THE ROLE OF ADMINISTRATIVE AUTHORITY IN REGULATING GENETICALLY MODIFIED FOOD

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Abstract:

This research paper aims at exploring the importance of administrative authorities in regulating the genetically modified food which is becoming rampant with emerging technology to feed the growing population and eliminate hunger but simultaneously posing threat to human health, animal, environment, risks of new diseases, growing of patent matters in relation to GM foods. Furthermore, this paper centralises its attention toward Food Safety and Standards Act, 2006, Food Safety and Standards Regulations, 2011, voluntary product gradations, International Agreements to regulate the food standards and quality assurance. Above all of these, the earth has enough to feed the world but not the greed, so authorities should maintain and regulate the resources, its distribution and allocate the resources towards traditional agricultural methods so as to reduce the dependency on genetically modified food.

Key Words:

Genetically Modified Food, Genetic Engineering, Hybrid Foods (Cross-breeding), Plant Genomes, Patents, Bio-piracy.

Introduction:

As the population is increasing day by day, one of the most upsetting and alarming factors is the increase in undernourished people who are dying of extreme hunger and on the other side the obesity has doubled since 1990. In 2022, about 2.5 billion adults were overweight[1]. Obesity is a serious disease which can create various health problems like heart disease, diabetes etc which are causes of death in many. In 2023, 2.33 billion people were severely affected of food insecurity and it is estimated that 582 million[2] people will be facing extreme hunger by 2030.

Despite the frightening statistics, the world has enough food to feed every person but the rise in the hunger level can be linked to factors like: (1) not given enough resources and support by government to traditional agriculture which reduces the confidence of farmers, (2) ongoing worldwide crisis, (3) and the consequence of the above two factors led to increase in food prices making it affordable for few by dragging many in the grip of hunger.

The evolution of agricultural biotechnology has facilitated the growth of farming in a more efficient and effective way. This has decreased the burden on fertile land to feed huge population and at the same time the usage of pesticides is fewer. However, it is too complicated to be evaluated only on an individual factor. Because Genetically Modified Food raises huge implication on health risk, environment, consumer choices, threat to animals as they are used for testing purposes, risk of outbreak of new diseases etc.

People will always be sceptical towards GM foods as humankind is modifying the natural consumption eventually producing artificial life. Even though GM foods getting positive estimation for being efficient, highly productive and pests resistant, not much assessment is done towards the effect of such foods on human health. In addition to such risks, the authorities that constitute such GM corporations always have absence of transparency and often mislead the public by withholding censorious information. As well as when we talk about biotechnology industry it is very much concentrated and the power dynamics is with the few authorities who play with it which can lead to traditional agricultural sector somewhere at a risk.

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[1] *Obesity and Overweight,* World Health Organisation, WHO, 1 March 2024, (Sept. 28, 2024, 19:43 PM), Obesity and overweight (who.int).

[2] THE STATE OF FOOD SECURITY AND NUTRITION IN THE WORLD, *FINANCING TO END HUNGER, FOOD INSECURITY AND MALNUTRITION IN ALL ITS FORMS*, CHP 2,13, 2024, The State of Food Security and Nutrition in the World 2024 (fao.org).

Food Standards and Regulation in India:

In 1988, the Prime Minister's Council on Trade and Industry designated a group on food and agro-industry suggested for an extensive legislation on food. The Standing Committee of Parliament expressed the importance of such legislation and thus the UPA government proposed a bill called as the Food Safety and Standard Bill 2005 on 25th August 2005 in Lok Sabha which was passed in the year 2006.

The chief purpose of such bill was to bring out a single statute regarding the food laws and to provide a structured base for the food and agro-industries. The Bill embodies the instrument of Codex Alimentaries Commission which is associated to food safety norms and is made keeping in vision the international practices.

The Food Safety and Standards Act, 2006[3] received the Presidential assent on 23rd August 2006 and came into force on 5th August 2006. This Act repealed the earlier existing eight food regulatory laws by notification issued by Ministry of Health and Family Welfare on 4 August, 2011 integrating them into Food Safety and Standards Rules and Regulations 2011 under a single regulator known as The Food Safety and Standards Authority of India. This law ensures quality food to the consumers, protects them from deceptive advertisement and preventing adulteration in any form. Beside this, it also sermonizes the present-day challenges like Genetically Modified crops, global food trade etc.

The Food Safety and Standards Authority of India (FSSAI) is an autonomous body created under the umbrella of the Ministry of Health and Family Welfare, Government of India, which oversees the safety of food products to safeguard public health through regulatory oversight and supervision. It has successfully implemented scientific backed regulations for food products and monitors their production, storage, distribution, sale and import to guarantee the availability of safe and nutritious food for consumers. FSSAI has been created under the Food Safety and Standards Act of 2006, a comprehensive law governing food safety and regulations in India. This statutory Act confers various powers on FSSAI and they have to work according to the power delegated to them.

- Developing regulations to maintain food safety standards.
- Establishing criteria/guidelines for accrediting food testing laboratories.
- Provide expert scientific advice and technical support to the Central Government.
- Supporting the creation of international guidelines on food safety.
- Collecting and compiling statistics on food consumption, contamination, emerging hazards, etc.
- Conveying information and raising awareness about food safety and nutrition in India.

In a collective approach it can be viewed that the Act aligns and adopts global standards with establishing a comprehensive regulatory framework, offering a centralized platform for individuals engaged in food industry, encompassing manufacturing, marketing, processing, handling, transportation, production, sale, service, storage, distribution, transport and import of food[4].

Unravelling the Science of Genetically Modified Food: How Genetic Engineering Works:

Genetic modification is a technique that transcends the boundaries of species, enables the transfer of genes from one species to another, irrespective of taxonomic proximity. Whereas conventional breeding is more constrained as it is limited to same species thereby restricting the gene pool and available phenotypic variations. The majority of genetic modifications involve the introduction of genes from viruses, bacteria, and other plants. Notably, gene transfers have been achieved between animals and plants, further expanding the possibilities of genetic engineering.

Agricultural biotechnology has revolutionized plant breeding by enabling to cross the species barrier. This technological advancement allows for the creation of new seeds and plants possessing desirable traits through the strategic insertion of genetic material that would not otherwise be inaccessible through normal breeding practices in the field. These genetically engineered plants have diverse array of new traits, including herbicide resistance and the production of endogenous pesticides by inserting genes derived from naturally insecticidal bacterium Bacillus thuringiensis (Bt)[5].

[3] Food Safety and Standards Act,2006, § 3, No. 34, Acts of Parliament, 2006 (India).
[4] FSSAI, SAFE STORAGE, DISTRIBUTION & TRANSPORTATION OF FOOD PRODUCTS, https://fostac.fssai.gov.in/doc/Food%20Safety%20training%20manual%20storage,%20transportation%20v2%20-%20June%2014,%202017%20with%20checklist.pdf, (Oct.2, 2024).
[5] MOHAMED A IBRAHIM, NATALYA GRIKO, MATTHEW JUNKER, LEE A BULLA, BACILLUS THURINGIENSIS, (Oct.2, 2024, 11:26 AM), Bacillus thuringiensis - PMC (nih.gov).

Insect resistance in genetically modified crops is conferred the integration of the above Bt toxin, a substance conventionally employed as an agricultural insecticide deemed safe for human consumption by the world Health Organisation. GM crops engineered to perpetually produce this toxin have shown reduction in insecticides where pest pressure is high. Virus resistance in GM plants is achieved through the incorporation of a gene derived from specific viruses that reduce plant diseases resulting in higher yields. In situations where weed pressure is high, the cultivation of such crops has resulted in reduction of herbicide usage[6].

A brief history of GM Crops:

As per the World Health Organization (WHO), the primary impetus for the development of the genetically modified plants was to enhance crop protection against plant diseases caused by insects, viruses, or herbicides. The GM crops was first produced in 1984 and their commercialization occurred in 1996, in the United States, where the cultivated area increased to 55 million hectares.

The pervasive influence of US hegemony within the early post-war global political economy expanded to the agricultural sector, exerting a profound impact on global food for decades. The strategic promotion of agricultural sector coupled with transnational corporate investment, gene revolution in the developing nation provided many benefits to US. This strategy was used to bolster farmer incomes domestically, expand the global reach of US-based food corporations and solidify the US hegemony in the food sector[7].

As the global food system evolved, the redistribution of surplus and the proliferation of industrial farming practices, including the adoption of genetically modified (GM) crops, were widely regarded as important components. However, the underlying foundation proved to be very fragile and susceptible to repeated crises. Rather than addressing the fundamental core issues, policies predominantly focused on global agricultural trade and the intensified application of scientific and technology in agriculture.

Hybrid seeds: A trade secret for big businesses:

Historically, seed production relied solely on natural pollination by wind and insects. Over time, seed producers developed techniques to manually cross-pollinate plants, by creating hybrid seeds with enhanced characteristics such as increased yield or insect resistance. While the first generation of hybrid seeds consistently produced desired traits, subsequent generations, grown from open pollination in farmers' fields, exhibited inconsistent and undesirable qualities. This limitation necessitated farmers to purchase new hybrid seeds each planting season from the producers.

By maintaining the secrecy of the parent inbred lines used to create hybrid seeds, private seed producers were able to protect their trade secrets and thus conducting business under the protection of trade secrets law[8].

Innovation to Consumption: The role of big industry players:

The US leads the world in genetically modified crop production, followed by Canada, Brazil, India and Argentina. A significant portion of the products in supermarkets, including corn-containing items are genetically modified. These products are in wide range, from high-fructose corn syrup in beverages to items like ketchup, syrups, cake mixes, salad dressing, vitamins etc[9].

The biotech food products industry is targeted by three major companies: Monsanto, DuPont's Pioneer Hi-Bred, and Syngenta. These companies develop most of the genetically modified traits and license to each other, smaller companies and public companies. Monsanto particularly has the largest share in US market and focuses on corn, cotton, and soybean crops due to their higher investment. Now with the advent of technology, genetic engineering now allows transfers between any genus or species. And a notable feature of GM seeds which is engineered to work together in union with certain brands of herbicides and pesticides. The line between the seed industry and chemical industry have somewhere become blurred as industry started to work in both and the foremost example

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[6] GREENPEACE, *GM Contamination Register Report 2007,* (Feb. 2008), https://www.greenpeace.org/static/planet4-netherlands-stateless/2018/06/gm-contamination-register-2007.pdf.

[7] Factsheet: *Genetically modified Crops in the United States,* PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY (Sept. 7, 2004), Genetically Modified Crops in the United States | The Pew Charitable Trusts (pewtrusts.org).

[8] Benjamin Ikuta, *Genetically Modified Plants, Patents, and Terminator Technology: The Destruction of the Tradition of Seed Saving,* 35 OHIO UNIV. L.. REV. 731-749 (2009).

[9] BRANDON H MAI, LIANG-JUN YAN, *The negative and detrimental effects of high fructose on the liver, with special reference to metabolic disorders,* (Oct. 2, 2024, 12:42 PM), The negative and detrimental effects of high fructose on the liver, with special reference to metabolic disorders - PMC (nih.gov).

hear is Monsanto which was a chemical company and they ventured into agricultural industry whereby changing the dynamics of agriculture and encouraging the chemicals they sell.

Patenting on Genetically Modified Food:

In India, the Patents Act of 1970 governs the procedure for granting patents. Through amendment the words "plant" has been deleted from non-patentable list making it eligible for patent protection. The patent can be granted if there is a significant human intervention in the invention related to the gene. It should have a significant impact or benefit on the industry.

The Protection of Plant Variety and Farmers Right Act, 2001 safeguards the innovation of new plant varieties through seeds made by biotech company or a farmer. A transgenic plant variety is a plant that has been genetically modified to contain one or more genes from a different organism. This modification is achieved through biotechnology process. In India, plant varieties, including transgenic varieties stands protected under this Act.

Supreme Court in Monsanto Technology LLC v. Nuziveedu Seeds Ltd., AIR 2019 SC 559[10], held that GM cotton seeds are patentable because such is made by human intervention and not exist in nature.

Challenges on patenting of such GM plants are:

- Bio-piracy: It occurs when private corporations or individuals claim ownership over biological resources which was originally developed by farmers. By patenting these plants, corporations or individuals whoever claims creates a monopoly over it limiting farmers choice and hinders scientific research on the same. Before patents, innovation flourished through exchange of seeds but now because of lack of collaboration and sharing has hindered the scientific innovation[11].
- Restricts breeding: Numerous companies mandate the farmers to enter into agreements that forbidding them from breeding the plants.
- Restraining farmers choice: Farmers are compelled to buy GM crops at exorbitant prices, even when they prefer conventional varieties or plants with fewer genetically modified traits.
- Risk of being sued: Large corporations that hold patents on GM plants often sue farmers for growing these plants without authorization.
- Inequality in economic power: The food industry has become dominated by large corporations that own patents on genetically modified plants and control the production of herbicides and fertilizers. This concentration of economic power has shifted the balance in favour of these corporations.

Effects of Genetically Modified Food on Human Health:

The potential health effects from genetically modified food remains uncertain. While, many concerns have been identified and raised, the ongoing research is still incomplete and uncertain to the extent of its risk on human health. One specific concern is the potential for GM foods to transfer allergens as the DNA is transferred from a donor to another it can also add a foreign protein to it. This can lead to transfer of allergens from a food to which someone is allergic (like nuts) into a food that they are not allergic leading in unexpected trigger and can cause life-threatening situations.

One major challenge posed by GM foods on health is the difficulty in identifying and weighing the potential consequences. Example, if a consumer ingests a genetically modified food and faces any health issue or allergic reaction, he/she will never be aware of it because of lack of labelling and this will make it impossible for them to connect their health problems to their consumption of such food. This means that it will take years to gather enough data to determine the full extent as to how these foods can affect the human health.

[10] Monsanto Technology LLC and Ors. v. Nuziveedu Seeds Limited and Ors, AIR 2019 SC 559.

[11] YOONUS IMRAN, NALAKA WIJEKOON, LAKMAL GONAWALA, YU-CHUNG CHIANG, K. RANIL D. DE SILVA, *Biopiracy: Abolish Corporate Hijacking of Indigenous Medicinal Entities,* (Oct. 2, 2024, 12: 49 PM), Biopiracy: Abolish Corporate Hijacking of Indigenous Medicinal Entities - PMC (nih.gov).

While genetic engineering itself doesn't pose health risks, the potential of its negative consequences cannot be ruled out. Studies on animal have revealed a concerning result. For instance, rats that were fed with genetically modified potatoes experienced organ damage, including their livers and testicles[12].

Genetically modified food contains Bt genes, which produce a toxin that kills insects. While, this can reduce the need for chemical pesticides, it drastically enhances more concentration in the plants than the natural Bt spray used by farmers and this cannot be easily washed off from the foods. Despite its claim by various big businesses as safe and harmless the effect is negative on human health.

In India, animals graze on cotton plants after the harvest. In the village of Andhra Pradesh, animals used to graze on cotton plants but on 3 January 2008, the animals grazed on Bt cotton plant and all died the next following day. One of the eye-witness reports mentioned that when animals were given choice, they avoided GM foods[13].

Impact of Genetically Modified Food on Environment:

Proponents of genetically modified organisms argue that they are addressing the world hunger challenges, the loss of biodiversity, soil degradation, pesticide overuse and climate change. However, the implications of such remains high.

One of the concerns is that it has the potential to escape in wild and crossbreed with natural species which could disrupt ecosystems and have unintended consequence. As well as, it can have a long-term effect on soil health and traditional agricultural practices. Additionally, GM crops if interbreed with related wild plants can alter the ecological role and potential outcompete other species.

It can also pose significant threat to biodiversity when new traits are introduced it can lead to widespread cultivation of only few crop varieties reducing genetic diversity. This monoculture approach increases the risk of crops to climate change, pests and diseases ultimately putting consumer at risk of new disease outbreak[14].

Silent Spring[15] an environmental book by Rachel Carson expresses the dangers of conventional farming and usage of pesticides. The book explains how these chemicals can enter our ecosystem and affect environment, animals and human.

Responsibility of FSSAI in the regulation of GM organisms in India:

1. Organizational structure:
   To effectively manage the regulatory program for GM foods, the Food Safety and Standards Authority of India (FSSAI) plans to establish a new secretariat within FSSAI, namely Office of GM Foods that will oversee regulatory framework and policies related to GM foods and GM Food Safety Assessment Unit that will be responsible for conducting detailed safety assessments of GM foods, including its toxicology and risk assessment.

   Initially staffed with two Scientific officers, the Office of GM Foods will be responsible for the following functions:

   - Receiving and administratively reviewing GM food safety applications;
   - Verifying of submitted application;
   - Administering communication with the applications;
   - Providing a secretariat function for the GM Food Safety Assessment Unit and Expert Committee on GM Foods.
   - Maintaining communication and fostering a strong hold with various stakeholders and the public regarding GM food regulation, decisions, policy, its implications through providing information on its FSSAI website.

[12] Katherine Goldstein & Gazelle Emami, *Monsanto's GMO Corn Linked to Organ Failure, Study Reveals, Huffington Post,* (Sept. 30, 2024, 18:14 PM), Monsanto's GMO Corn Linked To Organ Failure, Study Reveals - Organic Consumers.
[13] Jeffrey Smith, *65 Health Risks of GM Foods,* Institute for Responsible Technology, (Sept. 30, 2024, 18:34 PM), 65 Health Risks of GM Foods - Institute for Responsible Technology.
[14] Charles W. Schmidt, *Genetically Modified Foods: Breeding Uncertainty,* ENVTL. HEALTH PERSP. (Aug.2005), Genetically Modified Foods: Breeding Uncertainty - PMC (nih.gov).
[15] RACHEL CARSON, SILENT SPRING, (1962).

The GM Food Safety Assessment Unit will be a disciplinary body consisting of scientists trained in GM food safety assessment, a molecular biologist, biochemist, immunologist, biochemist, food allergenicity specialist, toxicologist and nutritionist. It will be located at the National Institute of Nutrition, Hyderabad and will work in collaboration with Regulatory Coordination Mechanism and Genetic Engineering Appraisal Committee. The unit will report administratively to the Director of National Institute of Nutrition. It will have an expert committee consisting of Chief Executive Officer of FSSAI, Principal Scientific Officer, Chair of Scientific Panel on GM Organisms and Foods, Director of National Institute of Nutrition and Advisor from Department of Biotechnology.

The FSSAI will constitute the Expert Committee for following purpose:

- To oversee public consultation process for GM food applications;
- Consider and respond to public comments received during consultations;
- Recommend/suggest any conditions for product approval based on the safety assessment report by the GM Food Safety Assessment Unit.

2. Organisational Relationship within FSSAI for the Regulation of GM Foods:

- Application for approval of GM food safety will be submitted to the Office of GM Foods and it shall contain all required information outlined in 2008 Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants and protocols.
- The same procedure applies to both GM events developed in domestic and imported.
- The Office will conduct an administrative review of the same and ensure that all requirements are adhered and such will be entered into a tracking system. Incomplete application will be returned back to the applicant with 30 days with an explanatory letter for denial and they are allowed to re-submit the same.
- Such application is provided to The GM Food Safety Assessment Unit and the communication will be managed through the applicant and the unit by Office of GM. Upon completion of the safety assessment, the unit will prepare the report and will give its decision as to whether the application will be accepted or not according to its safety. The assessment, preparation of its report, and submission will all be completed within the 90 days' time frame excluding the time given to the applicant to raise its issues, give clarifications and may extend the time till 6-12 months.
- Such report will be submitted to FSSAI.
- The FSSAI will publish all the decision of the approved GM food and it will be posted on the website.
- The approval of such will give relaxation to the food importers and processors from submitting the application for the same approved GM event.

3. FSSAI's evaluation to GM Food Assessment:

- The FSSAI will be evaluating the GM food on the basis of its specific genetic modification event. The approval will cover the entire event like its offspring and any ingredients derived from its progeny[16].
- The assessment of the safety of the food will cover the entire food product or other primary component commonly consumed in India. Example, a genetically modified soybean would be assessed in raw soybean seed and processed form like protein isolate, protein concentrate, soybean oil, toasted meal. Processed food containing ingredients from approved list will not need further regulation. Further example to this, a biscuit containing soybean oil will not have to go through the assessment process as the soy oil has already been approved.

[16] FSSAI, *APPLICATION FOR THE APPROVAL OF FOODS DERIVED FROM GENETICALLY MODIFIED ORGANISMS (GMOs),* https://fssai.gov.in/upload/uploadfiles/files/Form1A_Notice_GM_Foods_04_01_2023.pdf.

- The scientific panel composed for GM food will discuss the regulatory issues and will provide strategic approach to the FSSAI. The panel's work is to only provide advice and has no role in the decision process[17].
- All the decisions, regulations, policies, standards, guidance related to GM food will be made available to the public by the FSSAI.

4. Interim Guidelines for GM Foods by FSSAI:

- The FSSAI will issue guidelines outlining the interim regulatory framework for GM Foods. These guidelines will be in function until a new regulation are notified under the Food Safety and Standards Act, 2006. It will include the application process and its procedures, Safety Assessment procedure including the format of the report, timeline for approval and review, confidentiality of the information, developing regulations for GM foods, defining the role of the scientific panel, outlining the purpose, composition and operation of Office of GM and the GM Food Safety Assessment Unit. And the guidelines followed for safety assessment provides a consistency and adherence to the internal standards by Codex Alimentarius[18].
- The FSSAI will also ensure that sufficient capacity building of the human resource, institution to implement the framework effectively. It will include training programme for safety assessment, detection, methodologies in GM food, secondly it will be establishing diagnostic laboratories for detection of unapproved GM and lastly it will also develop a certification scheme. This will ensure the effective regulation of GM food by administrative authority.

Voluntary Product Certification: A beneficial approach towards building Consumer's trust:

1. Bureau of Indian Standards (BIS):

The Bureau of Indian Standards established under the Bureau of Indian Standards Act, 2016 operates product certification scheme for various industries, ranging from agriculture and textiles to electronics. While, it is voluntary the Government has enforced mandatory certification for certain products for various control orders and these are issued under various acts and regulations such as the Food Safety and Standards (Prohibition and Restriction on Sales) Regulations, 2011.

The objective of BIS is to promote structured development of standardization, marking and quality control, secondly it provides a thrust to standardization and lastly it develops a strategy for recognizing and integrating standards with production and exports.

2. AGMARK:

The word Agmark comes from Agricultural Marketing which was established by the agricultural produce Act, 1937 is a voluntary certification scheme. It ensures quality of food commodities by setting up a standard. The scheme was implemented by the Directorate of Marketing & Inspection under the Ministry of Agriculture. This scheme is voluntary but Food Safety and Standards (Prohibition and Restriction on Sales) Regulations, 2011 has made it mandatory like BIS for certain commodities like edible oil, fat spreads etc. But, in certain commodities like clarified butter, Tea, strobilanthes callosa etc, FSSAI has prescribed certain conditional guidelines to be followed.

Conclusion:

While chief proponents of genetically modified food represent it as a solution to global food insecurity, a closer examination perpetuates how complex challenges it presents. While GMO can potentially increase crop yields and pest resistance, their negative effects on human health, environment is currently in void and lacks much

[17] FSSAI, *Reconstitution of Scientific Committee and Scientific Panels – reg,* (2023), Reconstitution_order_dated_24_02_2023.pdf (fssai.gov.in).
[18] Joint FAO/WHO Food Standards Programme, *CODEX ALIMENTARIUS COMMISSION* (2016), Codex_Working_Procedural_Manual_25_Edition_16_08_2018.pdf (fssai.gov.in).

needed research to accurately reveal its real problem[19]. Furthermore, the commercialization of GMO has raised significant concern regarding control of big industries and concentration of power in few. These corporations who often hold patent[20] on GMO seeds, limit the access for small-farmers and potentially driving them out of business as well as decreasing the importance of traditional agriculture. While, GMOs may provide interim benefits, their perdurable sustainability and ethical implication require careful consideration. A more comprehensive and safe approach is needed in addressing the global food problem rather than entirely depending on GM food and for this the FSSAI works endlessly to regulate the GMO by sub-delegating the power to various other offices to work effectively in operationalizing and regulating it so that safety is assured and only approved GM events are used for consumption.

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