INTERNATIONAL JOURNAL FOR LEGAL RESEARCH AND ANALYSIS

Open Access, Refereed JournalMulti Disciplinary
Peer Reviewed Edition :

www.ijlra.com

 ISSN: 2582-6433

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ISSN: 2582-6433

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ISSN: 2582-6433

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INTERNATIONAL JOURNAL FOR LEGAL RESEARCH & ANLAYSIS ISSN

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www.ijlra.com
Volume 2 Issue 7 | March 2024
ISSN: 2582-6433

THE GROWING NEED FOR A DEDICATED REGULATORY FRAMEWORK FOR GENETICALLY MODIFIED FOODS IN INDIA

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Abstract:

The rapid advancement in genetically modified foods (GMFs) offers a promising solution to enhance crop yields, improve food security, and address nutritional deficiencies. Originating from organisms with modified DNA to exhibit traits not naturally occurring, such as increased resistance to environmental stressors, GMFs carry the potential to revolutionize agricultural practices. However, alongside their benefits, GMFs present significant health and ecological risks, including potential allergenicity, gene disruption, and ecological imbalance, necessitating a careful examination of their long-term impacts. In India, the regulation of GMFs is in its infancy, characterized by a fragmented legal framework governed by multiple authorities with overlapping jurisdictions. The current regulatory regime, underpinned by the Genetic Engineering Appraisal Committee (GEAC), Food Safety and Standards Authority of India (FSSAI), and guidelines from the Indian Council of Medical Research (ICMR), struggles to keep pace with the rapid advancements in biotechnology, leading to inconsistencies and gaps in governance. This paper underscores the urgent need for a cohesive, comprehensive regulatory framework for GMFs in India, one that balances the benefits of genetic modification with the imperative to safeguard public health and the environment. It advocates for the establishment of a dedicated regulatory body to oversee GMF governance, ensuring that regulations evolve in tandem with biotechnological innovations and are aligned with international biosafety standards. Moreover, it highlights the importance of transparent labelling and strict traceability measures to inform consumer choice and facilitate responsible trade. Ultimately, a balanced, forward-looking regulatory approach is essential to harness the potential of GMFs while mitigating their risks, thereby contributing to sustainable agricultural development and food security.

Keywords: Genetically Modified Foods (GMFs), Regulatory Framework, Agricultural Practices, Food Security, Biosafety Standards

ISSN: 2582-6433

Introduction:

Foods that have been genetically modified (GM) are those that come from creatures whose DNA has undergone changes that do not occur normally, such as the insertion of a gene from another organism are referred to as genetically modified foods. The majority of GM foods currently on the market come from plants that have been engineered to increase crop yields, lower costs for food or drug production, reduce need for pesticides, improve nutrient composition and quality, greater food security, and medical benefits for the world's expanding population are a few advantages of genetic engineering in agriculture.[1] These GM crops mature more quickly and can withstand environmental stresses like drought and frost. This enables plants to grow in environments where they could not normally thrive.[2]

While GMOs are beneficial for consumers of their nutritional value and shelf life, there are risks associated with them which include health risks and ecological risks. Health risks here are those associated with the functioning of the human body. Such risks can cause allergies, disrupt the natural genes in an organism, and cause the inability to conceive among individuals. Ecological risks mean killing non-target weeds which actually help the plant and the constant use of GMOs can disrupt the food web. While the biggest problem in the use of GMOs is resistance to antibiotics, which can usually kill the good bacteria which are needed to protect from harmful antibiotics. [3]

The regulatory aspects relating to genetically modified foods is limited as the concept is new and evolving. The environmental risks that the genetically modified crops impose are regulated by the "Rules for the Manufacture/Use/Import/Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells, 1989 which are notified under the Environment (Protection) Act, 1986. Additionally, the Genetic Engineering Appraisal Committee (GEAC) was the only competent authority which dealt specifically with genetically modified foods until the enactment of the Food Standards and Safety Act in 2006. The FSSAI has a dedicated scientific panel that deals with GMFs. The Indian Council of Medical Research (ICMR) has also released

[1] Shahla Wunderlich, Kelsey A Gatto, Consumer Perception of Genetically Modified Organisms and Sources of Information, Advances in Nutrition, Volume 6, Issue 6, November 2015, Pages 842–851, https://doi.org/10.3945/an.115.008870
[2] Shukla, M., Al-Busaidi, K.T., Trivedi, M. and Tiwari, R.K., 2018. Status of research, regulations and challenges for genetically modified crops in India. *GM crops & food*, *9*(4), pp.173-188.
[3] Zhang, C., Wohlhueter, R. and Zhang, H., 2016. Genetically modified foods: A critical review of their promise and problems. Food Science and Human Wellness, 5(3), pp.116-123

ISSN: 2582-6433

"Guidelines for Safety Assessment of Foods derived from GE Plants, 2008".[4]

While the general concept of GMF remains the same, it is ever-evolving with the invention of newer and more sophisticated techniques. For this, there needs to be a dedicated body that is tasked with the governance of the GMFs. Currently, in India, GMFs have regulations made by multiple authorities.[5] Sometimes, they are conflicting with each other and since the regulations are made and implemented through multiple agencies, the regulations are not comprehensive.

Part I: Existing Framework

Genetically Modified Foods (GMFs) come under the umbrella of genetically modified organisms and are specifically related to edible items. The Food and Agriculture Organisation (FAO) of the United Nations defines genetically modified organisms as "products that do not occur naturally either by mating or through natural recombination" and genetically modified food as "food that is produced from the genetically modified organisms".[6] Under Indian legislation, especially with regards to food safety, "genetically engineered or modified food" means food and food ingredients composed of or containing genetically modified or engineered organisms obtained through modern biotechnology, or food and food ingredients produced from but not containing genetically modified or engineered organisms obtained through modern biotechnology"[7] is defined in the Food Safety and Standards Act,2006.

Since there are various acts that govern GMOs, there are overlaps that take place, many of which are contradictory. GMOs can also have negative effects that necessitate a comprehensive regulatory framework to make sure that it does not harm the environment. There is a gap that exists between the current guidelines and rules on GMOs and the loopholes caused by emerging biotechnology. Further, there should be mechanisms to ensure that evolution of the legislations keeps up with the emerging biotechnology to ensure safety.

This needs to be done with caution. The regulatory framework cannot give importance to agriculture since that would be trespassing on the individual State's authority to frame guidelines as agriculture is in the state list. Further, since the union and concurrent lists involve "agriculture-related" items, it is *intra vires* of the Legislature to formulate such guidelines. One example is

[4] T. Lang, J., 2016. What's so controversial about genetically modified food?. London: Reaktion Books Ltd, pp.7-24.
[5] Motasara, Namrata. (2019). Regulation of GMO release in India Ahuja, V. Regulation of emerging gene technologies in India. BMC Proc 12, 14 (2018)
[6] Food and Agriculture Organisation of the United Nations (2016)
[7] Food Safety and Standards Act,2006 § 22 (2)

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item number 51, which states that "Establishment of standards of quality for goods to be exported out of India or transported from one State to another".[8] Also, since India is a signatory to the existing Cartagena Protocol on Biosafety, the measures that are taken should follow some of the guidelines mentioned.

Currently, only *Bt Cotton* can be grown in India, there are no GMFs that are allowed to be grown or produced in the country. Further, any imported products have to adhere to the packaging and labelling regulations specified under the Food Safety and Standards Act,2006, as well as the notification from the Ministry of Consumer Affairs, Food and Public Distribution that mandates the labelling of genetically modified food.

Part II: Necessity of Dedicated Regulations

Use of GMFs in international trade poses a problem of traceability, making it difficult to identify the real modifications made as well as the quantity and quality of the modified crops used in the production of other food.[9] It also makes it difficult to trace who should be held liable in case any mishaps occur. International trade of GMFs also allows for adulterants to be added to the food, potentially making it unsafe.

The regulations are necessary to provide safeguards against the indiscriminate spread of GM food, especially with the ill effects they can cause. Since the technology involved in the genetic modification is still recent, there is not enough credible data on what the long-term effects are, but some of the known include fertility issues, allergies and possibly cancer.[10] There has been research that shows that consuming certain GM crops like corn and soy do cause hormonal imbalances and subsequent fertility issues in women, that then passes on to the next generation due to genetics.[11] There are also studies on the increase of disorders like attention deficit hyperactivity disorder(ADHD) and autism as well as mental health issues like depression and anxiety increasing due to the increase of genetically modified food.[12]

However, there are also those who advocate for the use of GM crops, since they can be modified to increase crop yields and increase disease resistance. This could help reduce the number of

[8] Constitution of India, Seventh Schedule
[9] Gautam, K. and Kushwaha, S., 2018. Genetically modified food trade: a case study of India. *Journal of Pharmacognosy and Phytochemistry*, *SP1*, pp.2272-2282.
[10] The Negative Side Effects of Eating Genetically Modified Foods, Soapboxie, https://soapboxie.com/social-issues/What-Genetically-Modified-Foods-Do-to-Our-Bodies (Last visited Oct, 25 2022).
[11] Processed or Genetically Modified Foods Affect Fertility, Fertility Factor.com,https://www.fertilityfactor.com/can-over-processed-or-genetically-modified-foods-affect-fertility.html
[12] *Id*

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people who face extreme hunger, which is in line with the sustainable development goals (SDG) set by the United Nations. Some of the varieties that could be useful include increased herbicide tolerance, pest and disease resistance, increased production and being able to handle greater environmental changes without affecting the yield of the crops.[13]

Part III: Possible Effects from Lack of Dedicated Regulations

If there are no regulations, then those who have the means to get GM crops can use them to cause resource drain for their competitors along with other nefarious activities like spreading pest-infested species or other harmful modifications. It is also necessary to take into account how the usage of such genetically modified crops affects the environment. The crops modified to grow faster might suck the nutrients from the soil as well as the groundwater, leaving the land barren once the crops are grown. Also, the crops that are genetically modified are like hybrid seeds. They can only be sown once and for the next season, the farmers need to procure more seeds. This makes the entire process more expensive, leading to the cost of food increasing, eventually defeating the purpose of higher yield if not everyone can afford it. The GM crops also consume more nutrients and water from the soil and make it difficult to then replenish. Further, due to the increased pest resistance, there are higher quantities of pesticides used which then harms the health of the people who consume the food.

These issues highlight the need for separate legislation that protects all the players involved and is also able to keep up with the evolving biotechnology. This in turn will be beneficial to India and help regulate international and domestic trade of such crops and foods while maintaining the labelling and safety standards as prescribed. Dedicated legislation would also clarify the traceability of food that is imported and contains some genetic modifications, helping society to understand what it is that they are eating. It could also help improve India's food security due to increased yield as well as greater resistance to changing temperatures and emerging diseases. It is important that such a framework be made as soon as possible to take into account the environmental risks associated with GMOs and then protect the natural resources that India already possesses. It would reduce confusion for the authorities for what regulations they should follow and at the same time, it closes the loopholes that unscrupulous companies can use to harm the people, the environment and the economy.

The FSSAI also needs to follow through with the draft resolutions that they propose and make

[13] Genetically Modified Foods: Benefits and Risks, Healthpedian.org, https://www.healthpedian.org/genetically-modified-foods-benefits-and-risks/

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sure that the policies that they propose do not become counter-productive for society. The draft regulations of 2018 had several lacunae, mostly with regard to specifying the details pertaining to the standards that they were trying to set. This needs to be rectified to ensure that any regulations that are made are actually useful and aid in safer food reaching the people.

Part IV: Recent Developments regarding GMO in India:

The landmark case in India that is related to GMOs and their regulation is *Aruna Rodrigues v. Union of India*[14]. In this case, the Supreme Court had laid down several guidelines that are to be followed during the research process for creating a genetic modification to any organism. The guidelines that the Committee has to follow for field trials of the GMO are:

To review and recommend the nature of sequencing of risk assessment (*environment and health safety)* studies that need to be done for all GM crops before they are released into the environment.

1. "*To recommend the sequencing of these tests in order to specify the point at which environmental release though Open Field Trials can be permitted.*
2. *To advise on whether a proper evaluation of the genetically engineered crop/plants is scientifically tenable in the green house conditions and whether it is possible to replicate the conditions for testing under different agro-ecological regions and seasons in greenhouse?*
3. *To advise on whether specific conditions imposed by the regulatory agencies for Open Field Trials are adequate. If not, recommend what additional measures/safeguards are required to prevent potential risks to the environment.*
4. *Examine the feasibility of prescribing validated protocols and active testing for contamination at a level that would preclude any escaped material from causing an adverse effect on the environment.*
5. *To advise on whether institutions/laboratories in India have the state-of-art testing facilities and professional expertise to conduct various biosafety tests and recommend mechanism to strengthen the same. If no such institutions are available in India, recommend setting up an independent testing laboratory/institution*."[15]

Recently, there have been discussions regarding the use of genetically modified mustard and there is currently a case pending at the Supreme Court regarding the same.

[14] (2011) 12 SCC 477
[15] *Ibid*

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Another development in this regard is a Delhi High Court decision regarding the restotation of the patent for a variety of potato that was owned by Pepsico.[16] This brings in another authority for the regulation of GMO under the intellectual property laws as well.

There can be patents and protections that are granted under the Plant Varieties and Farmers Rights Act, 2002, which results in further complications to the already existing variety of regulatory mechanisms in India.

Part V: Limitations

This research primarily focuses on the legal aspects of GMFs in India. A more comprehensive analysis would include a deeper dive into the scientific literature on the health and ecological risks associated with GMFs. Additionally, the research could benefit from incorporating the perspectives of stakeholders such as farmers, consumers, and biotechnology companies. Finally, the limitations of the current scientific understanding regarding the long-term effects of GMFs consumption should be acknowledged.

Conclusion:

Genetically modified foods (GMFs) offer a potential solution to global food security challenges by increasing crop yields and improving disease resistance. However, concerns exist regarding their potential health risks and ecological impact. The current regulatory framework in India for GMFs is fragmented and lacks comprehensiveness. This research highlights the necessity for dedicated legislation to govern GMFs in India. Such legislation should address traceability, long-term health effects, environmental impact, and affordability. A well-defined regulatory framework can ensure the safe and sustainable use of GMFs, contributing to India's food security and economic well-being.

[16] 2024 SCC OnLine Del 153