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AN OVERVIEW OF GENETICALLY MODIFIED ORGANISM AND THEIR REGULATIONS IN INDIA

DESHMUKH SB, PATEL S* AND PATEL P

Parul Institute of Pharmacy & Research, Faculty of Pharmacy, Parul University, Vadodara, Gujarat, 391760

***Corresponding Author: Ms. Sweta Patel: E Mail: sweta.patel19116@paruluniversity.ac.in**

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ABSTRACT

Global advancements and inventions across multiple fields are profoundly altering every aspect of society. Together, biotechnology and agriculture have developed several revolutionary approaches and techniques to improve both the quantity and quality of agricultural productivity. Each novel innovation that reaches the market looks beneficial at first because it handles a few significant problems swiftly but if its long-lasting effects on humans, animals, and the environment are thoroughly studied, it can lead to several unintentional health problems. Additionally, genetically modified organisms provided solutions for the limited availability of food, pest protection for plants, and increased crop productivity. Another significant body that recommends commercial genetically modified products for manufacture, distribution, importation, or usage under Rule 11 of Rule 89 is the Genetic Engineering Approval Committee (GEAC). The Genetic Engineering Approval Committee requires thorough testing for food safety, as well as testing for environmental risks, for recently invented genetically modified materials, such as food products, food components, and additives like processing aids that contain or include genetically modified organisms (GMOs). The study addresses the laws and regulatory framework that are in place in India concerning genetically modified organisms.

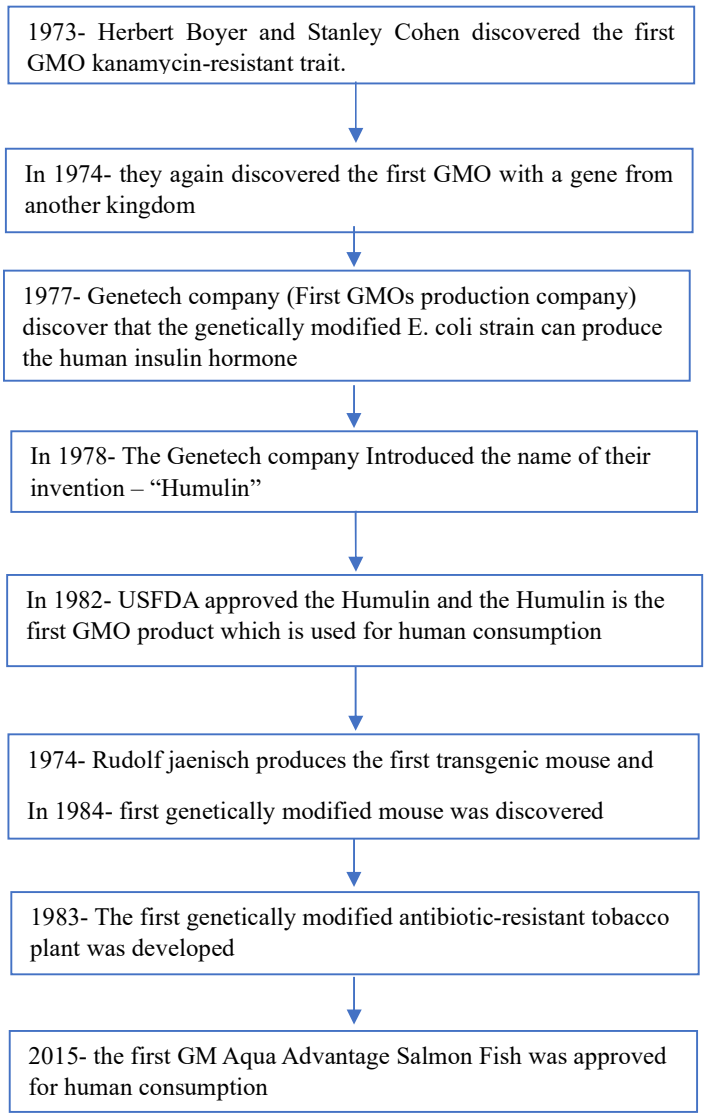
Keywords: GMO, DNA, gene technology, DBT, TALEN, CRISPR-Csa9

INTRODUCTION

A genetically modified organism (GMO) is any plant, animal, or microbe in which one or more variations have been introduced to the genome, usually by advanced genetic engineering, to modify the properties of organisms. It is possible to add, modify, or

eliminate genes within a species, between species, or even between kingdoms. GMOs can be utilized for many different things, such as making fermented drinks, generating human insulin, and developing crop plants to become resistant to pesticides **[1]**. An organism that has had changes made to its DNA through genetic engineering, be it a plant, animal, or microbe, is referred to as a genetically modified organism (GMO). Through selective breeding, particular features have been cultivated over centuries in domestic companions like dogs, cattle, and crops like maize. However, advancements in biotechnology over the past few decades have made it possible for scientists to directly alter the genetic composition of microbes, plants, and animals.

History of Genetically Modified Organisms (GMO) **[2]**:



Process Development of Genetically Modified Organism

GMOs develop by introducing foreign genes into a particular organism that have a beneficial characteristic. The entire procedure consists of several steps, such as selecting an organism which have desired characteristic, separating the gene that codes for that trait, marking the gene with a marker, promoter, and terminator gene or sequence, and then inserting the gene into the host's genome **[3, 4]**.

Basically, there are three methods:

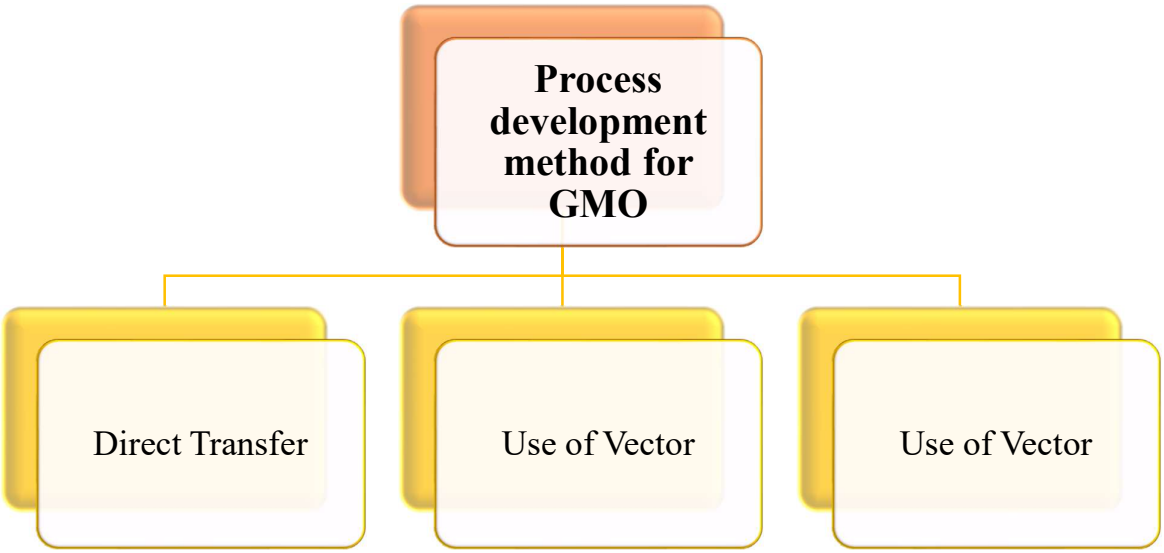
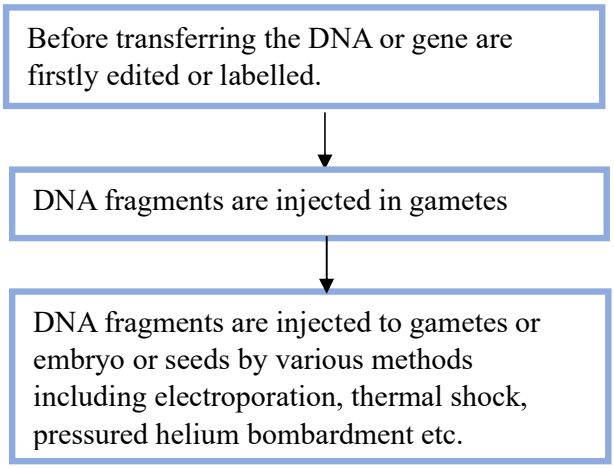


Figure 1: Developmental process of GMOs

1. Direct Transfer

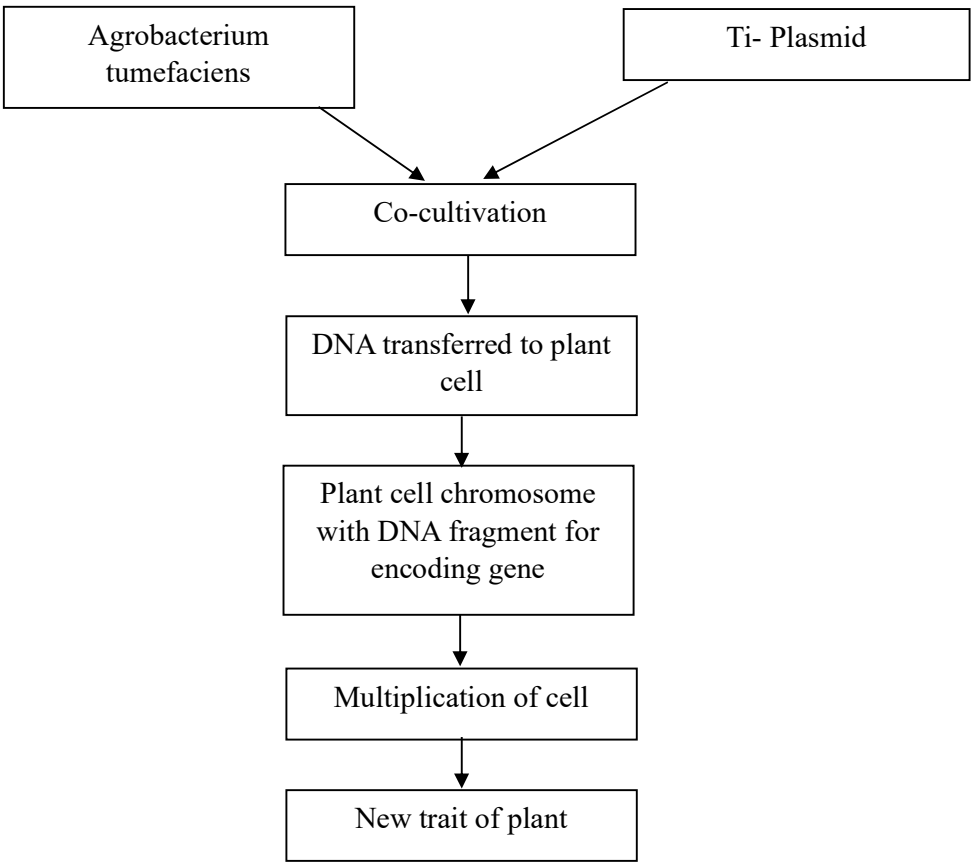
- It is a widely used and simple technique.
- It has low accuracy, efficiency and success rate.

Procedure:



2. Use of Vector:

Procedure:



3. Direct Editing of Existing DNA

- DNA editing is done by gene editing and gene targeting tools [CRISPR-associated protein 9 (CRISPR-Csa9)] and Nucleus associated gene editing technique [Transcription activator-like effector nucleases (TALEN)].

Uses of Genetically modified organisms **[5]**:

a) The production of complex pharmaceuticals was also transformed by genetically modified microbes, plants, and animals since this led to the development of safer and more affordable vaccines and therapies.

b) There are many products of medicine prepared by GMOs such as Antibiotics, hormones, proteins, amino acids, antibodies, and Vitamins.

c) Genetically modified organisms are utilized in research to test various theories, investigate new treatments,

d) GMOs are model organisms for developing specific characteristics

or chemicals, vectors, etc. in scientific research and biotechnological enterprises.

e) GM organisms as highly productive, resistant to pests and diseases, and better able to adapt to harsh environments in both domestic animals and crops.

Table 1: Commonly used Genetically Modified Organism (GMOs) [6-9]

Sr.no.	Name of Genetically modified Organisms (GMOs)	Name of Genetically Modified Traits
1.	Bt Cotton	Pest resistant GM version of cotton
2.	Bt Mustard	• Self-pollination
3.	Bean (Phaseolus vulgaris)	• Viral disease resistance
4.	Soyabean (Glycine max)	• Fatty acid resistance • Antibiotic resistance
5.	Salmon fish	Production of medicinal components • Increased growth in favourable climatic conditions
6.	Eggplant (Solanum melongena)	• Insect resistance • Antibiotic resistance

Regulatory Framework of GMOs in India:

1. India's position on genetically modified organisms is still a moving target.

2. several laws and policies apply to the use of genetically modified organisms (GMOs) in research and development, agriculture, and the labelling of imported food items as well as native food that has been processed and packaged **[10]**.

Scope:

The 1989 regulations encompass a wide range of actions related to genetically modified organisms (GMOs) and their products, including sales, storage, importation, exportation, manufacture, packaging, and so on **[11]**.

These regulations deal with research topics and large-scale uses of genetically modified organisms and their products. They apply to:

1. Manufacturing, importing, and storing genetically engineered goods and microorganisms

2. Genetically modified organisms (GMOs), cells, and the corresponding chemicals, products, foods, etc.

3. New gene technologies beyond genetic engineering and cell hybridization.

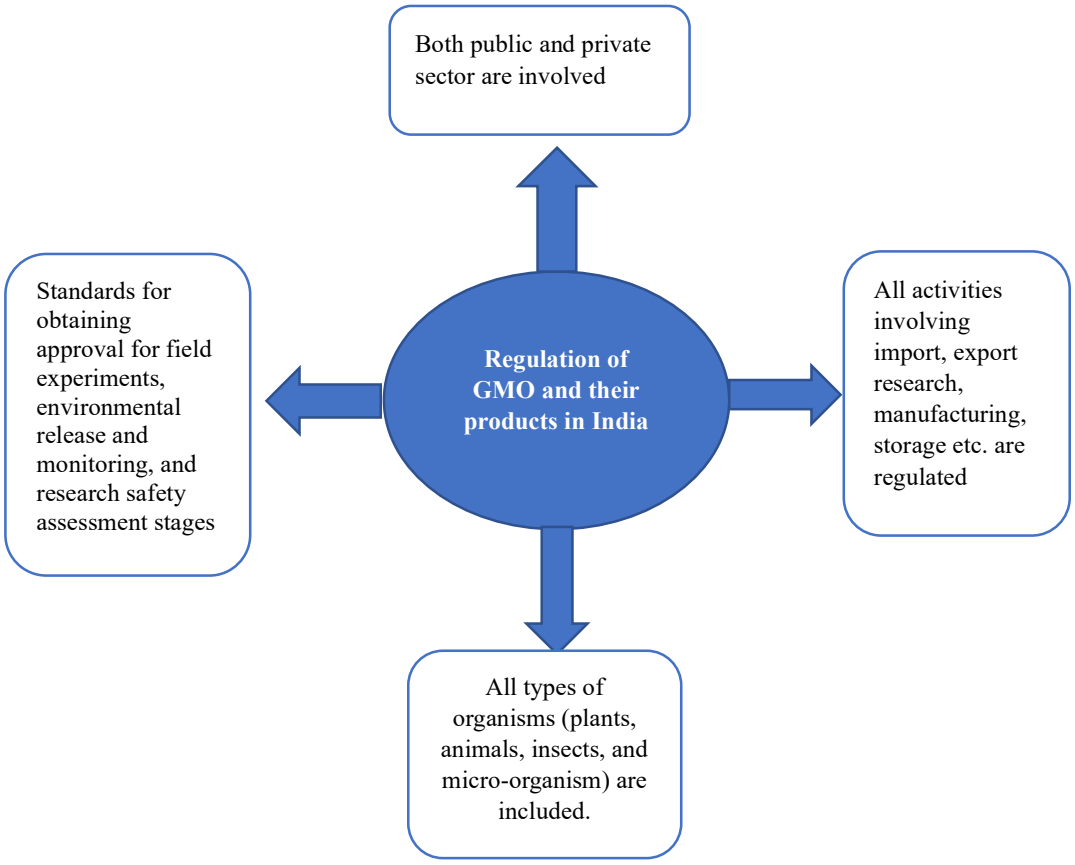


Figure 2: GMO regulations and their products

Regulation of GMOs in India:

Since the Indian government authorities in charge of protecting the environment and conserving biological diversity in 1961, the Ministry of Environment and Forests (MOEF) is in charge of assessing the safety and potential hazards associated with any commercial use of genetically modified crops **[12]**.

The MOEF created the EPA standards in 1989, which are related to genetically modified organisms and are found in section 1986 under hazardous chemicals **[13]**.

Rules for GMOs are implemented by the

a. Ministry of Environment, Forest and Climate Change (MoEF & CC),
b. Ministry of Science & Technology,
c. Department of Biotechnology (DBT),
d. Government of India and State Governments.

Table 2: Six competent authorities

Sr. No.	Competent authorities	Type of Committee
1.	The Recombinant DNA Advisory Committee (RDAC)	Advisory
2.	Institute Biosafety Committee (IBSC) Review Committee on Genetic Manipulation (RCGM) Genetic Engineering Appraisal Committee (GEAC)	Approval
3.	State Biotechnology Coordination Committee (SBCC) District Level Committee (DLC)	Monitoring

There are numerous restrictions on genetically modified organisms under the 1989 rule.

As per the guidelines, any individual or organization that wishes to sell, process, create, transfer, import, sell overseas, or transport genetically modified organisms must obtain approval from the Genetic Engineering Appraisal Committee.

It is strictly prohibited to conduct GMO studies laboratory tests or research for academic purposes without the required authorization **[14, 15]**.

Import and Export of GMOs:

Import of GMO

Plant material and genetically modified organisms have only been imported for study or experimentation up until now.

The Destructive Insects and Pests Act of 2003 established the Plant Quarantine Order.

No matter if a plant has undergone genetic modification or not, the Destructive Insects and Pests Act of 1914's Plant Quarantine Order (2003) prohibits or restricts the import of specific plant species or plants from certain nations.

The import of genetically modified plants for study or testing is generally governed by this directive. A permit must be obtained for such an import from the Director of the National Bureau.

The Indian Council of Agricultural Research is based in Delhi (NBPGR). The Department of Biotechnology, Government of India's Review Committee on Genetic Manipulation (RCGM) must grant import clearance before the permit may be given (DBT).

GM plants or planting material imported for research or experimental purposes require the following arrangements: (i) an Institute Biosafety Committee (IBSC) certification; and

(ii) a post-entry quarantine facility certified by DBT.

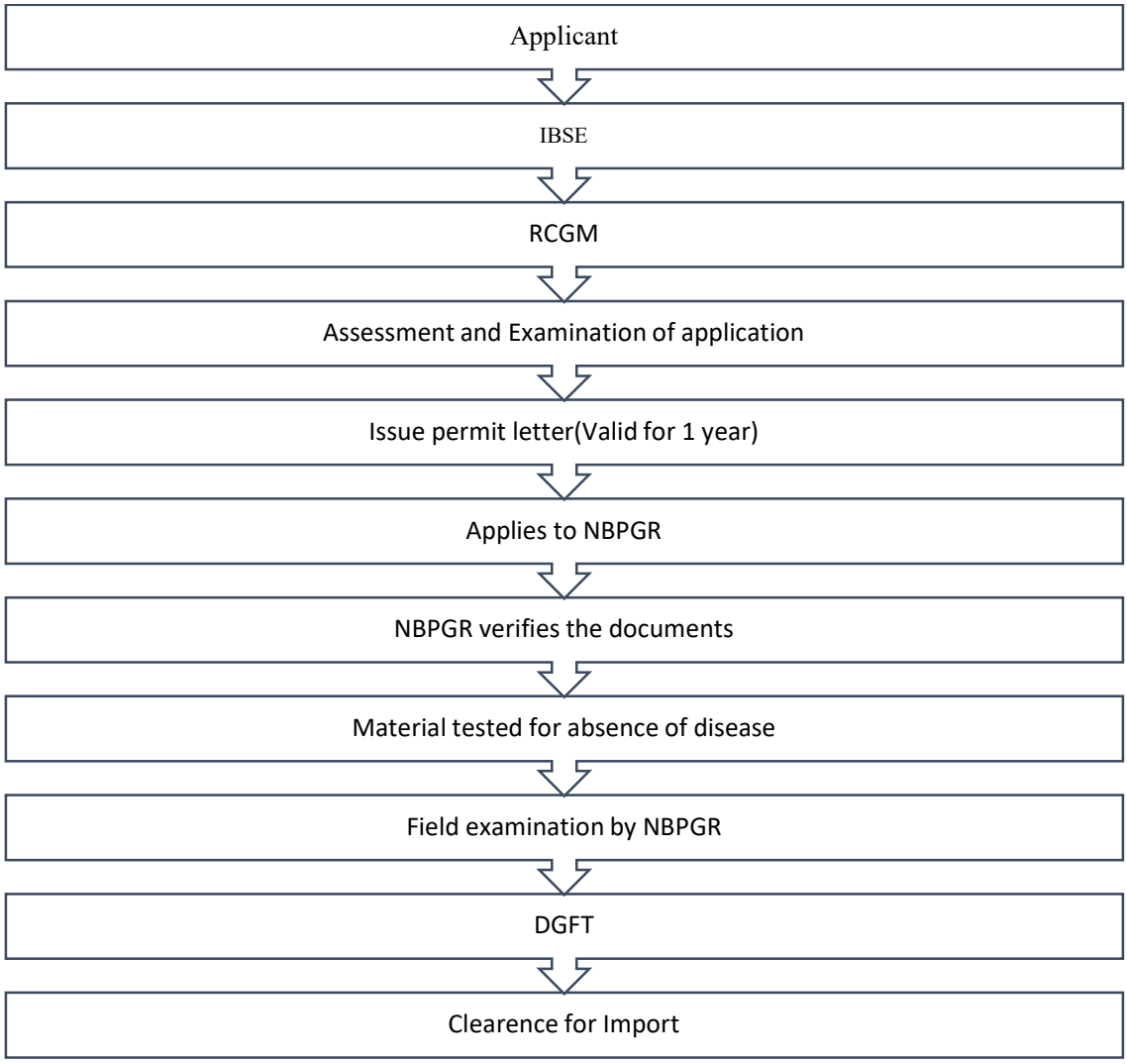


Figure 3: GMOs Import procedure in India

Export of GMO

The EPA Act of 1986 and the Foreign Trade (Development & Regulation) Act of 1992 both regulate the export of genetically modified organisms; in addition, the Biological Diversity Act of 2002 also governs the export of GMOs.

For export, any GMO-based plants or seeds must receive the Plant Genetic Resources Export Facilitation Committee's clearance **[16]**.

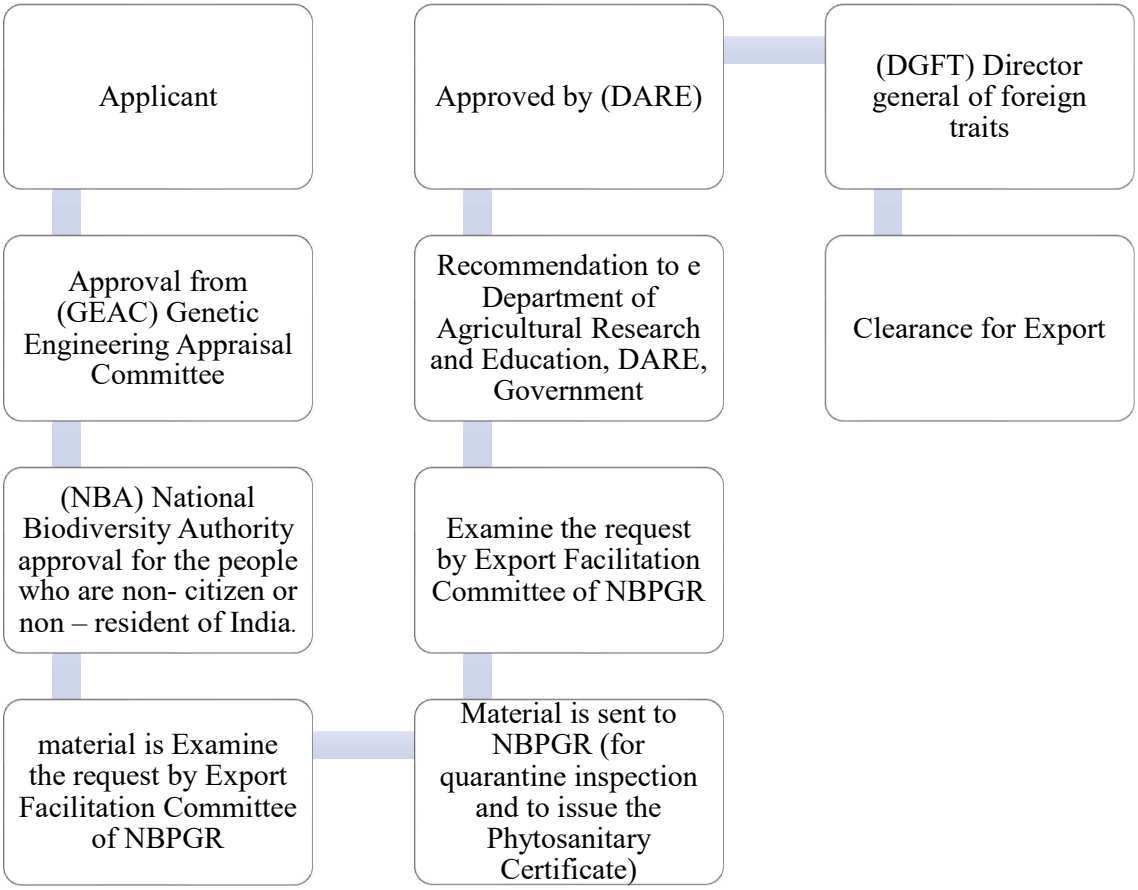


Figure 4: GMOs Export procedure in India

CONCLUSION:

Concerns regarding genetically modified organisms and genetically engineered food are significant for the environment, animal welfare, and human health. Multiple research studies have demonstrated that eating such food daily will have numerous long-term adverse effects on health for both humans and animals, as well as encourage the development of unknown diseases and other deficiencies in future generations.

Regulations associated with genetically modified ingredients used in processed and packaged foods need to be more precise and thorough. Every product that enters the market, whether from a foreign or domestic source, needs to be tested, and the results shouldn't be based just on the marketers' self-declaration claims. Given that children and young adults consume the majority of processed and packaged food these days, the government must amend the regulations about GMO labels on such goods. Legislation must prioritize food safety and purity since strong and healthy nations are built by their youth.

To determine the harmful impact of genetically modified organisms on many species, including humans, plants, and animals, further scientific research is needed. All Indian consumers will be enlightened by government agencies and consumer forums on genetically modified organisms (GMOs) and their detrimental side effects, enabling them to make informed judgments about food products.

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