same time, European Union approves the first GM Technology based crop "***Tobacco***" for commercial production. In March, 2002, the India's Environment Ministry (MoE & CC), approves a first GM Technology based crop "***Monsanto's Bt Cotton***" for market use in India for tree years. In March, 2009, the India's Environment Ministry (MoE & CC), approves a first GM Technology based vegetable "***Monsanto's Bt Brinjal***" for commercial cultivation in India.
3. **Genetically Modified Animals (GMAs)** – Transgenic animals are used in the production of specific food products. E.g. farm animals genetically altered to making allergy free food products. These animals are mainly used in production of transgenic models for human diseases. In 2003, the "US Food and Drug Administration (USFDA)" approve a first GM Technology based animal "***Glo Fish, a GM fluorescent fish***". It is a first commercial product available to public developed by GMAs. In 2015, the US Food and Drug Administration (USFDA) approve the first GM Technology based animal "***AqaAdvantage salmon***" as a food product.

3. Benefits of the Genetically Modified Organisms (GMOs)

Benefits of the GMOs can be classified into following sectors [6] -

In Agriculture Sector –

1) GMOs have enhanced disease, pests and herbicides resistance.
2) GMOs improved nourishments, crop production and biotic and abiotic stress tolerance such as cold/heat or drought/salinity.
3) GMOs decreased fruits or foods ripening time.
4) GMOs improved flavor, quality and quantity.
5) GMOs enhanced food security for increasing population.

In Animal Husbandry Sector –

1) GMOs enhanced animal variety and their health.
2) GMOs enhanced animal byproducts such as milk, eggs, meat and their nutritional value.
3) GMOs enhanced resistance to disease and biotic and abiotic stress tolerance.

In Environment Protection –

1) GMOs increased flora and fauna in natural environment and conserved the biodiversity.
2) GMOs decreased chemical pesticide application. Bioherbicides and bioinsecticides are "Eco friendly" GM products.
3) Clean up environment through bioremediation and phytoremediation.
4) GMOs decreased green house gas (Co_2) emission and global warming.

4. Risks and Concerns of the Genetically Modified Organisms (GMOs)

Major risks and concerns are connected with the use of GM Technology based organisms can be classified into following points -

1) GM Technology based products have the potential to be poisonous and dangerous to public's health.
2) GM Technology based foods may be induces fatal allergies due to the insertion of the novel genes.
3) Another cancers related to GMOs is that the mixing or outcrossing of GMOs with non GM products. It may be cause ecological imbalance in nature.
4) Another concerns related to GM Technology is that use of "Antibiotic Resistance Marker Genes (ARM)". These Genes may be recombining with harmful bacteria or microbes in atmosphere or in the animals or humans guts and cause antibiotic resistance.
5) Another concern is that GM technology based Crops are very unstable. It is possibility that transgenes may be introduce into native plants or producing pollen that kills bees and other pollinators while also posing a risk to humans.
6) Another concern is that GMOs may be a deliberate or accidental spread of recombinant genes into native environment there by disturbing natural ecosystems and biodiversity.
7) Another preambles related to GM Technology is that creation of superweeds and super pests.

8) Another risk related to GM Technology is that virus resistance GMO can cause viruses to mutate into new and more virulent forms [7].

5. India's Biosafety Regulations on Genetically Modified Organisms (GMOs)

In India, GM Technology based organisms and their foodstuffs are governed under Environment Protection Act (EPA), 1986. Under sections 6, 8 and 25 of the statute, "*Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells*" [8] have been notified by the Ministry of Environment, Forests& Climate Change through their Notification No. 621 in Official Gazette of Government of India on December 5, 1989. These regulations also know as "*Biosafety Rules, 1989"*. Biosafety regulations are implement in the following particular matters - "(a) Sale, offers for sale, storage for the purpose of sale, offers and any kind of handling over with or without a consideration of the genetically engineered cells or organisms; (b) Exportation and importation of genetically engineered cells or organisms; (c) Production, manufacturing, processing, storage, import, drawing off, packaging and repacking of the Genetically Engineered Products; (d) Production, manufacture etc. of drugs and pharmaceuticals and food stuffs distilleries and tanneries, etc. which make use of micro-organisms/ genetically engineered micro-organisms one way or the other" [9].

These rules are implemented by the following six competent authorities.

1) Recombinant DNA Advisory Committee (RDAC)
2) Review Committee on Genetic Manipulation (RCGM)
3) Institutional Biosafety Committee (IBSC).
4) Genetic Engineering Approval Committee (GEAC) [10]
5) State Biotechnology Co-ordination Committee (SBCC)
6) District Level Committee (DLC)

Constitution, functions and liabilities are mentioned in rule 4 of the Biosafety Rules, 1989.

In addition to the above, "Review Committee on Genetic Manipulation (RCGM)" also appoint a sub committee named "Monitoring Cum Evaluating Committee (MEC)" for monitoring the field trials of GMPs. **(See: Table - 1 & Figure - 1)**

These authorities are supervised and controlled by Government of India and State Governments mainly -

A. Ministry of Environment, Forest and Climate Change
B. Department of Biotechnology (DBT), Ministry of Science and Technology
C. State Governments **(See: Table - 1 & Figure - 1)**

Table - 1: Competent Authorities as per Biosafety Rules, 1989*

Statutory Committee	Functions	Nature of Function	Housed At
"Recombinant DNA Advisory Committee (RDAC)"	Review recent biotechnology breakthroughs at international levels and provide recommendations on gene technological based research and their applications.	Recommendatory	"Department of Biotechnology, Ministry of Science and Technology, GoI"
"Review Committee on Genetic Manipulation (RCGM)"	Review all ongoing rDNA projects and approve experiments falling in risk category III and above; also responsible for bringing out manuals of guidelines for conduct of GMO research and use	Regulatory/ Approval	
"Institutional Biosafety Committee (IBSC)"	Responsible for ensuring adherence to safety guidelines for experimentation at designated location		All organizations engaged in activities involving GMOs
"Genetic Engineering Approval Committee (GEAC)"	Authorized to review, monitor and approve all activities including import, export, transport, manufacture, use or sale of GMOs and products thereof from environment angle		Ministry of Environment, Forest and Climate Change, GoI
"State Biotechnology Co-ordination Committee (SBCC)"	Monitoring and supervision at state level	Monitoring	Concerned State Governments
"District Level Committee (DLC)"	Supervision and compliance at district level		

*Source: Handbook of Seed Inspectors prepared by MoE & CC, Government of India, p.13.

GMOs and products thereof can not be utilized without prior approval of the competent authorities. The main regulatory provisions on GM Technology based organisms and their foodstuffs under biosafety Rules, 1989 are following:

i. "No person shall import, export, transport, manufacture, process, use or sell any genetically engineered organisms (GMOs)/substances or cells except with the approval of the *Genetic Engineering Approval Committee* (GEAC)" [11].

ii. "Use of pathogenic microorganisms or any genetically engineered organisms (GMOs) or cells for the purpose of research shall only be allowed in laboratories or inside laboratory area notified by the Ministry of Environment and Forests for this purpose under the Environment (Protection) Act, 1986" [12].

iii. "Any person operating or using genetically engineered organisms (GMOs) / microorganisms mentioned in the schedule for scale up or pilot operations shall have to obtain licence issued by the Genetic Engineering Approval Committee (GEAC) for any such activity" [13].

iv. "Certain experiments for the purpose of education within the field of gene technology or microorganism may be carried out outside the laboratories and laboratory areas mentioned in sub-rule (2) and will be looked after by the Institutional Biosafety Committee (IBSC)" [14].

v. "Deliberate or unintentional release of genetically engineered organisms (GMOs)/hazardous microorganisms or cells, including deliberate release for the purpose of experiment shall not be allowed. The Genetic Engineering Approval Committee (GEAC) may in special cases give approval of deliberate release" [15]. "For the purpose of this rule, *deliberate release* means any intentional transfer of genetically engineered organisms/ hazardous, microorganisms or cells to the environment or nature, irrespective of the way in which it is done" [16].

vi. "Production in which genetically engineered organisms (GMOs) or cells or microorganisms are generated or used shall not be commenced except with the consent of Genetic Engineering Approval Committee (GEAC) with respect of discharge of genetically engineered organisms (GMOs) or cells into the environment" [17].

vii. "The Genetic Engineering Approval Committee (GEAC) supervises the implementation of the rules and guidelines" [18].

viii. "The Genetic Engineering Approval Committee (GEAC) may carry out this supervision through the State Biotechnology Coordination Committee or the State Pollution Control Boards/District Level Committee or through any person authorised in this behalf" [19].

ix. "If an order is not complied with, the District Level Committee or State Biotechnology Co-ordination Committee may take suitable measures at the expense of the person who is responsible" [20].

x. "In case where immediate intervention is required in order to prevent any damage to the environment, nature or health, the District level Committee or State Biotechnology Coordination Committee may take the necessary steps without issuing any order or notice. The expenses incurred for this purpose will be repayable by the person responsible for such damage" [21].

xi. "All approvals of the Genetic Engineering Approval Committee (GEAC) shall be for a specific period *not exceeding four year* at the first instance renewable for 2 years at a time" [22].

xii. "The Genetic Engineering Approval Committee(GEAC) shall have powers to revoke such approval in the following situations [23]:-

A. If there is any new information as to the harmful effects of the genetically engineered organisms or cells.

B. If the genetically engineered organisms or cells cause such damage to the environment, nature or health as could not be envisaged when the approval was given, or

C. Non-compliance of any condition stipulated by Genetic Engineering Approval Committee (GEAC)".

Rule 19 state that, "Any person aggrieved by a decision made by Genetic Engineering Approval Committee/State Biotechnology Co-ordination Committee in pursuance of these rules may within *thirty days* from the date on which the decision is communicated to him, prefer an appeal to such authority as may be appointed by Ministry of Environment and Forests [24] provided that the appellate authority may entertain the appeal after the expiry of the said period of thirty days if such authority is satisfied that the appellant was prevented by sufficient cause from filing the appeal in time" [25].

Rules of 1989 are implemented via six statutory agencies using a series of *Biosafety Guidelines*[26] with a view to diminish any undesirable effect that GM Technology based organisms and their foodstuffs would have on the biodiversity in addition to plant, animal or human fitness.**(See: Table - 2)**

Table - 2: Biosafety Guidelines for Genetically Modified Organisms (GMOs) in India*

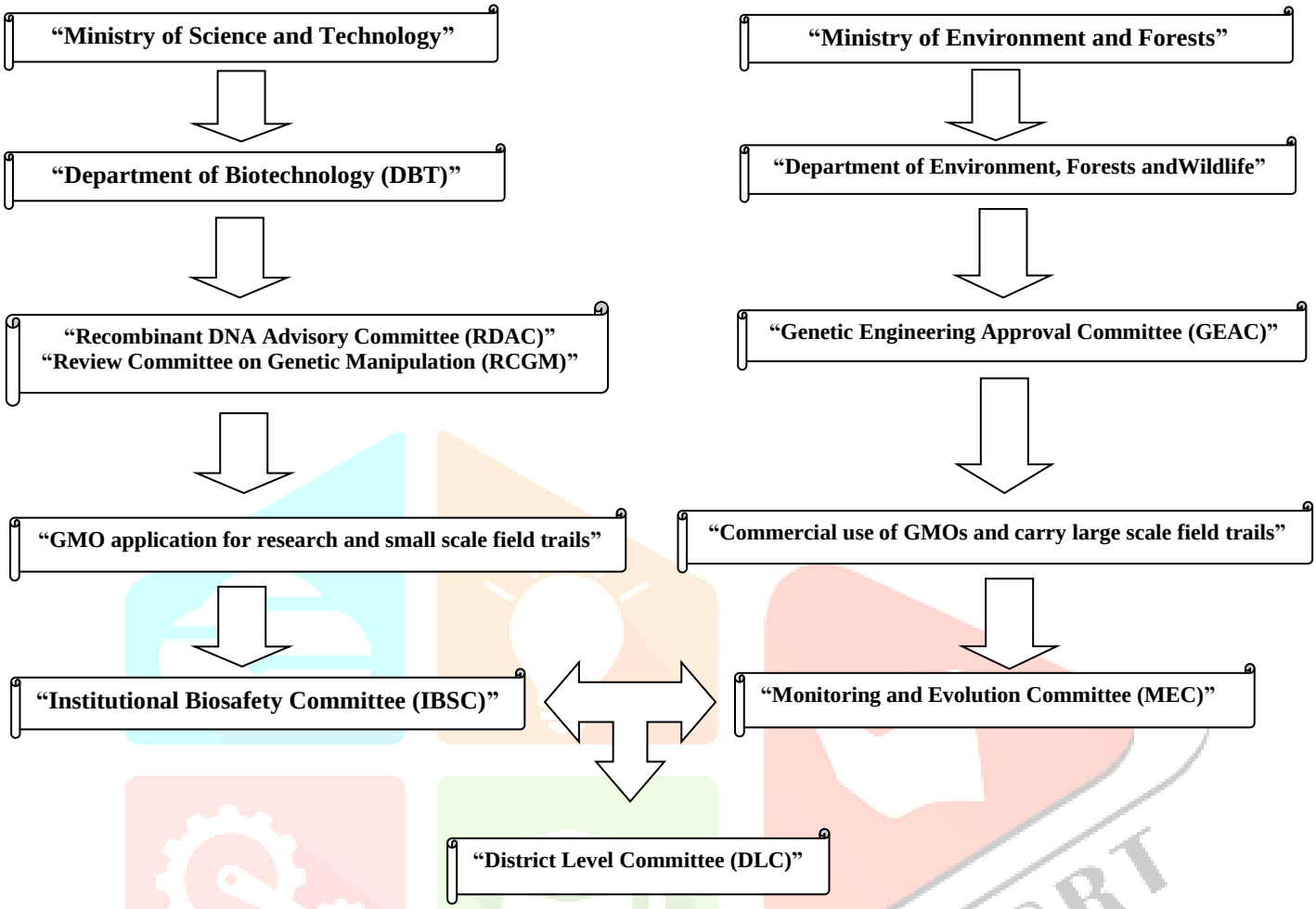
Name of the Guidelines	Prepared By	Related To
"Recombinant DNA Safety Guidelines, 1990"	"Department of Biotechnology, Ministry of Science and Technology, Government of India"	Experiments Under Controlled Environment, Experiments Under Natural Environment and Marketable Uses
"Revised Guidelines for Research in Transgenic Plants,1998"		Contained Use
"Protocols for Food and Feed Safety Assessment of GE Crops, 2008"		Food Safety Assessment
"Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants, 2008"	Indian Council of Medical Research (ICMR)	Food Safety Assessment
"National guidelines for Stem Cell Research, 2017"		Laboratory Experiments
"Guidelines for Confined Field Trials of Regulated Genetically Engineered (GE) Plants, 2008"	Department of Biotechnology and Ministry of Environment and Forests, Government of India.	Confined Field Trials
Standard Operating Procedure for Confined Field Trials of Regulated Genetically Engineered (GE) Plants, 2008		
"Guidelines for monitoring of Confined Field Trials of Regulated Genetically Engineered (GE) Plants, 2008"		
"Guidelines for Environment Risk Assessment for Genetically Engineered (GE) Plants, 2016"		Environment Risk Assessment
"Environment Risk Assessment for Genetically Engineered (GE) Plants: A Guide for Stakeholders 2016"		
"Regulations and Guidelines for Recombinant DNA Research And Biocontainment, 2017"		Experiments Under Controlled Environment, Experiments Under Natural Environment and Marketable Uses

*Source: Handbook of Seed Inspectors prepared by MoE & CC, Government of India, p.13.

6. Conclusion

In India, GM Technology based organisms and their foodstuffs are governed by the Environment Protection Act, 1986. All institutions (both government and non government), activities (laboratory experiment, exportation, importation, contained use, field experiments) or biological materials (microorganisms, plants or animals) related to GMOs are controlled under Biosafety Rules, 1989 which are notified under section 5, 8 and 25 of the above act. Prior permission of the "Genetic Engineering Approval Committee (GEAC)" is required for carry out of any these activities in India. "Genetic Engineering Approval Committee (GEAC)" is a main statutory authority under Department of Biotechnology, Ministry of Science and Technology, Government of India. Agriculture and animals are state subject matters under Constitution of India so state governments also involved in the approval process. On the basis of above in dept legal analysis we conclude that India's biosafety regulations on genetically modified organisms (GMOs) is well organized and have very rigorous and stick provisions on (GMOs) and products thereof. Finally, to sum up in the words of ***M.S. Swaminathan*** [27], "GM foods have the potential to solve many of the world's hunger and malnutrition problems, and to help protect and preserve the environment by increasing yield and reducing reliance upon chemical pesticides. Yet there are many challenges ahead for governments, especially in the areas of safety testing, regulation, industrial policy and food labeling."

Figure: 1 –An Outline of the Biosafety Regulations on Genetically Modified Organisms (GMOs) in India*



*Source: Department of Biotechnology, Government of India & Compiled By Authors

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9. Section 2 (4) of the biosafety rules, 1989

10. Gazette Notification No. G.S.R. 613 (E) dated 16th July 2010 the name of the Genetic Engineering Approval Committee has been changed to Genetic Engineering Appraisal Committee.
11. Rule 7(1) of the Biosafety Rules,1989
12. Rule 7(2) of the Biosafety Rules,1989
13. Rule 7(4) of the Biosafety Rules,1989
14. Rule 7(5) of the Biosafety Rules,1989
15. Rule 9 of the Biosafety Rules,1989
16. Explanation of the Biosafety Rule 9
17. Rule 8 of the Biosafety Rules,1989
18. Rule 14(1) of the Biosafety Rules,1989
19. Rule 14(2) of the Biosafety Rules,1989
20. Rule 15(1) of the Biosafety Rules,1989
21. Rule 15(2) of the Biosafety Rules,1989
22. Rule 13(2) of the Biosafety Rules,1989
23. Rule 13(2) of the Biosafety Rules,1989
24. "National Environment Appellate Authority (NEAA)" works as appellate authority for these rules.
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