RIGHT TO HEALTH AND GENETICALLY MODIFIED (GM) FOOD - A CRITICAL ANALYSIS

A Dissertation submitted to the National University of Advanced Legal Studies, Kochi in partial fulfilment of the requirements for the award of L.L.M Degree in Public Health Law

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CERTIFICATE

This is to certify that Register No. LMO320001 has submitted her dissertation titled, “RIGHT TO HEALTH AND GENETICALLY MODIFIED (GM) FOOD- A CRITICAL ANALYSIS" in partial fulfilment of the requirement for the award of Degree of Masters of Laws in Public Health Law to the National University of Advanced Legal Studies, Kochi under my guidance and supervision. It is also affirmed that the dissertation submitted by her is original, bonafide, and genuine.

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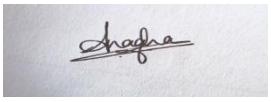

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Anagha C S

LETTER OF APPROVAL

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ABBREVATIONS

1.	AAAS	American Association for the Advancement of Science
2.	AAFC	Agriculture and Agri-Food Canada
3.	AIA	Advance Informed Agreement
4.	AIR	All India Report
5.	ANZFA	Australia New Zealand Food Authority
6.	Art.	Article
7.	BMA	British Medical Association
8.	BRAI	Biotechnology Technology Regulatory Authority of India
9.	BSE	Bovine Spongiform Encephalopathy
10.	Bt.	Bacillus Thuringiensis
11.	CAC	Codex Alimentarius Commission
12.	CBD	Convention on Biotechnology
13.	CCMB	Centre for Cellular and Molecular Biology
14.	CFIA.	Canadian Food Inspection Agency
15.	CONST.	Constitution
16.	CSA	Climate Smart Agriculture
17.	CSAPH	Council of Science and Public Health
18.	DBT	Department of Biotechnology
19	DFO	Department of Fisheries and Oceans

20.	DNA	Deoxyribonucleic Acid
21.	DPSP	Directive Principles of State Policy
22.	EC	Environment Canada
23.	EFSA	European Food Safety Authority
24.	EPA	Environment Protection Agency
25.	EU	European Union
26.	FAO	Food and Agriculture Organization
27.	FDA	Food and Drug Administration
28.	FD&C	Federal Food, Drug and Cosmetic Act
29.	FSB	Fruit and Shoot Borer
30.	FSSA	Food Safety and Standards Act
31.	FSSAI	Food Safety and Standards Authority of India
32.	GC	General Comment
33.	GE	Genetically Engineered
34.	GEAC	Genetic Engineering Appraisal Committee
35.	GOI	Government of India
36.	GM	Genetically Modified
37.	GMC	Genetically Modified Crops
38.	GMO	Genetically Modified Organisms
39.	IBSC	Institutional Bio safety Committee
40.	ICAR	Indian Council of Agricultural Research
41.	ICESCR	International Convention on Economic, Social and Cultural Rights, 1966

42.	ICMR	Indian Council of Medical Research
43.	IPPC	International Plant Protection Convention
44.	ISAA	International Service for the Acquisition of Agri-biotech Applications
45.	JAS	Japanese Agricultural Standards
46.	LMO	Living Modified Organism
47.	MAFF	Ministry of Agriculture, Forestry, and Fisheries
48.	MEC	Monitoring and Evaluation Committee
49.	MHLW	Ministry of Health, Labour and Welfare
50.	MOEFCC	Ministry of Environment, Forests and Climate Change
51.	MOH&FW	Ministry of Health and Family Welfare
52.	NBPGR	National Bureau of Plant Genetic Resources
53.	NFSA	National Food Security Act, 2013
54.	NGO	Non- governmental Organization
55.	NOC	No Objection Certificate
56.	OECD	Organization of Economic Co- operation and Development
57.	OGTR	Office of Genetic Technology Regulator
58.	PFA	Prevention of Food Adulteration Act
59.	PIL	Public Interest Litigation
60.	PVPFR	Protection of Plant Varieties and Farmer's Rights
61.	PPV & FR Act	Protection of Plant Varieties and Farmer's Rights Act, 2001
62.	PUCL	People's Union for Civil Liberties
63.	RCGM	Review Committee on Genetic Manipulation

64.	RDAC	Recombinant DNA Advisory Committee
65.	rDNA	Recombinant DNA
66.	S.	Section
67.	SBCC	State Biotechnology Coordination Committee
68.	SC	Supreme Court
69.	SCC	Supreme Court Cases
70.	SCR	Supreme Court Report
71.	SE	Substantial Equivalence
72.	TRIPS	Agreement on Trade Related Aspects of Intellectual Property Rights
73.	UDHR	Universal Declaration of Human Rights
74.	UK	United Kingdom
75.	UN	United Nations
76.	UPOV	International Union for the Protection of New Varieties of Plants
77.	US	United States
78.	USDA	United States Department of Agriculture
79.	Vol.	Volume
80.	WFS	World Food Summit
81.	WHO	World Health Organization
82.	WP	Writ Petition
83.	WP (C)	Writ Petition All Orders Civil

TABLE OF CASES

TABLE OF CONTENTS

CHAPTER- 1

INTRODUCTION

The controversy over the health implications of genetically modified crops has raged in both the Indian and international spheres in recent years. Genetically Modified (GM) Foods are foods derived from genetically modified organisms (GMOs). The safety of genetically modified foods has been a source of worry[1]. Despite the fact that genetic modification is widely regarded as a technology with potential benefits for farmers and consumers in a variety of food and agriculture fields, there is concern about its possible effects on human health and the environment. For a long time, the term biotechnology (also known as biotech) has been in the spotlight, owing to its close association with "genetically modified foods." Many people believe that biotechnology is a relatively new discipline that has recently attracted a lot of interest and that it merely entails new advanced techniques. Many people associate biotechnology with the development of genetically modified organisms (GMOs, also known as transgenic). Despite the fact that GMOs have captivated the public's interest and resulted in significant corporate investment, a significant amount of research has been undertaken and numerous applications of the technology, including agricultural biotechnologies, have been created. In fact, different biotechnological techniques are widely used in daily life, such as in baked goods and fermented foods.

The term "gene technology" refers to one type of modern biotechnology. This technology, termed as "recombinant DNA technology," entails a variety of approaches for controlling or modifying genes, as well as transferring them between related and unrelated species. This technology can take many forms, including transferring DNA from one plant to another, from a plant to an animal, from microbes to plants or animals, and so on. The resulting living organism is referred to as "transgenic," which refers to the regulated transfer of genes between living species. Gene technology aims to manage and control the cell's ability to make proteins, resulting in the production of new desirable proteins that perform new activities or achieve new goals. Agriculture and medicine are two fields where gene technology is commonly used. For example, in the medical industry, the technology is utilised in "gene therapy" to control or treat disorders that are more closely linked to a person's genetic make-up. It can also be utilised to develop new medications and vaccines, as well as to improve diagnostic and testing methods.

Genetic technology is often known as genetic engineering, genetic modification, or genetic manipulation. New DNA is created by isolating or duplicating the genetic material of interest via recombinant DNA technologies, or by synthesising the DNA artificially. To introduce this DNA into the host organism, a construct is normally built. The new DNA might be put into the genome at random or targeted to a specific region. Genetically modified (GM) organisms are organisms that have been created through genetic engineering (GMO). In the wording of

[1] Amit Khurana, Sonam Taneja & Bhavya Khullar, *Genetically Modified Processed Food in India*, CSE India, 6 (2018), http://cdn.cseindia.org/attachments/0.59829700_1532595750_genetically-modified-processed-foods-india-report.pdf.

the Rules, 1989, the terms "gene technology" and "genetic engineering" were defined as follows:

1. “Gene Technology” refers to the use of genetic engineering techniques such as self-cloning and deletion, as well as cell hybridization.

2. “The term “genetic engineering” refers to the technique of inserting heritable material that does not normally occur or will not occur naturally in the organism or cell in question from outside the organism or cell. It also includes the incorporation of a cell into a host cell, where they occur naturally (self-cloning), as well as the modification of an organism or a cell by deletion and removal of parts of the heritable material.

In 1973, Herbert Boyer and Stanley Cohen created the first GMO, a bacteria. When Rudolf Jaenisch put foreign DNA into a mouse in 1974, he developed the first GM animal. Human insulin was genetically modified in 1978, and insulin-producing bacteria were commercialized in 1982. Since the release of the Flavr Savr tomato in 1994, genetically modified food has been available for purchase. Although the Flavr Savr was designed to have a longer shelf life, most modern GM crops have been changed to boost insect and herbicide resistance. In December 2003, GloFish, the first GMO developed as a pet, was sold in the United States. Salmon that have been genetically engineered with a growth hormone were sold in 2016.

According to the World Health Organization (WHO), genetically modified organisms (GMOs) are organisms whose genetic material (DNA) has been altered in a way that does not occur naturally; they are produced to provide benefits such as lower cost, longer durability, or higher nutritional value, or both. A GMO is an organism whose genetic material has been altered in a way that does not occur naturally through mating and/or natural recombination. In general, any living creature that has been genetically modified is referred to as a GMO.

GMCs, GM crops, and biotech crops are all terms for the same thing. The resulting organism is known as a GM crop when GM is carried out in agricultural plants. The goal is to introduce new features into the plant that are not found naturally in the species. Herbicide tolerance, viral resistance, late ripening, and other traits are already being inserted into food plants using this technology. “Biopharm” is the term used to describe GE crops designed to produce pharmaceutical drugs and industrial chemicals. Frankenfoods is another term for GM foods that refers to the storey of Frankenstein and science gone wrong; biotech foods, gene foods, bioengineered foods, gene-altered foods, transgenic foods, and foods that have been developed using GE; GM foods are foods made from organisms (plants or animals) that have had specified alterations to their DNA incorporated into their DNA using one of the GM procedures. GM has been utilised in a variety of ways to help with food production and to increase things like food preservation and nutritional value. GM components can be found in a lot of processed foods. Non-GM (conventional) foods differ from GM foods in that they contain or are created from a GMO, or they contain GM ingredients.

GMO distinguishes direct manipulation of genetic material from the traditional approach of selective breeding to improve the genetic material of plants and animals. Genes from one organism can be transferred to an unrelated organism using DNA recombinant technology. GM foods are processed foods made from genetically modified plants or animals, such as oil used as a cooking medium or snacks like chips or breakfast cereal made from GM crops like soya bean, corn, cottonseed, tomato, and potato. GM crops are created and promoted as a result of perceived benefits to producers or consumers, such as pest resistance, herbicide tolerance, or higher nutritional value. However, there are concerns about the stated benefits of GM crops/foods, as well as their safety for human, animal, and environmental health. Because of these concerns, the development of genetically modified crops and the availability of genetically modified foods are regulated in several regions of the world. 99 percent of the world's GM crop acres are in maize, rapeseed, soya, and cotton. Since 2002, India has only approved the commercial growth of one genetically modified crop/food, Bt (Bacillus thuringiensis) cotton[2].

Old biotechnology techniques employed in agriculture have some drawbacks thus prompting researchers to hunt for more efficient, less time-consuming, and precise alternatives. One of the biggest concerns that have arisen as a result of traditional procedures, such as breeding or selection, is the danger of introducing an undesired gene. The science of molecular biology has made rapid advances in the realm of biotechnology over the previous few decades. Modern tools for modifying the genetic material of living beings have been created. Efforts by modern biotechnologists led to the use of genetic modification to alter agricultural properties for similar reasons. The created current technique of GM is intended to achieve the same objectives as traditional breeding.

Foods made from genetically modified organisms are genetically engineered foods commonly known as biotech foods. GM crops are those whose DNA has been altered using genetic engineering techniques in order to impart a new trait to the plant that does not exist naturally in the species. Specific alterations to the DNA of these crops are made to urge the plant to produce more nutrients or to boost faster growth and disease resistance, among other things. Almost every sector of the food industry is adopting genetic modification to create foods that taste better, grow quicker, resist pests, and increase the quantity of nutrients available. Corn has an insect resistance gene, which means farmers don't have to use pesticides that are detrimental to both the land and the crop. Soybean, on the other hand, is widely utilised in a variety of changed forms that are also genetically created, allowing farmers to avoid using insecticides and herbicides. They have been genetically modified to produce healthier edible oils with enhanced oil profiles for processing. Tomatoes have been genetically engineered to extend their shelf life. To keep it from decomposing, it was genetically engineered. Pesticide resistance has been genetically engineered into canola oil.

[2] Cheng Zang, Robert Wohlhueter & Han Zang, *Genetically Modified Foods: A critical review of their promise and problems*, 5 Food Science and Human Wellness, 116-123 (2016), https://www.sciencedirect.com/science/article/pii/S2213453016300295#:~:text=Genetic%20modification%20is%20a%20biological,all%20kinds%20of%20living%20organisms.&text=With%20DNA%20recombinant%20technology%2C%20genes,another%2C%20usually%20unrelated%2C%20organism.

Food security will be the most critical social concern over the next 30 years since the world's population is predicted to nearly double by 2050[3]. To feed the predicted 6 billion people, food output will need to be doubled, preferably tripled. Increased productivity in developing countries, particularly in areas of subsistence farming, where an increase in food production is urgently needed and crop yields are significantly lower than in other parts of the world, would be a more effective strategy for ensuring sufficient levels of food production on a global scale. GM foods aid in meeting the world's ever-increasing food demands. However, whether it is safe for human consumption is debatable, as scientists believe that mixing GM and non-GM crops may jeopardise biodiversity.

According to WHO guidelines, GM foods currently on the international market have passed safety tests and are unlikely to pose a health risk to humans. According to the guidelines, "no consequences on human health have been shown as a result of the general population's use of such foods in the nations where they have been approved[4]." According to the World Health Organization, there is no way to make a broad statement on the health effects of genetically modified foods, and each product must be examined individually for safety. Otherwise, it would be tampered with to create a bio-weapon.

Imports of genetically modified foods in India are subject to two laws: the Environment Protection Act of 1986 and the Food Safety and Standards Act of 2006. While the former considers the impact of food on the environment, the latter considers the impact of food on human health. GM products are still prohibited in the country because no regulations have been finalised. With legislation spanning the fields of science and technology, environment and preservation, agriculture and advancement, food and health, and GMO trading, India's existing legislative framework on genetically modified organisms is arguably comprehensive.

The World Health Organization (WHO) defines health as a condition of complete physical, mental, and social well-being, not just the absence of sickness. The WHO goes on to say that it is the state's legal responsibility to provide all of its citizens with uniform access to "timely, acceptable, and affordable health care of appropriate quality, as well as the underlying determinants of health, such as safe and potable water, sanitation, food, housing, health-related information and education, and gender equality[5]." This right, which is a natural result of supporting public health in India, is guaranteed in many ways under the Indian Constitution.

The Directive Principles of State Policy (DPSP), enshrined in Chapter IV of the Constitution of India, require the state to, among other duties,

- Improve the well-being of its citizens[6].

[3] Madhura Karnik, *There will be 1.8 billion Indians by 2050. GM crops are the only way to feed them all.* QUARTZ INDIA, (April 27, 2021), https://qz.com/india/740532/there-will-be-1-8-billion-indians-by-2050-gm-crops-are-the-only-way-to-feed-them-all/.

[4] WHO, (last visited Oct. 5, 2021), https://www.who.int/news-room/q-a-detail/food-genetically-modified

[5] JSA, (last visited Oct. 5, 2021), https://www.jsalaw.com/covid-19/right-to-health-as-a-fundamental-right-guaranteed-by-the-constitution-of-india/,

[6] INDIA CONST. art. 38.

- Safeguard their health and strength from abuse[7].
- Offer public assistance in the event of illness, incapacity, or "unjustifiable poverty"[8].
- Ensure reasonable and humane working conditions; and
- Increase nutrition levels, promote living standards, and prioritise public health[9].

In addition to the DPSP, the 11th and 12th Schedules contain various health-related rules that fall under the competence of Panchayats and Municipalities, respectively. These include the responsibility to provide safe drinking water, proper healthcare and sanitation (including hospitals, primary health care facilities, and dispensaries), family welfare, women's and children's development, and social welfare promotion, among others.

Part III of the Indian Constitution does not explicitly mention the right to health as a basic right (Fundamental Rights). However, this has been read into the fundamental right to life and personal liberty (Article 21) by judicial interpretation and is now deemed an inseparable aspect of the Right to Life.

In State of Punjab v. Mohinder Singh Chawla[10]**,** Supreme Court held that the right to health is an integral and fundamental part of the right to life. The government has a constitutional obligation to provide healthcare facilities. In *State of Punjab v. Ram Lubhaya Bagga*[11], the court further stated that it is the duty of the State to maintain health services in the nation. The private health sector is responsible for most healthcare in India, and most healthcare expenses are paid directly out of- pocket by patients and their families rather than through health insurance. Government policy has thus largely encouraged private sector expansion but limited public health programs. India has construed health as a Fundamental Right under Article 21. Supreme Court held right to live with dignity under Article 21 derives its life and breathe from the Directive Principles of State Policy of Article 39(e) and (f) and Article 41 and42, therefore include protection of health as envisaged in the directives. *Mahendra Pratap Singh v. Orissa State*[12]**,** stated people are entitled to adequate healthcare.

The history of legislation for healthcare dates to pre-independence, the Coroner's Act enacted by the colonial government in 1871 defined the role of medical professionals in conducting autopsies and inquests. Then the Epidemic Diseases Act, 1807 was enacted and is still applicable with amendments. In *Paschim Banga Khet Mazdoor Samity v. State of West Bengal*[13] Supreme Court held that in a welfare state, the primary duty of the government is to secure the welfare of the people. Moreover, the government should provide adequate medical facilities for its people

[7] INDIA CONST. art. 39, cl. (e).

[8] INDIA CONST. art. 41.

[9] INDIA CONST. art. 47.

[10] State of Punjab v. Mohinder Singh Chawla, 1997 2 SCC 83.

[11] State of Punjab v. Ram Lubhaya Bagga, (1998) 4 SCC 117.

[12] Mahendra Pratap Singh v. Orissa State, AIR 1997 Ori 37.

[13] Paschim Banga Khet Mazdoor Samity v. State of West Bengal, (1996) 4 SCC 37.

One of the most fundamental human rights, the right to food is inextricably related to the right to life. There can be no governmental practise or action that denies people this right. Human rights are inalienable and indivisible. The denial of one right has an inevitable impact on the enjoyment of other rights, as well as the intrinsic link between the rule of law and the preservation of other human rights, including the right to food. Effective rule of law encompasses not only legal requirements on paper, but also their proper implementation and avenues for remedy. The right to food in particular, must be made justifiable in courts of law. Hunger-stricken people are also deprived other basic human rights, such as civil and political rights, as well as economic, social, and cultural rights. And in every case, these rights are harmed by systemic negligence and poor distribution, not by natural causes or a lack of resources.

True, the country currently produces enough food to feed all of its citizens. India no longer experiences large-scale famines as it once did. Rapid rises in hunger in some parts of India are now commonly blamed on short-term natural disasters like storms or droughts. These are referred to as "transitory, episodic events," or "temporary aberrations from the norm." However, this optimistic portrayal of India's food situation ignores the country's pervasive chronic malnutrition. Natural disasters generate temporary interruptions in the food chain, which are terrible for so many people since they live on the verge of disaster under normal circumstances. India has enough food to feed its entire population, yet it does not. In terms of the basic necessities of human dignity, the chronic conditions that are the norm for many millions of people in India are intolerable.

The human right to adequate food is articulated in modern international human rights legislation as part of the broader human right to an adequate standard of living. "Everyone has the right to a standard of living appropriate for the health and well-being of himself and his family, including food," states article 25(1) of the 1948 Universal Declaration of Human Rights. Subsequently the human right to adequate food was reaffirmed in two major binding international agreements such as the International Covenant on Economic, Social, and Cultural Rights and the Convention on the Rights of the Child, both of which include two articles on nutrition.

India will undoubtedly require new technology to supplement agricultural production in order to increase yields and provide food security for a rapidly growing population. Another key reason for the use of technology is to maintain nutritional security. Swaminathan has emphasised the importance of focusing on "Nutrition Security," which he defines as "physical, economic, and social access to a balanced food, safe drinking water, environmental hygiene, primary health care, and nutritional knowledge."The nexus between biotechnology and food security and the need for legalizing GM foods in India are examined in this paper.

1.1 STATEMENT OF PROBLEM

Millions of children risk poverty and hunger as a result of the on- going record surge in Covid- 19 cases. India with a population of 1.3 billion people already has the largest population facing food shortages in the world with an estimated 189 million people already

undernourished even before the pandemic began. The efforts of Indian farmers are in vain because agricultural productivity is affected due to the climate change. Also the sudden imposition of an unprecedented and prolonged lockdown during the pandemic has also affected the farmers. This has brought renewed focus on the problems of hunger and food insecurity. Though WHO and other international organizations have already declared that GM foods are safe for human consumption and have no environmental impacts India is not ready to increase even the field trials of GM crops. Indian regulatory frameworks for GM foods are panoramic. Even though some crops have passed the field test, anti GMO protestors are not allowing its release saying no long term effects of such crops have been tested and also spreading misconceptions. All laws are discussing about regulating the use and release of GM foods but there are no provisions about increasing and managing field trials and no strict rules against spreading the misconceptions. None has discussed about the national and international laws to consider right to adequate food as a fundamental right to which laws are required to regulate rule of biotechnology in attaining food security. In the light of various international laws and conventions India should try to make a bio safety regulation for this problem.

1.2 SCOPE OF STUDY

The term “genetically modified organisms (GMO)” has become a contentious topic due to its benefits for producers and consumers, as well as concerns about biomedical risks and environmental side effects. The public's growing concern over GMOs, particularly in the form of genetically modified (GM) foods, is focused on the potential for short- and long-term health risks as a result of this advanced biotechnology. The ability of genetic engineering to eliminate malnutrition and hunger by producing crops that are resistant to pests and diseases, have longer shelf-lives, refined textures and flavours, higher yields per unit of land and time, are tolerant to adverse weather and soil conditions, and generate employment cannot be underestimated. This technology can be used to improve agriculture in order to increase food production for the human population while remaining environmentally friendly. Thus it is necessary to increase the research in GM food. So far, Bt cotton is the only GM crop that has been approved for commercial cultivation in India. Even though Bt brinjal was cleared for commercial cultivation by the Genetic Engineering Appraisal Committee (GEAC), it was placed under an indefinite moratorium. Indian regulatory frameworks for GM foods are panoramic. There are many challenges in the areas of safety testing, regulation, industrial policy and food labelling. So there is a need for a national bio safety regulation to deal with these issues and in increasing the field trials and in legalizing more GM foods.

1.3 RESEARCH QUESTIONS

1. Whether the existing national laws are compactable in India with regard to legalizing GM foods?
2. Whether use of GM foods causes any health or environmental impacts?
3. Whether GM food helps to addresses the issues of hunger and food insecurity?
4. Whether legalising GM Foods in India affect the right to health?
5. Whether the International regulations of GMOs across the world are effective?

1.4 RESEARCH OBJECTIVES

The specific objectives of the study are:

1. To study the concept of food security and biotechnology.
2. To analyze the benefits of genetically modified foods and its ability to promote the right to adequate food.
3. To study the national and international laws in regulating the use and release of GM foods.

1.5 HYPOTHESIS

GM food addresses the issue of hunger, food insecurity and mal-nutrition. Legalizing GM food does not violate the right to health rather it safe guards the right and promotes the right to adequate food. India needs a specific bio safety legislation to govern the research, transit, import, containment, environmental release, manufacture, and use of all biotechnology goods, with all licences provided through a multi-level evaluation procedure conducted by scientific experts. This new body will be able to provide an effective single-window system for GM agricultural research, safety concerns, and regulatory measures. Thus regulated biotechnology may help in securing food adequacy.

1.6 RESEARCH METHODOLOGY

The research methodology adopted in this dissertation is purely doctrinal. The doctrinal research will be on the basis of primary data like statutes, case study and reports and secondary sources include United Nations Covenants, Universal Declaration of Human Rights and documents published by Specialized Agencies of United Nations, books, articles, journals newspapers and websites.

1.7 LITERATURE REVIEW

1. **Salah E. O. Mahgoub, Genetically Modified Foods, Basics, Applications and Controversies, (2016), Taylor & Francis Group-** This book seeks to provide a complete overview of genetically modified foods and technology. It discusses GM food laws and regulations, as well as how they affect mandatory and voluntary labelling. Various issues and arguments are explored from both pro- and anti-GM food labelling parties. The report covers GM food labelling from a worldwide viewpoint, as well as the perspectives of a few countries. The opinions of consumers on the labelling of genetically modified foods are also discussed. Patenting of GM foods and the potential for monopoly as a result of having intellectual property rights on them are also discussed. It discusses the concerns and debates surrounding GMOs and GM foods. It also covers the arguments of proponents of biotechnology and genetically modified foods, as well as those of opponents and sceptics.

2. **Genetically Engineered Foods, Handbook of Food Bioengineering, Volume 6, 2018, Academic Press-** The goal of this book was to compile the most recent advances in the field of genetically altered foods, emphasising contemporary

techniques, current issues in the biotechnological and food industries, and the success of very recent innovations. This book also contains an updated review of where we are now in terms of genetically altered foods, as well as where we are headed.

3. **David E. Newton, GMO Food A Reference Handbook, 2014, ABC CLIO-** This book is intended to provide the facts that this paper needs for a better understanding of the debate over genetically modified foods, as well as the tools it needs to do the study on the subject. It examines some of the most pressing challenges and difficulties surrounding genetically modified crops, including the benefits and drawbacks of their production and use.

4. **Ronald Rose Watson & Victor R. Preedy, Genetically Modified Organisms in Food Production, Safety, Regulation and Public Health, 2016, Academic Press-** This book focuses on the scientific review of available research linked to public health authorities' general responses to new GMO food products in order to establish their safety and potential health dangers. It also explains why India requires biotechnology in order to ensure food and nutrition security.

5. **Genetically Modified Crops Issues and Challenges in the context of India, Research Unit Rajyasabha, 2009-** This paper tries to describe the various aspects of GM crops and briefly examines the application of genetic engineering in Indian agriculture, highlighting the concerns and challenges that come with it.

6. **N. S. Sreenivasulu, Law Relating to Biotechnology, Oxford University Press, 2016-** This paper attempts to present the law surrounding biotechnology regulation. Law and policy issues relating to today's most promising, sophisticated, and yet contentious technology have been explored, debated, analysed, and presented in a straightforward, scientific, and detailed manner

1.8 CHAPTERIZATION

1. **INTRODUCTION**: First chapter deals with general introduction to study of Genetically Modified Organisms and Food which includes scope of the study, research objectives, research problems, hypothesis and the research methodology.

2. **INTERNATIONAL REGULATIONS ON GMOs:** This chapter examines different laws at the International regimes regarding GMOs and GM foods. It examines the various regulations and labelling of GM food across different countries such as:
   a) Australia- New-Zealand
   b) Canada
   c) European Union
   d) Japan

e) United States of America

3. **GM FOOD AND LEGAL FRAMEWORK IN INDIA:** This chapter focuses on the current Indian legal frameworks for the regulation of GM foods in India such as
   (a) Rules 1989
   (b) Seed Policy, 2002
   (c) Prevention of Food Adulteration Act, 1954
   (d) Food Safety and Standards Act, 2006
   (e) Patents Act, 1970
   (f) The National Policies.

4. **ROLE OF GM FOOD IN ACHIEVING THE RIGHT TO ADEQUATE FOOD AND ERADICATING POVERTY:** This chapter examines the need for legalizing GM foods in India and its urgency in increasing its field trials. It also discusses the concerns of issues and its benefits to the ever increasing population and the farmers in India. The chapter also examines the human rights related with GMOs.

5. **CONCLUSION AND RECOMMENDATIONS:** This chapter consists of the Cruz of the study and concludes the ways in which how the legal frameworks regarding GM foods in India can be strengthened. This chapter focuses on how to improve the Indian legal frameworks regarding the regulation of GM foods. It also gives suggestions based on the discussion in various chapters of the present study.

CHAPTER- 2

INTERNATIONAL REGULATIONS AND LABELLING OF GM FOODS

2.1 INTRODUCTION

Many customers are unaware that they have been eating food products containing GM elements for decades. Many studies have attempted to ascertain how the consumer feels about GM foods and whether GM foods should be labelled or not. Some customers want to know if their food contains genetically modified components, just as they want to know if their food is natural or organic. The fundamental motive for labelling has been to inform customers about food constituents. Regulation of GM crops and foods has proven to be a complex, multifaceted subject that requires serious consideration. It has been an issue of concern to the public, scientists, policymakers, and the food industry. Weirich in 2007 edited a book named "Labeling Genetically Modified Food", examines GM food labelling policies and the cases that bring them up. It is widely regarded as the first comprehensive, interdisciplinary examination of the GM food labelling debate. The contributions include food and agricultural scientists, economics, attorneys/legal scholars, bioethicists, and philosophers[14].

Governments worldwide have made GM regulation and labelling a top priority and are working hard to establish regulatory procedures for GM foods. Different governments have taken different approaches based on the political, social, and economic factors of the region or country in question. As a result, there are substantial variances in regulations between countries, with the most pronounced differences between the United States and Europe. In general, most governments have prioritized "protection of public health as it relates to food consumption" as a top priority to be addressed through promoting and enforcing strong food safety standards across the supply chain.

Some of the important questions related to the regulation of GM foods and the exact responsibilities of different parties such as the government and the food industry are frequently questioned. They must satisfactorily answer the questions for the benefit of the consumer. Some of the questions that need to be answered and clarified are: what type of agency or body would be most appropriate to handle GM food regulation, the importance of penalties or sanctions for non-compliance, the need for new regulations for gene technology, and the extent to which governments can promote trade and commerce at regional and international levels and the ability of national governments to streamline and handle any conflict that might arise between international obligations and local.

Several challenges confront governments in the process of drafting regulatory framework for GM foods. Governments must ensure consumer protection, as well as trust and confidence in the regulations that they impose. Consumers must also be involved in the decision-making process concerning regulation development. Governments should have processes that will not

[14] SALAH E.O. MAHGOUB, GENETICALLY MODIFIED FOODS, BASICS, APPLICATIONS AND CONTROVERSY, 183 (CRC Press, 2016).

impede the development of the technology at all levels, such as research and commercial levels. Governments must strike a reasonable balance between international regulatory systems and foreign trade, as well as state sovereignty. The regulatory process is further complicated by the requirement for specific and distinct regulations for the different stages of using gene technology to produce foods, namely in the laboratory, industrial, and marketing levels.

The regulatory process is further complicated by the requirement for specific and distinct regulations for the various stages of the use of gene technology to produce foods in the laboratory, and at the industrial, and marketing levels. The need for regulations originated from the belief that, in addition to the identified benefits, this new technology may pose some risks. It was necessary to regulate this category of foods since GE technology was then utilised to produce different kinds of food that were identified as GM or GE foods. The primary goal of the GM food regulation has been to ensure safety. The Organization for Economic Cooperation and Development (OECD), the World Health Organization (WHO), and the Food and Agriculture Organization (FAO) have been collaborated to create the basic concepts for ensuring the safety of foods derived from GMOs.

An outcome of that collaboration came in the year 2003 when the Codex Alimentarius Commission (CAC) of the FAO/WHO produced the document "Principles and Guidelines on foods derived from biotechnology" (Codex Alimentarius Commission 2003). The goal of this publication was to assist countries in establishing, coordinating, and standardising GM food regulations in order to ensure consumer safety while also harmonising and facilitating international trade. CAC also produced a relevant document in 2004 that updated the criteria for food import and export. (Codex Alimentarius Commission 2004)[15].

2.2 THE PRINCIPLE OF SUBSTANTIAL EQUIVALENCE

The term "substantial equivalence," or SE, is an internationally recognised standard that determines whether a biotech food or crop has similar health and nutritional properties to its conventional counterpart (Council for Biotechnology Information 2001). It is widely used by national and international bodies dealing with GM foods as the starting point for assessing the safety of GM foods, for example, FAO, WHO, OECD, USFDA, and by some countries such as Canada (through the Canadian Food Inspection Agency) and Japan (through Japan's Ministry of Health and Welfare). SE believes that the most practical way to determine the food safety of a novel food or one of its components is to see if it is substantially equivalent to an analogous conventional food product, if such a product exists. SE embodies the idea that if a new food or food component is discovered to be substantially equivalent to an existing food or food component, it can be treated similar manner in terms of safety (i.e., the food or food component can be concluded to be as safe as the conventional food or food

[15] *Modern Food Biotechnology, Human Health and Development: an evidence-based study*, Food Safety Department WHO, 2005, https://www.who.int/foodsafety/publications/biotech/biotech_en.pdf.

component)[16]. GM foods that are considered to be substantially equivalent are thought to be as safe as their conventional counterparts. Food products that are not substantially equivalent, on the other hand, may still be safe if they are subjected to a variety of other tests to confirm their safety before they can be marketed.

SE considers the presence of naturally harmful or toxic substances, as well as antinutrients, in plant-based foods. Such foods are still safe to eat. To determine whether a modified food is substantially equivalent or not, the manufacturer tests it for the presence of any changes in certain defined components such as toxins and allergens that were not present in the conventional counterpart. The results of such tests are further evaluated by an official regulatory body, for example, the USFDA. The data and comments from the initial test, as well as those from the regulatory agency, are then forwarded to regulators, who must decide whether there are significant changes between the modified and unmodified items. If no differences are discovered, regulators will usually not recommend additional food safety testing. Under certain conditions, regulators may require additional safety testing, such as if the tested product lacks a natural equivalent or exhibits significant differences from the unmodified food[17].

SE derived from an OECD working group report. The group was mandated to draft a document on the safety implications of modern food biotechnology. The background documents used in the report were derived from previous examples of how the safety of novel foods and food components had been assessed. The report included recommendations on some concepts and principles pertaining to the safety assessment of foods developed using modern biotechnology. These principles are consistent with FAO and WHO recommendations and have gained widespread international acceptance.

When applying the SE principle, certain factors must be considered. Such factors include the composition and properties of both the counterpart and novel foods, the method used to change the nature of the new food, and the manner in which the new genetic material is expressed[18]. If the new food is considered to be substantially equivalent to an existing food, any additional safety or nutritional concerns are deemed insignificant. This food would then be treated in the same way as the natural counterpart to which it was compared. Regulators may be confronted with the introduction of a completely new class of foods. In such a situation, it would not be practical to apply the SE principle and previous experience and judgment used in the evaluation of materials of similar nature is taken into account. If a product is judged not to be substantially equivalent to an existing one, then further tests would be recommended.

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[16] JOINT FAO/WHO EXPERT CONSULTATION ON BIOTECHNOLOGY AND FOOD SAFETY, 1996, http://www.fao.org/ag/agn/food/pdf/biotechnology.pdf.

[17] *Safety Evaluation of Foods Derived by Modern Biotechnology Concepts and Principles*, OECD 1993, https://www.oecd.org/science/biotrack/41036698.pdf.

[18] *Statement of Policy- Foods Derived from New Plant Varieties*, U.S. FOOD AND DRUG ADMINISTRATION, May 1992, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/statement-policy-foods-derived-new-plant-varieties.

2.3 GM FOOD LABELLING AND ISSUES

In today's society, labelling food that contains GMO ingredients has become a controversial and divisive issue. It has been one of the primary issues that authorities have been concerned about. Some of the contentious issues that have sparked much debate, similar to GMOs in general are: Should GM products and GM foods be labelled or not? Should labelling be mandatory or voluntary? There is widespread scientific agreement that food generated from GM crops presents no greater danger than conventional food on the market[19]. There are claims that there is no evidence to support the view that consuming genetically modified foods is harmful to human health[20]. Some opponents of GM technology, on the other hand, are calling for additional and more rigorous testing of GM foods. People in the agribusiness industry believe that labeling should be voluntary and that the demands of the free market and consumer preferences would influence the labeling process. In case consumers prefer labeled foods over unlabeled ones, the industry would regulate itself or run the risk of losing consumers. On the other side of the debate are consumer interest groups that support mandatory labelling of GM foods, claiming that people have the right to know what they are eating.

There are a number of questions that need to be answered before regulating a mandatory nature for GM foods. One major question concerns the additional production costs and the economic impact of mandatory labelling of GM foods. This extra cost comes as a result of constructing two separate production lines at the industrial level as well as a result of practices at the farm level where farmers will try to keep GM crops separate from non-GM crops during planting, harvesting, and shipping. Testing and meticulous record-keeping are required at various stages of the food supply chain. The cost of mandatory labelling has been estimated to range from a few dollars per person per year to about 10% of a consumer's food bil[21]l. The industry is expected to pass on the additional cost burden to consumers in the form of higher food prices.

Another point to consider is the acceptable level of GM contamination (if any) in non-GM products. At what level can these boundaries be established? Who would be in charge of ensuring that food-producing companies are in compliance? What kind of punishment would be levied? As with other issues related to GM technology, there is a divided difference of opinion among different nations, for example, the EU has determined that 0.9% is an acceptable level of cross-contamination, Australia and New Zealand decided a threshold value of 1%, while Japan has specified a 5% threshold (Hansen 2001). Many consumer

[19] *supra* note at 4.

[20] Report on Council on Science and Public Health, CSAPH Report 2- A- 12, https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/about-ama/councils/Council%20Reports/council-on-science-public-health/a12-csaph2-bioengineeredfoods.pdf.

[21] Guillaume P. Gruere & S.R.Rao, AgBioForum, *A Review of International Labeling Policies of Genetically Modified Food to Evaluate India's Proposed Rule*, Volume 10, No.1, 2007, AgBioForum http://citeseerx.ist.psu.edu/viewdoc/download;jsessionid=1D56F47DB45B8E9FAFCC162CBF049006?doi=10.1.1.178.597&rep=rep1&type=pdf.

interest groups believe that only 0% would be acceptable. On the other hand, some food-producing companies such as Gerber Baby Foods and Frito Lay have pledged not to use any GM ingredients in manufacture of any of their products.

There are two methods for regulators to determine whether or not a food has been genetically engineered. The first is a content-based approach in which foods are tested for the presence of foreign DNA or protein. Auer (2003) discusses the methods used to detect genetically engineered (GE) components in crops and processed foods. Process-based verification is the second method for confirming the presence of GE components[22]. It entails meticulous documentation of seed source, field location, harvest, transport, and storage. Concerns about GM food labelling also include the detectability of GM food cross-contamination and public awareness of GM food labels. With regard to detecting GMO contamination, it has been found that current techniques are not able to detect minute quantities of contamination. This means that ensuring a 0% level of contamination will not be possible. There is disagreement among scientists as to what level of contamination is practically possible. With regard to public awareness and to what extent would consumers understand the meaning of food label information, the question is who would be responsible to educate the public about GM food labels? Would it be of any benefit to label GM foods if consumers are not able to interpret the meaning of the information on the label?

2.4. GM FOODS REGULATIONS AND LABELING IN SELECTED COUNTRIES

Typically, the introduction of new food safety regulations follows the occurrence of an unanticipated problem, such as the restrictions on the processing and sale of beef once the nature of BSE was recognised[23]. However, regulations governing genetically modified (GM) products (including GM foods) followed a different pattern. They were actually created prior to the occurrence of any threats to human health or the environment. Governments around the world have adopted a variety of strategies and approaches to GE and its applications in the development of GMOs and products derived from them, particularly GM foods. Different approaches have been taken to assess and manage potential risks associated with the use of GE techniques. In some countries, GE, like any other technology, is regulated. Other countries are still working on enacting relevant legislation. There are significant differences in the regulation of GMOs and GM foods between countries, with some of the most significant differences observed between the US and Europe. The main factors considered when developing GMO and GM food regulations are human health and environmental safety.

One of the most pressing issues confronting GM food regulators is whether or not they should be labelled. Labeling can be mandatory or optional. The threshold for GM content in mandatory labelling varies by country. The details of these levels are discussed in the

[22] P. Byrne, D. Pendell, & G. Graff, Colarado, *Labeling of Genetically Modified Food*, COLARADO STATE UNIVERSITY EXTENSION, https://extension.colostate.edu/topic-areas/nutrition-food-safety-health/labeling-of-genetically-modified-foods-9-371/.

[23] *Genetically Modified Crops: the Ethical and Social Issues*, NUTFIELD COUNCIL ON BIOETHICS, 2014, https://www.nuffieldbioethics.org/wp-content/uploads/2014/07/GM-crops-full-report.pdf.

sections dealing with labelling in various countries. The debate over GM food labelling stems from differing perspectives on whether GM foods on the market pose any greater risk than conventional foods. On this subject, scientists have differing opinions. There appears to be a broad scientific consensus that GM foods are as safe as their conventional counterparts and that there is no clear evidence to support the belief that consuming GM foods is harmful to human health[24]. On the contrary, some scientists and anti-GM organisations believe that the issue of GM food safety has not been resolved and that more rigorous testing of GM foods is required.

2.4.1 AUSTRALIA- NEW ZEALAND

Food Standards Australia New Zealand (FSANZ), formerly known as Australia New Zealand Food Authority (ANZFA), is the official government body responsible for developing food standards for Australia and New Zealand (Food Standards Australia New Zealand 2014). Relevant government agencies and other stakeholders are consulted by the FSANZ during different stages of food standards development. Typically, standards are developed following a rigorous scientific assessment of the risk to public safety and health. The FSANZ's decisions must be approved by a joint Australia-New Zealand Food Regulation Ministerial Council. This Council includes health ministers of all Australian states and territories as well as health minister of New Zealand in addition to other ministers nominated by each country. FSANZ assesses the safety of GM foods in accordance with internationally established scientific principles and guidelines developed through the work of the OECD, the FAO, the WHO, and the CAC. The safety assessment in Australia and New Zealand is characterized by:

1. Case-by-case consideration of GM foods.
2. Consideration of the intended and unintended effects of the genetic modification.
3. Comparisons with conventional foods having an acceptable standard of safety (Food Standards Australia New Zealand 2007).

FSANZ and the Office of Gene Technology Regulator (OGTR) took over the responsibilities and activities of GE in Australia from the Genetic Manipulation Advisory Committee in 2001. The OGTR is a Commonwealth Government Authority within the Department of Health and Ageing, reporting to Parliament via the Ministerial Council on Gene Technology. FSANZ assesses the following aspects of GM foods or ingredients: nutritional content, any nutritional changes, toxicity, allergenicity, and stability, as well as any unintended effects of the inserted genetic material[25]. FSANZ is legally obligated to evaluate and report on the safety of all GM foods and ingredients sold in Australia and New Zealand. FSANZ conducts mandatory pre-market safety assessments on all GM foods and ingredients before they enter the country and are used in foods for human consumption. No food will be allowed to be sold unless it has been proven to be safe to consume. In Australia and New Zealand, GM food labelling is mandatory. These regulations became law in December 2001, with the goal of

[24] *supra* note 20.

[25] *Food Genetically Modified(GM),* BETTER HEALTH CHANEL, (last visited July 21, 2021), https://www.betterhealth.vic.gov.au/health/healthyliving/food-genetically-modified-gm.

assisting consumers in making informed decisions about whether or not to purchase or consume GM foods. Before a food made from GM material or using GE enzymes can be sold in Australia or New Zealand, it must be approved by FSANZ. Lists of foods which meet criteria for such approvals are periodically updated and published on the FSANZ website.

All foods marketed in Australia, including products containing GM ingredients, must comply with the Australia New Zealand Food Standards Code (referred to as "the Code"). The code regulates GM foods and ingredients under "Standard 1.5.2—Food produced using gene technology". Standard 1.5.2 does not apply to GM food additives or processing aids, which are already covered by other food standards. Any GM foods (or ingredients derived from them) that are listed in Standard 1.5.2 have passed the safety assessment and approval process, and can therefore be sold in Australia and New Zealand, and used to make other foods[26].

In the Australia New Zealand Food Standards Code[27]:

- The use of additives, processing aids, and nutritive substances in food is prohibited unless these compounds have received specific authorisation following a safety assessment.
- Use of novel foods, irradiated foods, and foods made with gene technology is prohibited unless a particular permit has been granted following a safety assessment.
- Maximum limits for pollutants and natural toxicants in food are established.
- Establishes food microbiological and processing standards.
- For several commodities, it specifies the composition and labelling standards.

FSANZ had approved 34 GM food commodities as of August 2008, including GM corn, cotton, canola, sugar beet, soybean, and potato varieties. Although commercial cultivation of GM canola has been approved, only GM cotton from which cottonseed oil is extracted is currently grown commercially in Australia. Following the announcement by the Minister for Agriculture and Food on December 22, 2008, that the State Government had approved limited commercial-scale trials of GM canola, the State Government of Western Australia established an interdepartmental committee to investigate GM food labelling (Western Australian Agricultural Authority 2011)[28]. It aimed to answer the following questions:

1. Does the current GM food labelling encourage informed consumer choice?
2. What are the drawbacks of mandating additional GM food labelling?
3. What can the state government do to educate and support consumers' decisions about genetically modified foods??

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[26] *Safety Assessment of Genetically Modified Food*, FOODS STANDARDS AUSTRALIA NEW ZEALAND, 2005, https://www.foodstandards.gov.au/consumer/gmfood/safety/documents/GM%20Foods_text_pp_final.pdf.

[27] *Id.*

[28] *An Investigation of Labelling Genetically Modified Food*, DEPARTMENT OF AGRICULTURE AND FOOD GOVERNMENT OF WESTERN AUSTRALIA, 2011, https://www.parliament.wa.gov.au/publications/tabledpapers.nsf/displaypaper/3814485c74d13040d2558f9e482579f4000e72b6/$file/4485.pdf.

The committee's main recommendations emphasised the importance of public education programmes in order to improve understanding of GM foods and their labelling. It has also been suggested that GM foods be labelled mandatorily to indicate which GM DNA and/or proteins have been removed during processing. The committee also recommended that the industry should be encouraged to adopt more informative labeling of GM foods and to provide adequate GM food information to consumers on a voluntary basis.

2.4.2 CANADA

In Canada, GM foods are regulated by Health Canada (HC), the Canadian Food Inspection Agency (CFIA), Environment Canada (EC), Agriculture and Agri-Food Canada (AAFC), and the Department of Fisheries and Oceans (DFO). Under the Food and Drugs Act, HC and the CFIA are tasked with evaluating the safety and nutritional value of GM foods. HC works to protect Canadians' health and safety through science-based regulation, guidelines, and public health policy, as well as health risk assessment of the food supply. The Plant Biosafety Office (PBO) working under the umbrella of the CFIA is responsible for the environmental assessment of biotechnology derived plants. Regardless of method of origin, the Canadian regulatory system is based on whether a product has "novel" features or not. In Canada, novel foods fall into the following categories: Foods resulting from a previously unutilized food process; products that have never been used as a food; and foods that have been genetically modified, thus GM foods fall under the umbrella of novel foods[29]. HC is responsible for regulating novel foods in Canada via a pre-market notification requirement outlined in Division 28 of Part B of the "Food and Drugs Regulations" (Novel Foods). This notification is required for, and contributes to, the assurance of food safety when prepared or consumed as intended.

The Canadian regulation of biotechnology-derived foods is a lengthy process that includes 7–10 years of research, development, testing, and evaluating the safety of a new GM food. To complete the process, there are eight steps that must be taken[30]. These steps are

1. Pre-submission consultation
2. Pre-market notification
3. Scientific assessment
4. Request for additional information
5. Summary of report of findings
6. Preparation of food rulings proposal
7. Letter of no objection
8. Decision document on Health Canada website

The Government of Canada believes that labelling biotechnology-derived foods is an important issue that influences consumer preference or choice. The Canadian General

[29]Stavroula Malla, Jill Hobbs & Eric Kofi Sogah, *Functional Foods and Natural Health Products Regulations in Canada and Around the World: Nutrition Labels and Health Claims*, CAIRN, 2013, http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.500.3804&rep=rep1&type=pdf.
[30] *supra* note 14.

Standards Board formed a committee to develop a voluntary labelling standard for GE foods. The stakeholders represented in the committee included consumer groups, food companies, universities, government, and general interest groups. The standard is called "Voluntary Labeling and Advertising of Foods That Are and Are Not Genetically Engineered." This national standard was adopted by the Standards Council of Canada in April 2004. Under the Food and Drug Act, HC and the CFIA collaborate to develop food labelling policies. The role of HC in food labelling is to protect health and safety, whereas the CFIA is in charge of leading the programme to develop general food labelling policies and regulations. The CFIA's responsibilities include protecting consumers from fraud and misrepresentation in food labelling, packaging, and advertising, as well as developing food labelling and advertising guidelines. Currently, Canada has a mandatory food labelling policy in place if a food has a health or safety issue that can be mitigated through labelling, for example, presence of a food allergen or a change in food composition or nutritional value (Health Canada 2014). In such cases, special labelling is required to alert consumers or vulnerable groups. This is a general requirement that applies to all foods, including genetically modified foods.

The Canadian Federation of Agriculture opposes mandatory labelling, claiming that it would result in massive industry losses. They are concerned that consumers will interpret food labels as a warning and avoid such foods. Food processors may choose to avoid including GM components in their products rather than label them, necessitating reformulation. This is expected to raise food prices and have a negative impact on food markets.

2.4.3 EUROPEAN UNION

Anti-GM food groups in Europe have been very active in protesting the production, importation, marketing, and consumption of GM foods. These organisations took advantage of two major food scares that occurred in Europe, namely bovine spongiform encephalopathy (commonly known as mad cow disease) in the United Kingdom and dioxin-tainted foods from Belgium. Consumers' trust in the European food supply has been shaken as a result of these unfortunate health incidents. Europeans began to lose faith in what their governments told them about genetically modified foods. This public stance prompted European governments to respond in a way that may restore some public trust. This was reflected in the requirement for mandatory food labelling of genetically modified foods in stores. At the same time, the European Commission (EC) has set a 1% contamination threshold for unmodified foods[31]. Throughout the EU's existence, the general legislative approach has been "if anything can conceivably be regulated, regulate it." As a result, it had developed a comprehensive system and machinery for considering and approving (or not) applications for

[31]Pauline Verrièr, *Preventing GMO Contamination- An Overview of National Coexistence measures in the EU*, IFOAM EU GROUP, 2014, https://www.organicseurope.bio/content/uploads/2020/06/ifoameu_policy_gmos_dossier_201412.pdf?dd.

approval of specific lines of GMOs, as well as controlling the release of GMOs into the environment[32].

Until the 1990s, Europe's GM product regulations were less stringent than those in the United States. This situation has changed dramatically, and the EU now has some of the most stringent and strict regulations in the world regarding the presence of GMOs in food and feed[33]. All GMOs, as well as irradiated foods, are considered "new foods" and must be subjected to extensive, case-by-case, scientific-based food evaluation by the European Food Safety Authority (EFSA 2012). Foods are evaluated for safety, labeling, traceability, and freedom of choice.

The regulatory system and labeling of food products in the EU has witnessed a series of developments and changes which started during the early 1990s. Continuous updates are issued as the need arises or conditions change. The general principle is that before GM foods can be approved in the EU, they must be rigorously evaluated for safety in accordance with the "EC Novel Foods Regulation (258/97)," which came into effect on May 15, 1997. This is an EU-wide system that indicates that a "novel food" must be evaluated for safety before it can be marketed. In this context, a "novel food" is one that has not previously been widely consumed by humans in the EU, and it includes genetically modified foods. The European Commission's "Novel Foods and Novel Food Ingredients Regulation (EC 258/97)" applies labelling requirements to GM foods that will be approved in the future, including labelling if there are any health or ethical concerns or if it contains a live GMO. After many years of deliberation, this regulation was approved in 1997. The Novel Foods Regulation must be followed if any of the following conditions are met: Foods and ingredients derived from GM, modified, or new molecules, any product that has not previously been consumed in significant quantities by humans in the EU, and if novel processing methods are used. In addition to these, the Novel Food Regulation requires that labeling should be included if,

- The novel food differs from the equivalent familiar food due to a change in composition or nutritional value.
- Consumption of the novel food has health implications, for example, an allergen is present that is not present in the existing equivalent food.
- The novel food creates ethical considerations, for example, a food plant containing DNA of animal origin.
- The novel food is or contains a viable genetically modified organism

Following the Novel Foods Regulation, a labelling regulation was created specifically for GM soybeans, corn, and other GM foods. In September 1998, an amendment to this labelling regulation (EC 1139/98) was adopted and implemented by the various EU Member States.

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[32] Information Statement, *Genetic Modification and Food*, INSTITUTE OF FOOD SCIENCE AND TECHNOLOGY, 2008, http://ucbiotech.org/resources/reports/IFST_gm.pdf.

[33] Davison J & Ammann K, *New GMO regulations for old: Determining a new future for EU crop biotechnology*, GM Crops Food, 8(1):13-34 2017 Jan 2, https://www.tandfonline.com/doi/full/10.1080/21645698.2017.1289305.

Article 8 of the EU Novel Food Regulation requires the labelling of an ingredient that is no longer equivalent. One major requirement of the regulations is that products should be clearly labeled if they contain genes that may result in toxicity or allergenicity, particularly if such genes would not normally be expected to occur in the food. The EU has issued two directives (Directive 90/220/EEC on release and marketing and Directive 90/219/EEC on use in containment) that govern the production, release, and marketing of GM plants. They had to be implemented by EU member states through individual state regulations. The EU Regulation EC 1829/2003, referred to as "Labelling of Genetically Modified Foods and Feed"," was enacted in April 2004. The main objectives of this regulation are to:

- Ensure the safety of human and animal health by requiring rigorous safety testing of GM food and feed before it may be commercialised.
- Ensure that common risk assessment and authorization procedures are efficient, transparent, and quick.
- Ensure that consumers (including farmers buying feed) have access to clear labelling that addresses their concerns and allows them to make educated decisions. (European Commission 2014)

Regulation EC 1829/2003 applies to all GM food and animal feed, regardless of whether any GM material is present in the final product. As a result, if their original source is genetically modified, products such as edible oils, flour, and glucose syrups must be labelled as GM. Foods produced using GM technology, such as cheese made with GM enzymes, on the other hand, are not required to be labelled. Similarly, food products derived from animals on fed GM animal feed, such as meat, milk, and eggs, are not required to be labelled. This regulation was not well received by European food and feed manufacturers, as well as their overseas suppliers, and has been a major source of concern for them. In the EU, if a food contains or consists of GMOs, or contains ingredients derived from GMOs, the label must state so. For GM products sold "loose," information indicating that it is GM must be displayed immediately next to the food.

2.4.4 JAPAN

In Japan, the Ministry of Health, Labor, and Welfare (MHLW) is responsible for carrying out scientific reviews to evaluate and confirm the safety of new GM crops. On the other hand, the Ministry of Agriculture, Forestry, and Fisheries (MAFF) have been assigned with determining the safety of the environment and animal feed as affected by GM cropping. The MAFF is also in charge of approving new GM crops for feed use. In terms of GM crops approved for food use, Japan has approved 44 GM crops. There are 15 canola varieties, 12 corn varieties, 7 cotton varieties, 5 potato varieties, 4 soybean varieties, and 1 sugar beet variety[34]. The complete list of products that have undergone safety assessment and been announced in the Official Gazette as of April 2014 is published in the website of the Department of Food Safety, MHLW.

[34] THE ORGANIC AND NON- GMO REPORT, 2014, https://non-gmoreport.com/articles/millenium/japanlegislationlabelinggmfoods.php.

For GM crops approved in Japan, the MAFF and MHLW have implemented labelling requirements under the Food Sanitation Law and Japanese Agricultural Standards (JAS). JAS labelling requirements have been applied to some food products. The selection of these foods is based on the fact that they are made from ingredients that may contain GM products and that GM DNA or protein can be found in the foods. Selected foods include soy- and corn-based products such as tofu, natto, soymilk, miso, other soy-based products, corn snacks, cornstarch, popcorn, and other corn-based products (The Organic and non-GMO Report 2014). According to Japan's food labelling policy, if a food contains more than 5% GM ingredients, it must be labelled as "GM Ingredients Used" or "GM Ingredients Not Segregated." The GM content of a food product must be less than 5% in order for it to be labelled as "non-GM.[35]" It is the food processor's responsibility to demonstrate that all non-GM ingredients were identity preserved during production and processing. The supplier of the food product must provide documentation of this process. Labels such as "non-GM product segregated" or "not genetically modified" are permitted for these products. Compliance with these regulations is monitored by the MAFF and the MHLW. They test samples for the presence of GM content at random and on a regular basis. If a food sample contains more than 5% GM material in a product labelled "non-GM," the local Japanese manufacturer or food importer must update the labelling to indicate "GM ingredients."

When it comes to unapproved GM varieties found in foods, Japanese regulations are extremely strict. A "zero tolerance" policy is implemented in this regard. Processed and imported foods on the market are sampled and tested in order to ensure full conformity with this guideline. If an unauthorised GM component is found in a product at the point of entry, it will be re-exported, destroyed, or used in no-food products. If a breach is discovered at the retail level, the product producer will be ordered to recall the product immediately. Corn, soybeans, papaya, and potatoes are among the key goods being investigated. So far, the MHLW, which oversees the testing, has discovered one unapproved potato variety, two unapproved papayas, and one unapproved corn[36]. Grocery stores in Japan sell both GM and non-GM foods. This allows customers to select the type of food they want to eat. Customers are beginning to exhibit a significant preference for unprocessed fruits and vegetables, according to research.

2.4.5 UNITED STATES

Currently, the United States is the largest commercial producer of GM crops and GM foods in the world[37]. In the United States, food regulation is carried out by three agencies that work together. The Food and Drug Administration (FDA), the United States Department of Agriculture (USDA), and the United States Environmental Protection Agency (EPA) are the three agencies (EPA). The FDA is concerned about new plant varieties, dairy products,

[35] Setsuko Yasuda, *GMO Foods Labeling in India*, IATP, https://www.iatp.org/sites/default/files/GMO_Foods_Labeling_in_Japan_091299.html.

[36] *supra* note 34.

[37] *Pocket K No. 16: Biotech Crop Highlights in 2019*, ISAAA, 2019, https://www.isaaa.org/resources/publications/pocketk/16/.

seafood, food additives, and processing aids posing a threat to food safety. It regulates the sale of genetically modified foods to customers, as well as its incorporation into processed foods for sale to consumers. The USDA is in charge of meat and poultry product regulation, as well as monitoring the release of genetically modified plants and animals into the environment for field testing or commercial usage. Pesticides and pesticidal agents, including plants with pesticidal qualities, are regulated by the EPA because they can harm plants and animals in the environment. As a result, it may be required to approve new pest-resistant plant kinds. In other words, the EPA assesses GM plants for environmental safety, while the USDA assesses if they are safe to grow and the FDA assesses whether they are safe to eat. Because three different government agencies have control over GM foods in the United States, this regulation process is sometimes criticised as being confusing. There may be certain overlaps in responsibilities, making separation of powers problematic in the end.

The FDA regulates food labelling in a way that aims to give customers with health, nutrition, and safety information. The Federal Food, Drug, and Cosmetic Act (FD&C Act) establishes the FDA's science-based labelling policy, which applies to all foods, whether or not they are derived from transgenic crops or animals[38]. If a product fails to meet the requirements of Chapter 3 of the FD&C Act, the FDA has the right to take regulatory action. The FDA's framework for addressing bioengineered food labelling regulation is based by a legislation that covers the following points:

1. All food labels should include a name that accurately describes the basic nature of the food. With regard to bioengineered foods, name changes only apply if the food is significantly different from its traditional counterpart, such that the common or usual name no longer adequately describes the new food.
2. If food production processes result in major differences, for example, in nutritional profile or lead to any safety concerns, the food label must disclose these differences.
3. Voluntary labeling by food producers and processors about production methods is allowed by the FDA on the condition that the labeling is not misleading or carries false information.
4. The FDA discourages the use of acronyms, which might be confusing or misleading consumers, for example, “GMO-free.” Some consumers may not understand what the acronym stands for, while others might interpret “genetically modified” as referring to conventional techniques.
5. In general, the FDA believes that its current labeling policies, combined with pre-market safety assessments, are sufficient to ensure the safety of bioengineered foods.

The current FDA regulation (USFDA 1992) provides that agri-biotech businesses may request a consultation with the FDA on a voluntary basis. Companies developing novel genetically modified foods are not compelled to consult the FDA, nor are they required to adopt the FDA's recommendations after consulting with the agency (Whitman 2000). In 1992, the FDA adopted the criterion of "substantial equivalence," which said that GE food is basically equal to conventional varieties of food until evidence demonstrated otherwise. In

[38] *Report 2 of the Council of Science and Public Health (A-12), Labeling of Bioengineered Food*, (2012), https://ag.utah.gov/documents/AMA-BioengineeredFoods.pdf.

2006, the FDA adopted a set of guidelines for evaluating plants that have been genetically modified to produce new proteins, such as those used in pharmaceuticals. The FDA's position on food labelling is governed by the "Food, Drug, and Cosmetic Act." This Act solely applies to food additives, not to entire foods or food products that are labelled as "GRAS" (generally recognised as safe). The FDA considers the features of the food and its intended use, rather than the fact that innovative procedures were utilised in its manufacturing, to be the most important factors in determining its safety[39]. This is a basic difference between the United States and the EU regulations, which creates a major issue in the current controversy regarding GM foods.

The FDA requires labeling of GM foods in the following situations[40]:

1. If the food has a significantly different nutritional property;
2. If a newly developed food has an allergen that consumers would not expect to be present; and
3. If a food contains a toxicant beyond acceptable limits.

In 2001, the FDA proposed voluntary food labeling draft guidelines for foods that do or do not contain GM ingredients. This draft guidance represents FDA’s views on voluntary labeling of foods indicating whether foods have or have not been developed using bioengineering. According to the FDA, food labelling standards that apply to all foods should also apply to foods made with biotechnology. Furthermore, the FDA stated that all material details regarding the product must be disclosed on the food's label. Some examples cited by the FDA to substantiate that statement include

1. Bioengineered foods which are significantly different from their traditional counterparts should show that and should be labelled in a way to describe the difference
2. If it is not clear how the food or one of its constituents should be used, the label must include a statement to describe how it is used
3. In case a bioengineered food has a different nutritional profile, the label must reflect that difference
4. Unexpected presence of an allergen in a food based on its name necessitates disclosing of the allergen on the label.

These guidelines clearly aim to eliminate any statements on food labels that are deceptive, confusing, or ambiguous. The FDA's advice emphasises the importance of avoiding food misbranding. If a food's label contains assertions that are inaccurate or deceptive in any way, it is misbranded. It will be considered misleading if the label does not disclose all facts about the product, such as the potential consequences of its use. On the food labels of bioengineered foods or foods containing bioengineered ingredients, certain food manufacturers may desire to incorporate informative statements. The FDA understands this and permits the inclusion of such statements as long as they are clear and do not mislead the

[39] *supra* note 23.
[40] *supra* note 22.

customer or reader. To demonstrate this, the FDA provided examples with specific wording as well as their comments on each one. The following examples have been cited by the FDA.

1. “Genetically engineered” or “this product contains cornmeal that was produced using biotechnology.” FDA comment: “The information that the food was bioengineered is optional and this kind of simple statement is not likely to be misleading.”
2. “This product contains high oleic acid soybean oil from soybeans developed using biotechnology to decrease the amount of saturated fat.” FDA comment: “This example includes both required and optional information.”
3. “These tomatoes were genetically engineered to improve texture.” FDA comment: “To ensure that the consumer is not misled, a statement like ‘to enhance texture for processing' rather than ‘to improve texture' should be used if the alteration in the tomatoes was intended to assist processing but did not produce a perceptible difference in the processed consumer product. It is optional to declare that the tomatoes were genetically modified.”

The FDA stresses that words like "GMO-free" and "not genetically modified" are not really technically correct unless they're used in the context of bioengineering technology. On some items, the term "GMO-free" on food labels may be misleading because these foods do not contain whole organisms. However, using the term "free" in a food label to indicate the absence of bioengineering would very certainly be misleading. This is because it gives consumers the feeling that it is “zero” bioengineered. According to the FDA, the phrase "free" can only be guaranteed if there is a definition or a limit above which it cannot be used. There are currently no tests available to accomplish this. As a result, the FDA advises against using the term "free" in bioengineered statements unless there is a clear evidence that no bioengineered material is present. The FDA advises that statements on food labels be supported by evidence. A food manufacturer should be able to establish that a food or any of its ingredients is not bioengineered. Validated testing, which is regarded the most reliable technique to detect bioengineered foods or food ingredients, can help the manufacturer achieve this.

Many genetically modified foods produced and/or consumed in the United States are exempt from special regulations and are not separated from non-GM foods. Food crops exported to Europe, such as soybeans and corn, may face difficulties as a result of this. This is due to the fact that under the EU novel food law, such goods must be labelled. In the case of GM soya and corn imports into Europe, this concern has been handled by presuming that GM components will be present unless the source of the crop is confirmed to be free of GM material. Because more GM material is projected to be developed in the future, this can be used as a temporary solution. Although there are no mandatory labelling rules for GM foods at the federal level, certain states have moved forward with labelling measures. A number of states have approved legislation requiring the labelling of genetically modified foods. In May 2013, the state of Connecticut passed a bill requiring GMO labelling. The bill will not take effect until four other states pass legislation similar to it[41].

[41] Stephanie Storm, *Connecticut Approves Labeling Genetically Modified Foods*, THE NEW YORK TIMES, (2013), ,https://www.nytimes.com/2013/06/04/business/connecticut-approves-qualified-genetic-labeling.html.

On January 9, 2014, Maine's governor signed a bill requiring labeling for foods made with GMOs, with a similar triggering process as Connecticut bill. The House of Representatives of Vermont state approved a labeling bill on April 23, 2014. California Proposition 37 is another state-level campaign to require obligatory labelling of GM foods. This is a bill that would require the labelling of genetically modified foods. The proposal mandates the labelling of food supplied to customers that is created from plants or animals whose genetic material has been altered in specific ways, and prohibits the marketing of such food, as well as other processed foods, as "natural." On November 6, 2012, the proposition was defeated in a statewide election in California. Efforts to approve and implement mandatory labelling for genetically modified foods in the United States continue. In this regard, consumer protection organisations are very active. The Center for Food Safety filed a lawsuit against the FDA in June 2006, claiming that the FDA's regulation of GM foods is inadequate.

The US has often criticized the EU for its unscientific GMO laws, which it claims are a form of trade. After realising that other countries are no longer relying on GMOs developed in the United States and that these countries are producing and cultivating their own GMOs, the United States is now proposing to establish its own GMO regulatory system.

2.5 INTERNATIONAL AGREEMENTS

2.5.1 Cartagena Protocol on Biosafety

The Protocol is adopted in 2000 and entered into force by September, 2003. It is the first global legally binding instrument focusing on LMOs. The Protocol's goal is to establish adequate levels of protection in the field of safe transmission, handling, and use of LMOs emerging from modern biotechnology that may have negative consequences for biodiversity conservation and sustainable use, or constitute a health risk to human (art. 1; art. 4). Except for pharmaceuticals for humans, which are covered by other international agreements, the Protocol applies to all LMOs (art. 5). Articles 6 to 10 and Article 12 establish an Advance Informed Agreement (AIA), which requires a) a notification of the exporting party containing certain information, b) an acknowledgement of its receipt, and c) the written consent of the importing party prior to the first intentional introduction into the environment of an importing party. Decision-making criteria on importation are provided; they must, in particular, be based on a risk assessment. The AIA method only applies to LMOs that are intended for intentional release into the environment[42].

AIA does not relate to living modified creatures intended for direct use as food, feed, or processing, according to the Protocol. LMOs specified in a COP resolution as not expected to have negative effects on biodiversity conservation and sustainable use; LMOs in transit; and LMOs for contained usage are also exceptions. Article 11 says that a Party must notify the Biosafety Clearing House established under the Protocol for LMOs that may be susceptible to

[42] Alexandrova, K. Georgieva & A. Antanassov, *Biosafety Regulations of GMOS: National and International Aspects and Regional Cooperation*, TAYLOR AND FRANCIS GROUP, 19 sup3, 153-172 (2005), https://www.tandfonline.com/doi/pdf/10.1080/13102818.2005.10817294.

transboundary movement for direct use as food or feed, or for processing, if it makes a final decision for domestic use, including placing on the market. In addition, a particular amount of data must be submitted. Art. 11(4) permits parties to take an import decision under its domestic regulatory framework, provided this is consistent with the Protocol A contracting Party from a developing country or a nation in transition with no domestic regulatory framework can declare through the Biosafety Clearing House that its decision on the first import of an LMO for direct use as food, feed, or processing will be based on a risk assessment. (art. 11(6)). In both situations, a lack of scientific certainty due to a lack of relevant scientific information and understanding about the magnitude of potential harmful effects shall not prevent the contractual Party of import from taking adequate action to avoid or minimize such adverse impacts. (art. 11(8))[43]

The precautionary principle is well reflected into this article. This principle was established at the 1992 Rio Conference on Environment and Development, which resulted in the Rio Declaration, which declares that "in order to conserve the environment, States shall generally apply the precautionary approach according to their competence. Lack of full scientific certainty shall not be used as a reason to postpone cost-effective steps to avoid environmental degradation where there are concerns of serious or permanent damage." The Protocol confirmed the primary role of the Precautionary Principle at the CBD's COP in 2000 (Annex II of the Protocol). The Protocol provides risk assessment guidelines in Annex III. The risk assessment must be carried out in a scientifically sound, transparent, and case-by-case manner. The lack of scientific understanding or consensus should not be taken as implying a certain level of danger, the absence of risk, or a risk that is acceptable. The Protocol specifies general risk management measures and criteria (i.e., to the extent necessary to prevent adverse impacts within the importing Party) (art. 16(2)). Measures must be adopted to reduce the likelihood of inadvertent transboundary migration of LMOs (art. 16(3)). When an occurrence may result in an unintended transboundary movement, affected or possibly affected States must be notified (art. 17(1)).When it comes to biodiversity issues, the text of the article practically allows for both the negative and positive effects of LMO use to be taken into account. The parties are encouraged to collaborate on research and information exchange regarding the socioeconomic impacts of LMOs, particularly on indigenous and local communities (art. 26(2))[44].

2.5.2. Codex Alimetarius

The Codex Alimentarius is the primary collection of internationally recognised food standards in the field of food safety, and as such, it is vital to biosafety. The Codex has evolved into a seminal global reference point for consumers, food producers and processors, national food control agencies, and international food trade. Consumer concerns and general standards are given top priority in the formulation of commodity by both Codex subsidiary bodies and the Commission, an intergovernmental entity that develops and monitors the

[43] DAVIDE E. NEWTON, GMO FOOD, 246-247 (ABC CLIO 2014).

[44] *supra* note, at 42.

Codex. The adopted standard format reflects Codex's emphasis on ensuring that consumers receive products that are of a minimum acceptable quality, are safe, and do not pose a health hazard. The Codex Commission is also the key platform for discussing the food safety implications of GMOs. Food containing GMOs or LMOs is a type of "novel food" covered by the Codex. The Codex Guidelines for the Production, Processing, Labeling, and Marketing of Organically Produced Food; the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology; the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA Plants and Codex Alimentarius Proposed Revised Code of Ethics for International Trade in Food are among the six instruments that are relevant. The Proposed Draft Guidelines for the Labeling of Foods Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering is still in the process. In addition, the Codex Commission is working on a proposed Code of Practice on Animal Feeding, which aims to create a feed safety system that encompasses the entire "feed chain" from farm to table. This will eliminate potential dangers to human, animal, and environmental health. It will apply to the production and use of all animal, plant, and marine-derived components used in animal feed at all levels, whether they are produced in a factory or on a farm[45].

2.5.3. International Plant Protection Convention

The IPPC was enacted in 1952 and has been amended twice since then, once in 1979 and again in 1997. Plant pests are regulated by the IPPC. It also regulates "any organism, object, or material capable of harbouring or transmitting pests that damage plants or plant products." (art. I(4)). The purpose of the regulation is to prohibit “the proliferation and introduction of certain pests, as well as promote control measures” (ICPM, 2001a). IPPC's application to plants is not limited to cultivated plant protection or direct insect damage. The Convention's scope encompasses the preservation of both cultivated and natural flora, as well as plant products, and includes both direct and indirect pest damage. “Pest” is broadly defined in the Convention as “Any species, strain or biotype, animal life, or any pathogenic agent detrimental or potentially damaging to plants or plant products.” This definition includes alien creatures that fall within this category. The IPPC's applicability scope is broad enough to embrace genetically modified organisms (GMOs) as well as live modified creatures/products of modern biotechnology that may harm plants directly or indirectly. There is a risk of overlap between the CBD and the Cartagena Protocol, which is why the two agreements are cooperating more.

[45] *Id.*

2.6 CONCLUSION

Hence under the powerful wave of biotechnology, the use of genetic engineering in the food industry is seen as inevitable. Agricultural biotechnology has already proven to be a commercial success. Various countries have legalised the use of GM foods with proper regulations. Foods derived from GM crops or GM crops fed to animals are widely available, and additional GM foods are expected to be introduced in the future. While it may be beyond the government's ability and authority to ensure the safety of every GM food before it is marketed, the public demand for GM labelling is reasonable and ought to be heard. The US government has promised to review its laws on genetically modified organisms and products. A new rule or regulation is on the horizon, which might have a substantial impact on the development and commercialization of genetically modified foods[46].

Consumer concerns have sparked a debate about whether GM foods should be labelled, allowing customers to make better informed choices. There is no universal agreement on whether or not GM foods should be labelled, or whether or not labelling should be mandatory or voluntary. The labelling of genetically modified foods may indicate that they are distinct from non-GM foods. This may mislead people into believing that GM foods are hazardous for human consumption. Labeling might not be desired by all consumers. Consumers are expected to cover any additional production costs that may arise as a result of labelling.

All the GM products currently on the international market have passed safety tests conducted by national authorities. In general, these various assessments follow the same basic principles, including an assessment of environmental and human health risk. Codex documents are usually used to evaluate food safety.

[46] Alice Yuen-Ting Wong & Albert Wai-Kit Chan, *Genetically Modified Foods in China and the United States: A Primer of regulation and Intellectual Property Protection*, 5 FSHW, 124-140 (2016), https://www.sciencedirect.com/science/article/pii/S2213453016300076#sec0110.

CHAPTER- 3

INDIAN REGULATIONS ON GENETICALLY MODIFIED FOODS

3.1 INTRODUCTION

During the 1970s, India experienced the Green Revolution in wheat and rice, which enabled us to become self-sufficient in food grain production. Climate change and rising population pressure have significantly altered the situation in the 21st century. World hunger is on the rise again and, and eradicating hunger and malnutrition by 2030 will be a difficult task that will be accomplished through sustainable agriculture and collaborative efforts from all stakeholders[47]. Traditional technology will not be able to meet the needs for food and nourishment. When combined with traditional plant breeding techniques, advances in modern biology, particularly biotechnology and molecular biology, offer numerous benefits. Globally, scientific and technological advances in these areas have advanced at an astonishing rate over the last decade. GM crops are created by using laboratory techniques to transfer genes between organisms for specific traits. Plants derived from this method are referred to as GMOs (Genetically Modified Organisms), genetically engineered plants, or transgenic plants. Growing GM crops provides significant social, economic, and environmental benefits around the world, but many farmers and people in some countries are sceptical of GMOs. The majority of arguments for and against transgenic plants revolve around their effects and outcomes, whether on farmers, health and the environment, or economic performance. Climate change and the food crisis are two major issues that scientists and policymakers around the world are concerned about. Food crisis is spreading at an alarming rate as agriculture production struggles to keep up with population growth; as a result, scientists are looking to modern biotechnology to provide food security[48].

The path to the development and commercialization of GM crops has not been as smooth as that of many other technological advancements and developments in various scientific fields. Since its introduction and commercialization, there has been a great deal of debate, with many demonstrations and protests by NGOs, farmers, and the general public, as well as bans by many governments around the world. The United States, Canada, and Japan had commercialised a variety of food and non-food GMOs, which were well received by the public, with only minor sporadic opposition to some specific GM foods. Americans are confused about genetically modified foods, their safety, and the labelling of genetically modified foods. Recently, the majority of Americans voiced significant support for the labelling of genetically engineered goods. After the commercialization of the first GM crops

[47] *Sustainable Development Goals*, UNITED NATIONS, https://www.un.org/sustainabledevelopment/hunger/, (last visited Sep. 4, 2021).

[48] *How to feed the world in 2050*, FAO, http://www.fao.org/fileadmin/templates/wsfs/docs/expert_paper/How_to_Feed_the_World_in_2050.pdf.

in the United States roughly 20 years ago, the GM food issue spread to the developing countries[49].

Despite the fact that several scientific studies have shown that genetically modified foods are safe, India has yet to commercialise its first GM food. Bt brinjal deregulation was put on hold in 2010 by a moratorium, but Bt cotton was deregulated in India in 2002. Many GM crops, both food and non-food crops, are still in the laboratory or in limited field trials and are ready for commercialization, despite considerable opposition from some farmers affiliated with NGOs concerned about their safety and effects on biodiversity. In many developing countries, ideological beliefs, political reasons, and a lack of scientific knowledge are the main reasons for opposition to GMOs, whereas in developed countries, psychology, emotions, and politics are some of the reasons for opposition to GMO adoption[50].

Food safety, environmental consequences, and socio-economic issues have all been raised as a result of the increased production of genetically modified crops. Here we examined the current state of GM agricultural research in India, as well as the regulatory structure and issues associated with transgenic plant research.

3.2 REGULATORY FRAMEWORK IN INDIA

In India, the "Rules for the Manufacture/Use/Import/Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells, 1989" (commonly referred to as Rules, 1989) under the provisions of the Environment (Protection) Act, 1986 regulate all activities related to GMOs and their products. The 1989 Rules have a broad scope, effectively covering the full spectrum of operations involving GMOs and their products, such as sale, storage, exportation, importation, production, manufacturing, packaging, and so on. The Ministry of Environment, Forests and Climate Change (MOEFCC) and the Department of Biotechnology (DBT) of the Ministry of Science and Technology, Government of India, are in charge of enforcing these guidelines[51].

3.2.1 Rules, 1989

In India, the Ministry of Environment, Forests, and Climate Change (MoEFCC) enacted the Environment (Protection) Act, 1986 as an umbrella legislation to provide a comprehensive framework for environmental protection and improvement. Following that, a series of Rules were issued to address various issues such as hazardous chemicals, hazardous wastes, solid wastes, biomedical wastes, and so on[52].

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[49] Manish Shukla, Khair Tuwair Al- Busaidi, Mala Trivedi & Rajesh K. Tiwari, *Status of research, regulations and challenges for genetically modified crops in India*, Vol 9, GM CROPS & FOOD, 173-188 (2018), https://www.tandfonline.com/doi/full/10.1080/21645698.2018.1529518.

[50] *Id.*

[51] Vibha Ahuja, *Regulation of emerging gene technologies in India*, Vol 12 BMC PROC 12,14 (2018), https://bmcproc.biomedcentral.com/articles/10.1186/s12919-018-0106-0.

[52] *Id.*

The Environment (Protection) Act, 1986 is the central legislation for bio safety in India[53]. The MoEFCC notified the "Rules for manufacture, use, import/export & storage of hazardous microorganisms/genetically engineered organisms or cells, 1989" in connection with the use of microorganisms and the application of gene technology, as per the powers conferred by Sections 8 and 25 of the Environment (Protection) Act, 1986 under "Regulation of Genome Engineering Technologies in India. These regulations have a very broad scope, effectively covering the whole range of operations involving GMOs and their products. They also apply to any substances, products, food stuffs, and other items that contain such cells, organisms, or tissues. Aside from genetic engineering, new gene technologies have been included.

Section 6 of the Act empowers the Central Government to establish important rules on standard procedures, implement safeguards, and impose required restrictions on the handling of hazardous substances, as well as outright prohibit the use of others. Section 8 of the Act, on the other hand, prohibits a person from handling any substances classified as hazardous under the Act unless the processes and precautions have been followed. Finally, Section 25 of the Act delegates to the Central Government the task of establishing procedures and safeguards for handling hazardous substances. As a result, the general consensus in the Indian Judicial System is that the bio safety rules are statutory in nature, as they derive from the aforementioned provisions of the Environment Protection Act. These aforementioned provisions prompted the Ministry of Environment and Forests to issue the 1989 Bio safety Rules[54].

The Rule 8 of the statute requires regulatory bodies to approve the discharge or production of genetically modified organisms and cells prior to the release. The Rules 10 and 11 require approval for any such substances containing genetically engineered organisms or even cells. However, Rule 9 of this act is the most important since it expressly prohibits the deliberate and/or inadvertent discharge of genetically modified organisms (for experimental purposes) covered by its schedule, unless the relevant authority has recognised the circumstance as a "exceptional instance." The above-mentioned schedule is part of the Bio safety Rules of 1989, which classify human and animal diseases according to their risk profiles. The Biotechnology Safety Guidelines, implemented by the Department of Biotechnology, have effectively supplemented the 1989 Bio safety Rules[55]. The Biotechnology Safety Guidelines are the result of Rule 4(2) of the 1989 Bio safety Rules, which requires guidelines manuals to be specified by the Review Committee on Genetic Manipulation. This committee is a departmental offshoot of the Department of Biotechnology and is supported by it. These guidelines are concerned with the assessment of bio safety levels, which it examines in depth. There is also a detailed warning about recombinant DNA or rDNA-related activities,

[53] The Environment (Protection) Act, 1986 (Act No.29, Acts of Parliament 1986).

[54] *Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro Organisms/Genetically Engineered Organisms or Cells*, (*Rules 1989*), https://biosafety.icar.gov.in/wp-content/uploads/2015/11/Rules-1989.pdf.

[55] *Revised Guidelines for Research in Transgenic Plants and Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants And Plant Parts*, 1998, https://biosafety.icar.gov.in/wp-content/uploads/2015/11/Rev_Guidelines_Research1998.pdf.

experiments, shipments, and quality control produced by genetic engineering. Before reaching its current form and being issued by the Department of Biotechnology in 1990, the Biotechnology Safety Guidelines were revised and amended twice before being finally amended in 1998 in accordance with the progressive strides made in the field of rDNA research.

3.2.2 Regulatory Committees

There are four stages of departmental structures in the life-cycle of a genetically modified organism or a GMO-based product. Pre-research, research, release, and post-release are the stages. The Recombinant DNA Advisory Committee monitors the pre-research stage because it is the body that authorises and approves the research to be conducted. The Review Committee on Genetic Manipulation and the Genetic Engineering Appraisal Committee govern the release stage of a GMO's life cycle. The RCGM examines the process of research and experiment-based releases, whereas the GEAC monitors the commercial release of GMOs, either directly or indirectly. The Monitoring and Evaluation Committee, the State Biotechnology Coordination Committee, and the District Level Committee are the occupants of the post-release stage. These committees, however, frequently overlap into the research stages through data-provisioning submitted to the RCGM. Finally, the Institutional Bio safety Committee, led by the RCGM, SBCC, and DLC, implements standard safeguards at research and development sites. The Rules of 1989 have specified six competent authorities, as well as their composition and roles[56]. The functions of these six competent authorities are:

1. The Recombinant DNA Advisory Committee (RDAC) - keeps track of biotechnology developments at the national and international levels. It is advisory in nature and is expected to make recommendations on safety regulations in the research and applications of GMOs and their products from time to time. In 1990, this Committee developed the Recombinant DNA Biosafety Guidelines, which were adopted by the government for conducting GMO research and handling in India.
2. Institutional Biosafety Committee (IBSC) - Each institution that intends to conduct research involving mutation or alteration of any living entity, be it plants, animals, humans, or microorganisms, is required to constitute the ISBC.
3. Review Committee on Genetic Manipulation (RCGM) - It serves as a body that monitors the safety-related aspects of research, which includes ongoing research on hazardous microorganism projects. In order to maintain environmental safety, manuals of recommendations outlining the mechanism for regulatory process with respect to activities involving GE organisms in research, usage, and applications are also required.
4. State Biotechnology Coordination Committee (SBCC) – It is constituted in each State where research and applications of GMOs are underway.

[56] *Handbook for Genetically Modified Foods Safety Assessment and Regulations*, MINISTRY OF ENVIRONMENT FORESTS AND CLIMATE CHANGE AND BCIL, 2019, https://www.biotech.co.in/sites/default/files/2020-01/2019%20Handbook%20for%20Food%20Safety%20Officials%20%E2%80%93%20Genetically%20Modified%20Foods%20Safety%20Assessment%20and%20Regulations.pdf.

5. District Level Committee (DLC) – As the name implies, it is held at the district level. DLCs have been established in districts where necessary to monitor the safety regulations in installations engaged in the use of GMOs/hazardous microorganisms and their environmental applications. It occurs wherever it is necessary to monitor the regulations pertaining to safety and installation that have been engaged in the use of GMOs or hazardous microorganisms[57].
6. Genetic Engineering Appraisal Committee (GEAC) – It is a functioning apex body with representation from relevant agencies and specialists. It is responsible of accepting and approving operations involving large-scale usage of hazardous organisms and recombinant products in the research area and industrial production from an environmental standpoint. It is the highest body formed under the Environment Protection Act 1986's Manufacture, Storage, and Import of Hazardous Chemicals Rules, 1989[58].

i. According to the provisions of rules 1989, the Committee will serve as a Statutory Body under the Ministry of Environment and Forests to approve operations involving large-scale use of hazardous live microorganisms and recombinants in research and industrial production.
ii. The Committee shall also be in charge of approving proposals relating to the release of genetically engineered organisms and products into the environment, including experimental field trials, in accordance with the Rules, 1989..
iii. The Committee is responsible for approving proposals involving the use of living modified organisms in the manufacture/import of recombinant Pharma products, or when the end product of the recombinant Pharma products is a living modified creature.
iv. If necessary, the Committee may co-opt other members/experts to the GEAC in accordance with Section 4, paragraph 3 of the Rules, 1989.
v. The Committee may also appoint subgroups, subcommittees, or expert committees to carry out specific bio safety compliance operations.
vi. A quorum of one-third of the GEAC members will be required to convene the meeting.
vii. GEAC members will be required to sign a "Statement of Declaration of Independence" and a "Statement of Confidentiality" (as per enclosed Performa).
viii. The Committee will be in operation for three years from the date of this notification.
ix. Depending on the issues to be discussed, representatives from other Ministries and other experts may be invited as 'Special Invitees' to participate in the GEAC meeting with the approval of the Chairman of GEAC[59].

Out of these, the three agencies that are involved in approval of new transgenic crops are:

[57] *supra* note 51.
[58] *Id.*
[59] Alex Andrews George, *Genetically Modified Crops and Regulations in India*, (April 16 2020), https://www.clearias.com/genetically-modified-crops-and-regulations-in-india/.

1. Establishment of an **IBSC** at the institution level to monitor institute-level research in genetically modified organisms.
2. The **RCGM**, which reports to the DBT, is in charge of monitoring ongoing GMO research and small-scale field trials.
3. The MoEF's **GEAC** has the authority to authorise large-scale trials and the release of GMOs into the environment.

3.2.3 Precautionary Principle in India

In India, no explicit statutory authority has promulgated the precautionary principle. The resulting gaps in bio safety regulations, however, have been filled by Supreme Court judicial pronouncements, which have adopted the matrix of the principle in adjudicating legal disputes involving genetically modified organisms. The polluter pays principle and the precautionary principle was held to be essential components of promoting sustainable development in India in *Vellore Citizens' Welfare Forum v. Union of India*[60]. In terms of municipal law, the precautionary principle implies that: (i) authorities must "anticipate, prevent, and attack the causes of environmental degradation"; (ii) no cost-effective measures should be postponed in the face of scientific uncertainty and irreversible consequences; and (iii) the burden of proof for proving that a proposal is environmentally friendly lies on the proponent. The Supreme Court held that, while the principle is not enshrined in any Article of the Indian Constitution or any of the various environmental legislations, as a cardinal principle of international environmental law, it can be integrated into domestic legislation that is not in conflict with municipal laws and should be considered by the judiciary when deciding cases.

In the case of *Narmada Bachao Andolan v. Union of India*[61], the Supreme Court decided that the precautionary principle shall be applied in all circumstances where ecological impacts are uncertain. If, on the other hand, the impacts are certain or known, mitigation measures should be taken to keep the detrimental quality as contained as feasible.

3.2.4 Approvals and Prohibitions

Rules, 1989, require compliance with bio safety safeguards, and any violation or noncompliance in this area is subject to punitive actions under the EPA, 1986. The following are the approvals and prohibitions under Rules 1989[62]:

1. Except with the GEAC's approval, no person shall import, export, transport, manufacture, process, use, or sell any GMOs, substances, or cells.
2. Pathogenic organisms, GMOs, and cells shall be used in laboratories or inside laboratory areas that have been notified for this purpose under the EPA's 1986 regulations.

[60] Vellore Citizens' Welfare Forum v. Union of India, AIR 1996 SC 2715.
[61] Narmada Bachao Andolan v. Union of India, AIR 2000 SC 3751.
[62] *supra* note 54.

3. Anyone planning to scale up or conduct pilot operations with GMOs must first acquire clearance from the GEAC.
4. Experiments using GMOs for educational purposes can be carried out under the supervision of IBSCs.
5. The deliberate or unintentional release of GMOs is prohibited.
6. No production involving the generation or use of GMOs shall begin without the approval of GEAC. All approvals must be granted for a period of four years in the first instance, renewable for two years at a time.
7. The GEAC shall have the authority to revoke approvals in the following circumstances:
    i. Any new information on the harmful effects of GMOs.
    ii. GMOs cause environmental damage that could not have been predicted when approval was granted.
    iii. Failure to comply with any GEAC-mandated conditions.

The limitations of this regulatory framework are highlighted in a report by a standing parliamentary committee titled "Cultivation of genetically modified food crops- prospects and effects." According to the research, the majority of these committees lack statutory jurisdiction, and the lack of a centralised organisation obscures the entire process. Furthermore, despite being a member to the Cartagena Protocol, which outlines the essential infrastructure and redress mechanisms for biotechnology, India has failed to meet its treaty obligations. Furthermore, the committee believes that without a proper cost-benefit analysis, GM crops ultimately benefit only the industry that provides such seeds and crops, which is exacerbated by a lack of proper research and testing and is ultimately detrimental to the economic health of farmers as well as the environment. Furthermore, because agriculture is a state subject, open-field testing of GM crops should be a discretionary power of the state, but there were no provisions for mandatory consultation with state governments regarding such testing. As a result, the committee elucidated the non-sustainability of GM crops in a developing country like India.

3.2.5 Recombinant DNA Guidelines, 1990

With consideration to the advancement of Biotechnological research worldwide, various institutes and industries in India also have shown keen interest in this field of research. This gives the necessity to regulate the course of development of these researches. Therefore the Department of Biotechnology had formulated Recombinant DNA Guidelines in 1990 “to regulate the research and developmental activities on GMOs, transgenic crops, large-scale production and deliberate release of GMOs, plants, animals, and products into the environment, shipment and importation of GMOs for laboratory research. This guideline was further revised in the year 1994[63].

[63] *Project brief*, WORLD BANK, https://documents1.worldbank.org/curated/en/131131468752400413/pdf/260080India0Biosafety0100Project0Brief.pdf.

3.2.6 Guidelines for Research in Transgenic Plants, 1998

In the year 1998, the Department of Biotechnology of the Government of India created separate guidelines with the goal of managing transgenic plant research. These guidelines cover various aspects of, "toxicity and allergenicity of transgenic seeds, plants, and plant parts. These guidelines cover various areas of recombinant DNA research on plants, which include the development of transgenic plants and their growth in the soil for molecular and field evaluation. Along with this, guidelines also deal with import and shipment of genetically modified plants for research purposes. These guidelines also directed the RCGM to form a special Monitoring and Evaluation Committee (MEC) to monitor the environmental impact of transgenic plants over time. The committee undertakes field visits at the experimental sites and if required, suggests remedial measures to adjust the trial design, based on the on-the-spot situation. This committee also collects and reviews available information on the comparative agronomic advantages of the transgenic plants and accordingly advises the RCGM on the risks and benefits from the use of transgenic plants under evaluation".

3.2.7 Seed Policy, 2002

The Seed Policy, 2002 was issued by Ministry of Agriculture, Government of India. This policy contains a separate section (No. 6) on transgenic plant varieties. This section states that all genetically engineered crops/varieties will be tested for environmental and bio-safety before commercial release in accordance with the EPA's guidelines from 1986. According to the EPA, seeds of transgenic plant varieties for research purposes will only be imported through the National Bureau of Plant Genetic Resources (NBPGR). Before any transgenic crop or variety is officially released in the market, it will be tested to determine its agronomic value through the ICAR's All India Coordinated Project Trials, in conjunction with environmental and bio-safety clearance tests as required by the EPA. Following the commercial release of the transgenic plant variety, its seed will be registered and marketed in the country in accordance with the provisions of the Seeds Act. The performance of a transgenic plant variety in the field will be monitored for at least 3 to 5 years after commercial release by the Ministry of Agriculture and state agriculture departments[64].

3.2.8 Prevention of Food Adulteration Act, 1954

The Ministry of Health and Family Welfare (MOH&FW), which is part of the Central Government, is responsible for guaranteeing the quality and safety of food sold in India. The Prevention of Food Adulteration Act (PFA Act) was enacted in 1954 and went into effect on June 1, 1955, with the goal of ensuring food quality and safety while also encouraging fair trade practises. Several times, the Act has been revised to make the provisions more practical and consumer-friendly. This is the fundamental statute designed to safeguard consumers from the supply of tainted food, and it establishes food safety and quality requirements for consumer protection. Adulteration is defined as the addition of cheap or inferior components

[64] *Id.*

to deceive the consumer, as well as the presence of toxins that may render the food unsafe for human consumption. As a result, the goal of this regulation is not only to provide consumers with pure and wholesome food, but also to prevent fraud and deception. It stated that no one shall manufacture, sell, store, or distribute adulterated or misbranded food products that do not meet the guidelines' standards. The provisions apply to imported food as well as to food produced in India[65].

3.2.9 Food Safety and Standards Act (FSSA), 2006

GEAC was the authority in charge of approving or disapproving the introduction of genetically modified foods into the marketplace until 2006. This changed in 2006, when the Food Safety and Standards Act (FSSA) was passed, which included genetically modified foods in the definition of food. The Act incorporates, among other things, "the key elements of the Prevention of Food Adulteration Act of 1954" and is based on international legislation, institutions, and the Codex Alimentarius Commission (which related to food safety norms)[66]. In a nutshell, the Act addresses international practises and envisions an overarching policy framework as well as the establishment of a single point of contact to guide and regulate individuals involved in the manufacture, marketing, processing, handling, transportation, import, and sale of food. The main features of the Act are:

1. shift from multi-level and multi-departmental command to an integrated line of command; 2. a coordinated response to strategic issues such as novel / genetically modified foods and international trade;
2. the licencing of food products, which is currently granted by the Central Agencies under various Acts and Orders, would be decentralised to the Commissioner of Food Safety and his office;
3. the single point of contact for all matters relating to food safety and standards, regulations, and enforcement;
4. transition from a purely regulatory regime to self-compliance via food safety management systems.
5. the responsibility of food business operators to ensure that food processed, manufactured, imported, or distributed complies with domestic laws; and
6. provisions for graduated penalties based on the gravity of the offence, with civil penalties for minor offences and punishment for serious violations.

Section 22 of the Act states, "No one shall manufacture, distribute, sell, or import any novel food, genetically modified articles of food, irradiated food, organic food, food for special dietary uses, functional foods, health supplements, proprietary foods, or such other articles of food as the Central Government may notify." According to Explanation 2 of this section, ‘genetically engineered or modified food' refers to food and food ingredients made from or containing genetically modified or engineered organisms obtained through modern

[65] FOOD SAFETY AND STANDARD AUTHORITY, https://fssai.gov.in/cms/about-fssai.php.
[66] *supra* note 56.

biotechnology, or food and food ingredients made from but not containing genetically modified or engineered organisms obtained through modern biotechnology[67]."

Section 30 of this Act defines 'food' as follows any substance, whether processed, partially, or unprocessed, intended for human consumption, including primary food, genetically modified or engineered food or food containing such ingredients, infant food, packaged drinking water, alcoholic drink, chewing gum, and any substance, including water used in the food during its manufacture, preparation, or treatment, but excluding animal feed, live animals unless they are processed or prepared for human conception and plants before harvesting, drugs and pharmaceuticals, or other narcotic and psychotropic substances, provided that the Central Government may declare, by notification in the Official Gazette, any other article as food for the purposes of this Act having regards to its use, nature, substance or quality[68].

As a result, the Food Safety and Standards Authority of India (FSSAI) is the competent authority to regulate GM foods by incorporating "genetically modified or engineered food or food containing such ingredients" into the definition of food. The FSSAI has a separate scientific panel to deal with GMOs and foods, according to the provisions of the FSSA, 2006.

3.2.10 Guidelines for Safety Assessment of Foods derived from GE Plants, 2008

The Indian Council of Medical Research (ICMR) has also prepared "Guidelines for SafetyAssessment of Foods derived from GE Plants, 2008", which have been further updated in 2012. These guidelines have been adopted by the GEAC. The guidelines are based on principles and guidance issued by Codex Alimentarius Commission and elaborate on the steps for safety assessment of foods derived from GE plants. A comprehensive summary of information and data requirements that must be provided to regulatory authorities to demonstrate human health safety of foods derived from GE plants is also included.

The guidelines include three appendices: Dossier preparation checklist; Codex Alimentarius Principles for the risk analysis of foods derived from modern biotechnology; and Codex Alimentarius Principles for the risk analysis of foods derived from modern biotechnology. Annexes II and III of the Codex Alimentarius guidelines on food safety evaluation of foods produced from GE plants modified for nutritional or health benefits, as well as food safety assessment in cases when GE plant material is present in food at low levels[69].

A series of "Protocols for Food and Feed Safety of GE plants", prepared by the DBT in 2008 are also in place to specifically address key elements of the safety assessment of foods and/or

[67] Food Safety and Standard Act, 2006, S. 22, No.34, Acts of Parliament, 2006, (India), https://fssai.gov.in/upload/uploadfiles/files/FOOD-ACT.pdf.

[68] *Food Safety Management System, Guidance Document, 2019*, FSSAI, https://www.fssai.gov.in/upload/uploadfiles/files/FSMS_Guidance_Document_FruitsVegetable_15_03_2019.pdf.

[69] *supra* note 51.

livestock feed that may be derived from GE plants. The protocols have been prepared based on international best practices and include the following[70]:

a. Acute oral safety limit study in rats and mice
b. Sub-chronic feeding study in rodents
c. Protein thermal stability
d. Pepsin digestibility assay
e. Livestock feeding study

3.2.11 Ministries and Departments Related to the Regulation of GM food

For the regulation of GM food and products, several ministries and departments have been given certain sets of responsibility in India. These are[71];

- "Ministry of Environment and Forest: This Ministry houses the Secretariat of the Genetic Engineering Approval Committee, which is the apex body that approves the manufacture, sale, import, and export of all GMOs and products derived from them, such as foods, ingredients in foods, and additives derived from genetically modified (GM) organisms or cells.
- Department of Biotechnology: The Secretariat of the Review Committee on Genetically Modified Organisms, which approves research and small-scale field trials involving GMOs and their products, is housed in this department. It also communicates with Institutional Biosafety Committees (IBSCs) established in all organisations that engage in GMO-related activities.
- Department of Health in the Ministry of Health and Family Welfare: The Department of Health is in charge of enforcing the PFA Act, which governs food quality and safety. In addition, the Directorate General of Health Services has been designated as the nodal agency with the Codex Alimentarius Commission.
- The Indian Council of Medical Research (ICMR), established under the Ministry of Health and Family Welfare is the supreme body in India for the formulation, coordination, and promotion of biomedical research. The ICMR advises the MoHFW on a variety of issues, including genetically modified foods.
- Ministry of Agriculture: The Ministry of Agriculture is the country's nodal ministry for agricultural development. It is divided into three departments: Agriculture and Cooperation, Agricultural Research & Education/Indian Council of Agricultural Research (ICAR), and Animal Husbandry & Dairying. According to the Seed Policy, 2002, officials from the ICAR and the Ministry of Agriculture play an important role in the approval of GM crops.

[70] *supra* note 56.

[71] *Cultivation of Genetically Modified Crops- Prospects and Effects, 2012*, MINISTRY OF AGRICULTURE (DEPARTMENT OF AGRICULTURE AND COOPERATION), https://www.thehindu.com/multimedia/archive/01189/Cultivation_of_gen_1189244a.pdf.

- Ministry of Commerce and Industry: This ministry is in charge of developing the country's export and import (EXIM) policy. It implements legislation that establishes a quality control and inspection system for both export and import.
- Ministry of Food Processing Industries: This ministry is in charge of formulating policies that promote the healthy expansion of the food processing industry, as well as providing developmental assistance to these businesses. It encourages industry engagement in the establishment of food standards and their harmonisation with international standards by encouraging research and development efforts. This ministry also issues licences for the processing of fruits and vegetables.

In relation to regulation and management of GM foods and products there is an involvement of multiple ministries and departments. In this regard, National Intellectual Property Policy 2016, pointed out that there is a need to harmonious implementation of existing laws and regulations to avoid conflict, overlap or inconsistencies among them.

3.3 INTELLECTUAL PROPERTY RIGHTS OF GM FOODS

3.3.1 The Patent Act, 1970 and Subsequent Amendments

A patent is a monopoly right awarded to someone who has invented a new and useful product, an improvement on an existing product, or a new method of producing a product[72]. In *Biswanath Prasad Radhay Shyam v. Hindustan Metal Industries*[73], the Supreme Court of India stated that The goal of patent law is to promote scientific research, new technologies, and technological advancement. The grant of an exclusive right to own, use, or sell a patented process or product for a certain time fosters new invention of commercial utility. The disclosure of the innovation to the Patent Office is the price of the monopoly award. After expiry of fixed period of monopoly the invention passes to the public domain. A patent is only awarded for an invention that is new, non-obvious, and valuable, according to the fundamental concept of patent law. By the amendment in 2002, some major changes have been introduced in respect of compulsory licensing for non-working of the patent, even if the patented invention is not working in India and some other grounds included for compulsory licensing like national emergency and non-commercial use, if invention is related to a public health crisis.

By the Patent Amendment Act, 2005, for the first time, patent protection was extended to substances capable of being used as pharmaceuticals, food, and agrochemicals. By this amendment elaborate provisions have been introduced related to what inventions could be treated as a patentable subject matter and what would be excluded from this list. The most debating change that this amendment brought is section 3(d) i.e., The mere discovery of a new form of a known substance that does not result in an improvement in that substance's known efficacy, or the mere discovery of any new property or new use for a known substance, or the mere use of a known process, machine, or apparatus unless it produces a new product or uses at least one new reactant, is not patentable. Prior to 2005 amendment,

[72] The Patent Act, 1970, S.2(m), No. 39, Acts of Parliament, 1970 (India).
[73] Biswanath Prasad Radhay Shyam v. Hindustan Metal Industries, AIR 1982 SC 1444.

only process patent was practiced in India. This amendment has introduced for the very first-time, patent protection to the products. Under Patents (Amendment) Act 2005 patent protection is possible for both new product or process subject to conditions that it involves an 'inventive step' and capable of 'industrial application'[74].

3.3.2 Patenting of Biotechnological Inventions

India

Patents for "plants and animals other than microorganisms, and fundamentally biological processes for the production of plants or animals other than non-biological and microbiological processes" are prohibited under the TRIPS Agreement. As a result TRIPS makes it obligatory for all its signatories to extend patents for micro-organisms, non-biological and microbiological processes. Plants and animals, other than micro organisms, including seeds, varieties, and species, and fundamentally biological methods for the production or propagation of plants and animals, are not patentable under Section 3(j) of the Act. This particular provision creates lot of doubts and many times issues that come before the court to decide. In this regard there is a leading case, i.e., *Speaking Rose International v. Controller General of Patents*[75]. The issue involved in this case was, whether making image on organic flower is subject to patent protection or debarred by virtue of Section 3(j). Petitioner made it clear that he was seeking patent not for the flower but for making image on the organic flower through mechanical process. Here, the Court accepts the petition and granted patent for providing image on the flower However, the case of *Monsanto Technology LLC v. Nuziveedu Seeds Ltd*[76], contributed to the argument for genetically modified and live organism patents. In this decision, the Supreme Court ruled that genetically engineered cotton seeds were patentable, allowing Monsanto, the US Company to submit patent claims.

There was no real form of patent protection for inventions relating to life forms and genetically modified organisms prior to the 2002 amendment to the 1970 patent law. This changed following the *Dimminaco A.G v. Controller of Patents and Designs* decision[77]. The Calcutta High Court ruled that a process for preparing vaccines containing live viruses is patentable because the term "manufacture" includes and is not limited to living organisms. The court ruled that, even if the end product contains a live virus, the process involved in bringing the final product to light can be considered and classified as an invention for all intents and purposes.

USA

[74] Priyanka Rastogi & Anshul Bansal, *India: Patenting of Genetically Modified Crops In India Vis-A-Vis International Decisions*, MONDAQ, (Sept. 4, 2021, 2: 45 PM), https://www.mondaq.com/india/patent/300270/patenting-of-genetically-modified-crops-in-india-vis-vis-international-decisions.

[75] Speaking Rose International v. Controller General of Patents, 2007 (109) BOM LR 360.

[76] Monsanto Technology LLC v. Nuziveedu Seeds Ltd, AIR 2019 SC 559.

[77] Dimminaco A.G v. Controller of Patents and Designs, (2002) I.P.L.R 255 (cal).

Despite the fact that genetically modified organisms are living beings, they do not always occur in nature. This fact was recognised in the landmark American case of *Diamond v. Chakrabarty*[78], in which the US Supreme Court declared that a genetically modified bacterium capable of digesting multiple components of crude oil is patentable, citing the fact that the claimed bacterium was not found in nature, nor was its activity exhibited in any naturally occurring bacteria. The claimed bacterium also met the primary requirements for patentability, according to the court, because it was a creation of human ingenuity and intellect with its own distinct name, character, and specified use.

Canada

Monsanto Canada Inc v Schmeiser[79] is a Canadian landmark case involving patent rights in biotechnology. Monsanto sued Schmeiser (farmer) because he grew genetically modified canola plants that were resistant to the herbicide Roundup. This gene was owned by Monsanto, and Schmeiser did not pay a licencing fee. The increased use of genetically modified crops and the herbicides that go with them has a number of implications for both traditional and alternative farming practises. The Supreme Court ruled in 2004 that Monsanto's patent is valid. The origin of the GM canola seed is unknown. As a result, the final settlement was reached outside of court.

3.3.3 Protection of Plant Varieties and Farmer's Rights (PVPFR)

According to the TRIPS Agreement, "members shall provide for the protection of plant varieties either through patents or through an effective sui generis system, or by any combination thereof." To meet its obligations under the TRIPS Agreement, India enacted the Protection of Plant Varieties and Farmers' Rights Act in 2001. This Act was enacted to provide for the establishment of an effective system for protecting plant varieties, farmers' and plant breeders' rights, and to encourage the development of new plant varieties. The Act encourages investment in research and development to create new plant varieties. Such safeguards are also likely to facilitate the growth of the seed industry, ensuring farmers' access to high-quality seeds and planting materials.

Similarly as Patent Act, PPVFR Act also has provision for the compulsory license to establish balance between individual freedom and social good. As per this provision, "Authority after consultation with central government, on application make in this regard by any person interested on grounds of the reasonable demand of the seeds or other propagating material has not made satisfactorily or the seeds or propagating material is not available to the public at reasonable price, or to pray for a license to undertake production, distribution and sale of the seeds and propagating material may pass order for compulsory license. But any application in this regard will be entertained after the expiry of three years from the date of the registration. Thereupon, the authority may allow if satisfied[80]".

[78] Diamond v. Chakrabarty, 447 U.S. 303(1980).
[79] Monsanto Canada Inc v Schmeiser, [2004] 1 S.C.R. 902, 2004 SCC 34.
[80] Section 47, The Protection of Plant Varieties and Farmers' Rights Act, 2001.

PPVFR Act ensures intellectual rights to the plant breeders for developing advanced variety. But at the same time incorporate provisions for revocation of the registration in case the claimed variety should not be allowed to be hazardous to protection of the environment, health of the human being, other plants and animals. It incorporate the principle of equity, by making plant breeders bound for benefit sharing.

3.4 STATUS OF GM FOOD IN INDIA

3.4.1 Critical Analysis of Bt Brinjal Controversy

Facts

In India, Brinjal is grown all over the country and is one of the most popular vegetables. Farmers primarily grow it in small plots as a cash crop. Andhra Pradesh, Bihar, Karnataka, Maharashtra, Orissa, Tamil Nadu, Uttar Pradesh, and West Bengal are the most rapidly growing states. In India, there are many indigenous varieties, as well as improved varieties and hybrids. Brinjal is prone to insect pests and illnesses, the most dangerous and damaging of which is the fruit and shoot borer (FSB), which has been a major pest for the past two decades or more. Therefore, FSB-resistant brinjal or Bt brinjal was developed using a transformation process similar to the one used in the development of Bt cotton. According to the International Service for the Acquisition of Agri-biotech Applications (ISAAA), a non-profit organisation dedicated to promoting biotechnology, Bt brinjal contains the cry1Ac gene, which produces an insecticidal protein that confers resistance to the pest fruit and shoot borer. According to reports, the insect's digestive processes would be disrupted after ingesting the Bt toxin, eventually leading to the insect's death. The Maharashtra Hybrid Seeds Company is developing Bt Brinjal in India (Mahyco). In India, the Genetic Engineering Appraisal Committee (GEAC) approved Bt brinjal for commercial cultivation in 2009, but the following year, then-minister of state for environment Jairam Ramesh placed it under a "indefinite moratorium[81]."

Safety of Bt Brinjal

Bacillus thuringiensis is a species of bacteria that produces proteins that are toxic to certain insects. It is a safe microbial insecticide to control pest caterpillars. When people eat the same toxins, the toxins are not activated and no harm occurs. Toxins created by *Bt* are rapidly broken down by sunlight and in acidic soil. Other microbes in soil can also break it down. *Bt* does not readily leach in soil and it typically remains in the top several inches of soil[82].

[81] Taran Deol, THE PRINT, (Aug. 7, 2020, 7:23 PM), https://theprint.in/india/allow-field-trials-of-bt-brinjal-to-ensure-safety-of-crops-agri-tech-body-writes-to-govt/477112/.

[82] Perez. J, Bond. C, Buhl. K. & Stone. D, *Bacillus thuringiensis (Bt) General Fact Sheet*; National Pesticide Information Center, Oregon State University Extension Services, (2015) http://npic.orst.edu/factsheets/btgen.html.

Since 1938, Bt has been used extensively as a spray all over the world to control a variety of lepidopteron pests and mosquito larvae including India. Thus use of Bt is not new to the farmers[83]. Bt is safe to non- target organism such as animals (humans) because of very low pH level of stomach acid and absence of required receptors. Feed safety studies were conducted using high dose of Bt Cotton seed- meal/ protein on fish, birds, cows, rabbits, earth worms, ladybird beetles etc. The results revealed no ill- effects and confirmed that Bt is safe[84]. And also, there is no horizontal transfer of genes, it will not transfer to animals, there is only vertical transfer- from one generation to the next within the same species.

3.4.2 Bt Cotton

The genetically modified Bt Cotton was developed by the Maharashtra Hybrids Seed Company (Mahyco) in collaboration with the US seed company Monsanto to tackle the bollworm problem that had devastated cotton crops in the past, by introducing into the cotton seed a gene of the common soil microbe called Bacillus Thuringiensis (hence the name Bt. Cotton). In 2002, Bt Cotton became the first and only transgenic crop approved by the GEAC for commercial cultivation in six States namely, Andhra Pradesh, Tamil Nadu, Karnataka, Gujarat, Madhya Pradesh and Maharashtra. It has been further extended to Punjab and Haryana. The Bt Cotton seeds were marketed by the Monsanto-Mahyco joint venture. Though the public opinion has been divided on this issue, the Government has indicated satisfactory performance of the Bt Cotton. According to government statistics, the area planted with Bt Cotton expanded from 0.70 lakh acres in Kharif 2002 to 2.30 lakh acres in Kharif 2003, and then to 12.00 lakh acres in Kharif 2004. As per the latest unofficial report, India has become the fourth largest adopter of biotech crops in 2008 with cotton alone occupying 7.6 million hectares. On the one hand, it has been claimed as the 'Bt Cotton Revolution' with transgenic cotton being grown in 90 percent of the cotton growing areas, increasing yields by as much as 50 percent in certain regions[85].

3.4.3 GM Mustard

Dhara Mustard Hybrid-11, or DMH-11, is a genetically modified mustard variety produced by the Centre for Genetic Manipulation of Crop Plants at Delhi University. Using genetic manipulation, Delhi University researchers generated hybridised mustard DMH-11. It's an herbicide tolerant crop. The GEAC gave the green light to GM Mustard for field testing in 2016, but the Supreme Court stayed the order and asked for public input. If approved by the

[83] T. M. Manjunath, *Safety and Benefits of Bt and Bt- Cotton: Facts Refute Allegations*, RESEARCHGATE, https://www.researchgate.net/publication/297713962_SAFETY_AND_BENEFITS_OF_BT_AND_BT-COTTON_FACTS_REFUTE_ALLEGATIONS.

[84] *Health Risk Information about Bacillus Thurigiensis (B.t.),* MINNESOTA DEPARTMENT OF HEALTH, https://www.health.state.mn.us/communities/environment/pesticide/bt.html#:~:text=B.t.%20is%20considered%20safe%20for,by%20staying%20indoors%20during%20applications.

[85] *Genetically Modified Crops Issues and Challenges in the Context of India*), RESEARCH UNIT (LARRDIS) RAJYA SABHA SECRETARIAT NEW DELHI, https://rajyasabha.nic.in/rsnew/publication_electronic/gen_modify_crops.pdf.

Centre, this will be the country's second GM crop, after Bt Cotton, and the first transgenic food crop to be grown.

3.4.4 Greenpeace Campaigns against GM Food

Greenpeace is a nongovernmental environmental organization with offices in over 40 countries and with an international coordinating body in Amsterdam, the Netherlands. Green peace's mission is "to ensure the ability of the Earth to nurture life in all its diversity," and the organisation focuses its efforts on global concerns such as global warming, deforestation, overfishing, commercial whaling, genetic engineering, and anti-nuclear issues. A wide spectrum of non-profit nongovernmental organisations has long resisted genetically modified crops. "No genetic engineering of nature" is the chosen credo for their campaign. It uses direct action, lobbying, and research to achieve its goals. Greenpeace International and Friends of the Earth International, both located in Amsterdam, have led much of the resistance against GMOs among non-governmental organisations. Their campaign is focused on three themes[86]:

1. GM organisms should not be released into the environment until adequate scientific evidence has been obtained about their safety to human health and to the environment.
2. Food products containing GM elements should be labelled, and GM foods should be physically separated from conventional foods.
3. Patents should not be issued to organisms that have been created by genetic engineering.

Over a hundred Nobel laureates have signed a letter to Greenpeace, calling the organization's anti-genetically modified (GM) crop campaign "misleading" and "unscientific." The letter has reignited the debate about the safety of eating genetically modified foods. The letter, addressed to Greenpeace, the UN, and governments around the world, highlights how global food production will have to treble by 2050 to fulfil the demands of a growing global population. They have misrepresented their dangers, benefits, and impacts, as well as aided the illegal destruction of approved field trials and research projects, according to the letter. It also calls on Greenpeace and its supporters to revisit the issue in light of global farmer and consumer experiences, as well as fresh scientific findings. Greenpeace is being asked to discontinue its campaign against genetically modified crops in general, and Golden Rice in particular, according to the letter. It claims that Golden Rice, a genetically engineered rice type infused with Vitamin A, is essential for treating Vitamin A deficiency in children in Africa who suffer from partial blindness as a result of the deficiency[87].

Anti-GMO campaigners filed a writ petition in the Supreme Court of India in 2005, seeking a moratorium on the release of any genetically modified organisms (GMOs) into the

[86] Robert Paarlberg, *A dubious success: the NGO campaign against GMOs*, GM CROPS & FOOD vol. 5,3 (2014): 223-8, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5033189/.

[87] Vidya Venkat, *All you need to know about the GM food controversy*, THE HINDU, (July 8, 2016, 21:22 PM), https://www.thehindu.com/sci-tech/All-you-need-to-know-about-the-GM-food-controversy/article14483330.ece.

environment pending the completion of comprehensive, transparent, and rigorous bio-safety testing standards. According to pro-biotech specialists, the move has placed on hold opportunities for the Indian government to boost agricultural productivity using genetic engineering technologies in order to feed the country's rising population. As a result, field trials for key essential GM crops like Bt-Brinjal, hybrid mustard, and golden rice are still pending.

3.5 GM FOOD AND CONSUMER RIGHTS

In the contemporary times, when public awareness is increasing day by day, consumers are at the demanding end, not at the receiving end. The producer is supposed to feed the needs of the consumers to their satisfaction in accordance with the popular demand. The consumers would like to know the details of the product they are purchasing including how it is made and how it would perform. Even though the labelling of GM food has been made mandatory from 2013 in India, the move is not enough to provide for people's right to know and ethical concerns, amongst others. Due to the impending Biotechnology Regulatory Authority of India Bill, 2013, there is no regime for controlling imports and custom authorities are still not equipped to distinguish a consignment of GMO from that of a non- GMO. The Food Safety and Standards Act, 2006 (FSS Act), is the primary legislation amongst others to ensure that the GM food is fit for human consumption. The Ministry of Consumer Affairs through a gazette notification has made it mandatory to label food containing GM organisms from 1 January 2013. India also strives to follow the guidelines of the International Codex Alimentarius for food quality and standards. The objective of Food Safety and Standard Authority of India (FSSAI) is to ensure the safety of food produced, supplied and consumed in India, including GM food. The National Food Security Act, 2014, which intends to provide for right to food to all is perhaps a very significant legislation. The legislation acknowledges the contribution of biotechnology and its innovations in providing high yield and quality of food products. Food produced through biotechnology or otherwise should fulfil standards set under the FSS Act[88].

Despite pro-GM crop lobbying, the Food Safety and Standards Authority of India (FSSAI) has decided to proceed with labelling packaged food products containing more than 1% genetically modified ingredients. The food regulator's scientific committee has given the go-ahead for the labelling of GM food items for manufacture, sale, and distribution in India, with a 1% threshold value[89].

3.6 RECOMMENDATIONS ON BRAI BILL, 2013

On April 22nd, 2013, the Minister for Science and Technology, Mr Jaipal Reddy, tabled the Biotechnology Regulatory Authority of India Bill (BRAI Bill) 2013 in the Lok Sabha, proposing the enactment of a statute for the regulation of contemporary biotechnology in the

[88] SREENIVASULU, 278-280, LAW RELATING TO BIOTECHNOLOGY, OXFORD.

[89] Ians, *Labelling Required if GM content over 1%: FSSAI chief*, BUSINESS STANDARD, https://www.fssai.gov.in/upload/media/FSSAI_News_Labelling_BusinessStan_04_02_2019.pdf.

country. If the bill passes, the Environment Appraisal Panel, a component of the BRAI, will take over the job. It suggested the establishment of the National Biotechnology Regulatory Authority of India through the Biotechnology Regulatory Authority of India Bill, which will be the top authority on regulations and policies relating to genetically modified organisms in India once it is established. The highlights of the bill are[90]:

- The Bill establishes an independent authority, the Biotechnology Regulatory Authority of India, to regulate modern biotechnology organisms and products.
- The BRAI will regulate biotechnology product research, transportation, import, containment, environmental release, manufacturing, and use.
- BRAI regulatory approval will be granted after a multi-level assessment process conducted by scientific experts.
- BRAI will certify that the developed product is safe for its intended use. All other laws governing the product will remain in effect..
- A Biotechnology Regulatory Appellate Tribunal will hear civil cases involving a significant question of modern biotechnology, as well as appeals from BRAI's rulings and decrees.
- Penalties are outlined for giving false information to BRAI, performing unapproved field trials, impeding or impersonating a BRAI officer, and violating any other terms of the Bill.

3.7 CHALLENGES

Rapid research, development, and commercialization of GM crops in recent years has also raised significant concerns about their potential impacts on the environment, biodiversity, and, as a result, human and animal health. Concerns about bio safety, environmental impact, and ethical issues are some of the major challenges for GM crop research and deregulation around the world, including India. On a regular basis, the media has published a number of news articles, reports, and documentaries on the safety of GMOs. Some of the issues that should be addressed before releasing any GM crop for open field trials and commercialization are the ecological risk assessment of transgenic crops, the issue of gene flow, the development of secondary pest resistance, and the ecological risks associated with pollen flow. Bio safety concerns should be addressed at all stages of GM crop development and release on a case by case basis. Strong bio safety rules are important for evaluating GM crops, and they must be addressed at all stages of development and release of transgenic crops. Since then, a plethora of transgenic crops have been produced and released for open field testing and commercial cultivation on a regular basis, raising worries about the possible hazards to the environment, biological diversity, and human health. Over the last decade, significant risk assessments of GMOs have been conducted around the world, and a comprehensive risk assessment framework has been developed.

[90] *The Biotechnology Regulatory Authority of India Bill, 2013*, (last visited Sep. 4, 2021) https://www.lawctopus.com/academike/biotechnology-regulatory-authority-bill-2013/.

Following the commercial release of Bt Cotton in 2002, there was a surge in Bt technology research, resulting in the use of foreign genes in Brinjal, Cabbage, Cauliflower, Tomato, Lady's finger, Rice, Corn, and Groundnut for a variety of advantageous features. Except for Bt brinjal, which is now under moratorium, these crops are being examined in confined field trials. In India, political officials, scientists, and technocrats have recognised these prospects, and they are now frequently praising the potential contributions that biotechnology - including transgenic crops - could make to agricultural production, growth, and poverty reduction in the coming years. Many of India's top leaders have backed the benefits of agro-biotechnology in general, and treasury resources have been allotted to promote GM crop research inside the country's national agricultural research system. However, there are few professional viewpoints, and a parliamentary standing committee report on GM crops warns that integrating transgenic crops into agriculture is not a viable strategy to attain food security in India in the coming years. Critics of GM crops have been able to use India's open and democratic political structure to press for a cautious or even preventative approach to GM crops, particularly in the area of bio safety policy. The only way to tackle India's food and nutrition security dilemma is to increase agricultural production through a second green revolution.

The requirement for NOCs from state governments to conduct field trials of GM crops, illegal cultivation of HT cotton, and pink boll worm resistance to Bt cotton are all significant challenges for GM crops during and after the deregulation process. Because agriculture is a state subject, GEAC has introduced the requirement of a NOC (No Objection Certificate) from the state governments before conducting field trials. Despite GEAC approval, many state governments have refused to issue NOC[91].

3.8 CONCLUSION

The numerous benefits of transgenic crops for a society's food or nutrition security challenges have long been recognised. Many other benefits, including increased nutritional value, herbicide tolerance, viral resistance, and tolerance to various abiotic stresses, increase a fruit's shelf life and hence provide a strong market for growers. India's GM agricultural research programme must be continued urgently if it is to meet its food and nutrition security goals. Although there is little substantial scientific evidence opposing the safety of GM foods, the debate over whether they are safe or not will never stop. Surprisingly, few public sector intuitions expressed concern about GM foods. Intuitions funded by the GOI must adhere to the same broad policies as the Indian government and must join forces with the government to combat poverty and malnutrition. This valid point is raised because members of the Technical Expert Committee formed by the Supreme Court of India to review the safety and guidelines for GM crop research and offer recommendations for the future of GM crop research in India hold opposing viewpoints. Despite the fact that India lacks basic infrastructure and strict procedures for GM crop research and risk assessment, we cannot quit this effort due to India's pressing need. In an ideal world, India would continue to research

[91] *supra* Note 49.

GM crops and deregulation, as well as establish basic infrastructure and develop stringent bio safety and marketing guidelines. Although portals such as GEAC, IGMORIS (Indian GMO Research Information System), and Bio safety Clearing House are assessing bio safety and regulating GM crops, a single window system and online gateway for evaluation, control, regulations, and approval of GM crops is urgently needed. Every corporate and public sector institution should be required to register with this portal anytime they produce any event for transgenic development and begin field experiments before submitting for approval. Every novel transgenic event in development must display its registry number and date of registration on a website or online portal dedicated to obtaining marketing approval in any country. This type of webpage will be extremely valuable and user-friendly in generating good public perceptions about GM food research, safety, and current status.

CHAPTER- IV
ROLE OF GM FOOD IN ACHIEVING THE RIGHT TO ADEQUATE FOOD AND ERADICATING POVERTY

4.1 INTRODUCTION

Few issues in recent history have received more attention and wider debate than genetically modified (GM) foods. When it comes to the production and consumption of genetically modified foods, the world's population can be divided into three groups: supporters, opponents, and those who are confused. The first two groups constitute a minority, while the third group constitutes the majority. This same pattern is expected to continue for some time. There is a great deal of information available on the various issues surrounding GM foods. This makes it difficult to find answers to general public questions and concerns about the effects of genetically modified foods, particularly on human health and the environment. It has been discovered that GM foods have a variety of benefits and drawbacks. The extent to which they can benefit or harm humans and the environment is a contentious issue. There are arguments on both sides of the debate over why many countries throughout the world should or should not alter the genetic make-up of plants and animals. The debates concerning transgenic crops are about values, which are neither absolute nor universal, and the debates have polarised society into proponents and opponents, with once-trustworthy and ethically sound scientists now being viewed with distrust by many[92].

The debate over various aspects of GM foods, such as production, labelling, consumption, safety, ethics, and socioeconomics, has erupted into what appears to be a war. It appears to be a battle of words and an exchange of opinions rather than an exchange of facts and credible information. This debate is raging in both the developed and developing worlds. It is regarded as one of the most contentious and debatable issues in recent history.

Genetic modification is changing the nature of life as we know it, and it has the potential to change it even more. Depending on whether you support or oppose genetic modification, this statement can be interpreted as a positive or negative outcome. Proponents argue that the benefits of genetic modification outweigh the drawbacks[93]. They place more emphasis on the benefits and pay little or no attention to the drawbacks. Opponents, on the other hand, are more concerned with the negative consequences and refuse to accept the positive claims. In reality, supporters and critics are divided into two camps. Some critics understand some of the advantages of gene technology, while others see its possible drawbacks and dangers. The truth is that a logical strategy necessitates an approach that acknowledges and respects both sets of ideas. In the end, no human activity, including eating, is risk-free. This is not,

[92] *supra* note at 14.

[93] Dhan Prakash, Sonika Verma, Ranjana Bhatia, B. N. Tiwary, Risks *and Precautions of Genetically Modified Organisms*, INTERNATIONAL SCHOLARLY RESEARCH NOTICES, vol. 2011, 13, 2011. https://doi.org/10.5402/2011/369573.

however, a reason to blindly trust genetic modification. Risks must be discovered, assessed, and reduced to the bare minimum.

Both sides of the debate use science to back up their claims while questioning the independence or veracity of the other side's research. The question is, "Who should consumers believe?" Science cannot provide answers to all questions and will not be able to provide people with what they truly desire, namely total certainty. GM technology should be viewed similarly to other developed technologies in that it is expected to have some advantages and disadvantages. According to The Sustainable Future (2008), in order to gain a better understanding of what both sides of the argument are saying and to form a more informed opinion, people should conduct more research and seek credible information on a variety of issues surrounding the technology[94].

Various parties are involved in the debate over GM foods, including biotechnology companies and institutions, governmental and nongovernmental organisations (NGOs), United Nations organisations, scientists, the media, and consumers. Some governments and governmental institutions, such as regulators, UN organisations such as the Food and Agriculture Organization (FAO), World Health Organization (WHO), and some consumers, are supporters of the technology. On the other hand, there are a number of international organisations and groups that are opposed to the production of GM foods. Greenpeace, Friends of the Earth, the Christian Aid, the Institute for Food and Development Policy, and some consumers are examples.

The debate centres on the actual and potential effects of genetically modified crops and foods on human and animal health and the environment, as well as the credibility and objectivity of conducted and published research on gene technology and GM foods, GM food labelling, the impact of gene technology on farmers, and the conflict of interest among biotechnology companies, researchers, and government regulators, and the possible role of GM foods to help reduce food insecurity worldwide. Supporters argue that genetic modification can be used to improve plant and animal characteristics, that it can help reduce hunger and malnutrition worldwide, that it can lower the cost of producing plants and animals, and thus help food producers, and that there are no proven examples or cases of GM products posing health or environmental risks. Consumption of GM foods may pose a health risk, and these foods may be dangerous for humans, according to the concerns made against their manufacture. Another issue mentioned is that GM could harm the environment and cause unwanted changes and disruptions throughout the ecosystem.

Anti-genetically modified organism (GMO) campaigners' concerns about human health related to GM food consumption have resulted in a widespread belief among consumers that consuming GM foods is dangerous. Consumers are concerned about the potential risks of GM technology, according to the results of several public polls, and they want greater knowledge about the risks as well as a choice in how they are exposed to risks. The public's perspective of the use of genetically modified foods in food production is highly emotional, so it's critical

[94] *supra* note 14

to weigh the dangers and benefits carefully. Because of the polarity and passion of the debate, it is essential to carefully weigh the risks and benefits and draw conclusions that are beneficial to consumers[95].

Due to the concerns of both supporters and opponents, both sides of the debate have met in forums and summits around the world in recent years to discuss the issue. This trend aided in the development of a common language of understanding between the two opposing parties, as well as a degree of appreciation for both the benefits and risks by both supporters and opponents. This can be viewed as a positive step toward developing a more reasonable and objective position on GM foods that is acceptable to both proponents and opponents, and that would assist consumers in developing a better and clearer picture of GM foods and, as a result, making informed decisions about GM food purchase and consumption. In the next sections, the issues of controversy, the arguments presented by each side of the debate, and how each side reacts to those points will be discussed.

4.2 ISSUES OF CONCERNS OF GENETICALLY MODIFIED FOOD

4.2.1 Food Safety and Human Health

Specific potential food safety and human health problems that have been expressed are centred on the following points:

1. GM foods may be more dangerous than traditional foods. The health consequences of eating genetically modified foods are not fully understood. The most pressing general question raised by many consumers, and one that requires a satisfactory answer, is: "Is it safe to consume GM foods?" Improved and long-term food safety tests, as well as dependable technologies and protocols, are required to better identify and manage potential risks.
2. Consumers have expressed concern that they may be inadvertently exposed to allergens. One of the safety concerns that must be addressed is the possibility of a GM food causing an allergic reaction. If a person is allergic to one food and a gene from that food is transferred to another, the person may become allergic to the second food as well. Testing for allergens in GM foods is part of the research and development process for GMOs intended for human consumption. It is critical that allergenicity tests be improved and that potential allergens found in food be labelled. On the plus side, the possibility of using GM to eliminate allergens from foods should be investigated.
3. Antibiotic resistant marker genes have raised many concerns, as they may limit the efficacy of antibiotics in treating human and animal diseases. Antibiotic resistance marker genes may be present in current transgenic crops. Such GM crops may contribute to the spread of antibiotic resistance as a problem with environmental and health consequences.

[95] Kanchana Karyawasam, *Legal Liability, Intellectual Property And Genetically Modified Crops: Their Impact on World Agriculture*, 19 PAC R. L & Pol, 459 (2010), https://research-repository.griffith.edu.au/bitstream/handle/10072/36929/67758_1.pdf?sequence=1.

4. Another issue has been raised about the potential carcinogenic effects of GM foods. Is there a chance that eating genetically modified foods can cause cancer in people who eat them?

4.2.2 Environmental Concerns

With respect to the environment, the following issues and concerns have been raised[96]:

1. The uncertainty and unpredictable behaviour of GM microorganisms in the environment has been a source of concern. Microorganisms are noted for their ability to rapidly generate and mutate, to easily share genetic information among themselves, and to be difficult to detect in the environment. These GM microbes have the potential to survive in the soil, be absorbed by plants, or contaminate the water supply.
2. One concern raised about GM crops is that releasing GM organisms into the environment constitutes a form of "genetic pollution." Concerns have long been raised about the transfer of GE crop plants to wild related species, which could result in an uncontrollable generation of weeds known as "super weeds." This weed group has the potential to outcompete and disrupt an area's natural biodiversity. To control them, stronger herbicides would be required.
3. There is also a concern that herbicide-tolerant genes may be passed to nearby organic crops, non-GM crops, or other GM crops. This gene transfer, which is considered a sort of contamination, would result in crossbreeding, which could lead to the development of herbicide-tolerant plants. If a GM crop polluted a non-GM crop, farmers' ability to grow non-GM foods would be jeopardised.
4. The prospect of horizontal gene transfer has been suggested as a source of concern (HGT). HGT refers to the transfer of genetic material from one organism to another that is not its offspring. The genetic material is then integrated and expressed after this translocation. Plants used as feed for animals used for food or plants used as food for humans can both result in HGT.
5. Another prevalent concern is that herbicide-resistant crops may cause agricultural areas to become “sterile,” leaving them devoid of plants that birds and insects rely on for food, disturbing the natural ecology.
6. Insect resistance has been a source of concern. Crops that have been genetically manipulated to be insect-resistant by adding a toxin may contribute to a larger problem of toxin resistance, limiting other farmers' usage of these toxins.
7. Another problem is the use of an antibiotic-resistant gene as a genetic marker in GM technology to generate transgenic crops. This gene has the potential to be passed on to hazardous bacteria, resulting in superbugs that are resistant to antibiotics.
8. As a result of the introduction of GM crops, fewer cultivars will be utilised overall. They could also have an impact on the variety of other living organisms in the long

[96] A. A. Snow, D. A. Andow, P. Gepts, E. M. Hallerman, A. Power, J. M. Tiedje & L. L. Wolfenbarger, *Genetically Engineered Organisms and the Environment: Current Status and Recommendations*, 12 ECO APPLI, 377-404, https://www.jstor.org/stable/4543362.

run. This would result in a negligible decrease in crop genetic diversity. Concerns have been raised about the impact of this effect.

4.2.3 Regulatory and Legal Concerns

There has been widespread concern about the role of governments in establishing or controlling the rules and regulations governing gene technology and its numerous applications. A number of issues have been raised in connection with this concern. These issues include the types of responsibilities that governments should have and what should be left to the industry, the appropriate government agencies to regulate gene technology, regulation monitoring, compliance, and enforcement, the need for new and separate regulations for gene technology, and governments' expected role in harmonising international obligations and local demands[97].

4.2.4 Animal Health and Welfare

A growing concern has been raised about animal health and welfare. Classic animal breeding is said to have been successful in increasing farm animal output and well-being. Animal welfare and health are feared to be jeopardised if gene technology is used on them. This is because the majority of qualities in livestock are controlled by numerous genes, making it difficult to determine which genes should be modified to increase animal productivity or health[98].

4.2.5 Ethical Concerns

A number of ethical concerns have been raised in relation to gene technology applications in general. The most common immediate reaction to gene technology is one of "messing with nature." There are concerns that GM technology will raise a slew of ethical issues regarding how humans interact with nature. In theory, gene technology has an infinite number of applications: Gene transfer can occur between all types of living organisms, and genes can come from plants, animals, fish, or microorganisms. This has sparked widespread concern, particularly among religious groups, who believe that it represents interference in natural processes overseen by God.

4.3 AUTHORITATIVE SOURCE

The GM food safety issue was investigated in a joint FAO/WHO expert consultation on the safety aspects of GM foods of plant origin in 2000. The consultation agreed in its report that assessing the safety of GM foods requires an integrated, step-by-step, case-by-case approach, which can be aided by a structured series of questions. The similarities and differences between GM foods and their conventional counterparts would aid in the identification of potential safety and nutritional issues, and are regarded as the most appropriate strategy for

[97] *Regulation of Current and Future Genetically Engineered Crops*, THE NATIONAL ACADEMIES, (Sept. 27, 2021, 01:00 AM), https://www.scconline.com/blog/wp-content/uploads/2020/07/20th-Harvard-bluebook.pdf.
[98] *Adoption of Technologies for Sustainable Farming Systems Wageningen Workshop Proceedings*, OECD 2001, Sept 25, 2021, 8:00 PM), https://www.oecd.org/greengrowth/sustainable-agriculture/2739771.pdf.

GM food safety and nutritional assessment. The consultation has recommended the use of the concept of "substantial equivalence," provided that some aspects of the steps in the safety assessment process are refined[99]. Furthermore, the WHO, in collaboration with the FAO, has convened several expert consultations on the evaluation of GM foods and provided technical advice to the Codex Alimentarius Commission, which was incorporated into the Codex Guidelines on the safety assessment of GM foods. In close collaboration with FAO and other international bodies, the WHO promises to pay close attention to the safety of GM foods from the standpoint of public health protection.

WHO (2014) compiled a list of frequently asked questions and answers in response to inquiries and concerns from WHO Member State Governments about the nature and safety of genetically modified foods. The questions and answers cover a wide range of topics, including the nature of GM foods, why they are created, their safety to human health, their potential environmental implications, how they are regulated, and the future of GM foods. The World Health Organization underlines that genetically modified crops are safe for human consumption because they have passed all safety tests in various parts of the world. The WHO also states that it has been actively involved in the debate over genetically modified foods, citing the benefits and possibilities of biotechnology to promote public health while also considering the need to investigate any potential detrimental impacts on human health[100].

The GM crops on the market have been found to be safe for the environment. Crops will only pollinate other varieties of the same crop, and this will only happen to a substantial extent if the crops are close enough together, the flowering seasons are similar, and the receiving crop hasn't already self-pollinated. There has never been a documented incidence of an organic farmer losing their organic certification due to contamination from a GMO crop in the United States. These crops are important assets for enhancing agricultural environmental sustainability by allowing farmers to produce more crops with less input. GMOs in agriculture can help to preserve biodiversity by sparing less intensively cultivated fields, boost productivity, reduce soil erosion, conserve water, and reduce pesticide use.

Transgenic modification for the manufacture of human pharmaceuticals or transplant organs, in contrast to genetic manipulation of farm animals for production attributes, is generally not intended to create changes that have physiologic impacts on the animals themselves. While unexpected and undesirable phenotypic effects can still occur as a result of gene insertion or cloning technology, there are generally fewer potential animal welfare concerns associated with the production of transgenic farm animals for biomedical purposes than with the production of transgenic farm animals for agricultural purposes[101].

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[99] *Safety aspects of genetically modified foods of plant origin*, Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology, WHO 2001, http://www.fao.org/fileadmin/templates/agns/pdf/topics/ec_june2000_en.pdf.

[100] *Food, Genetically Modified*, WHO 2014, https://www.who.int/news-room/q-a-detail/food-genetically-modified.

[101] Louis-Marie Houdebine, *Impacts of genetically modified animals on the ecosystem and human activities*, GLOBAL BIOETHICS (2014), https://www.tandfonline.com/doi/full/10.1080/11287462.2014.894709.

4.4 ARGUMENTS IN FAVOUR OF GENETICALLY MODIFIED FOOD

4.4.1 Benefits for farmers:

Farmers cultivate a variety of crops, including cereal crops, legume crops, and oilseed crops. Some farmers also raise livestock for milk or meat. Another activity in which some farmers are involved is poultry production. All farmers, whether they produce plants or animals, are thought to benefit from biotechnology. Because food is mostly derived from agricultural products, the manufacturing of GM foods has numerous advantages for farmers.

In general, genetically modified organisms (GMOs) will enhance farm income. Farmers may be able to earn more money as a result of using various biotechnological approaches. Farmers' income rises as a result of the following factors:

- Higher crop yields- One of the benefits of genetically modified organisms is an increase in crop yield, either per individual plant or per cropped area. This increase in crop production means that the farmer can produce more with the same resources as before GM. Increased yield also relates to products derived from animals that have been genetically changed in some way. The adoption of herbicide-tolerant and insect-protected crops has previously been proved to boost yields by minimising crop loss to pests[102].
- Improved quality attributes of plants and animals- GM can be used to obtain desired quality attributes in plants or animals. Nutritional, storage, freshness, and processing qualities are all examples of increased quality traits. Improved pest and disease resistance, selective herbicide and insecticide tolerance, ability to endure weather swings and extreme weather conditions, water tolerance, and temperature and saline extreme circumstances are also contributing factors.
- Better resistance of crops to stress- The usage of GM crops would lower the likelihood of crop failure owing to biotic and non-biotic factors. This is due to the development of pest-resistant GM crops that can withstand extreme environmental conditions such as cold, drought, and hot temperatures.
- Less use of herbicide and pesticide- The farmer will need to use less herbicide and insecticide, resulting in lower agricultural costs and higher profitability. Herbicide-tolerant crops enable farmers to control weeds, allowing crops to grow[103]. Farmers will be able to get healthier and damage-free crops by planting insect-resistant crops. Farmers would be better protected against insecticide poisoning resulting from crop spraying. This is simply due to the fact that they may use less insecticide on Bacillus thuringiensis crops generated through genetic engineering.
- Farmers will be able to sell their farm produce in other nations where GM is legal.

[102] Godfray HC, Beddington JR, Crute IR, Haddad L, Lawrence D, Muir JF, Pretty J, Robinson S, Thomas SM & Toulmin C, *Food security: the challenge of feeding 9 billion people*, NIH, 2010, https://pubmed.ncbi.nlm.nih.gov/20110467/.

[103] *Graham Brookes & Peter Barfoot, Environmental impacts of genetically modified (GM) crop use 1996–2015: Impacts on pesticide use and carbon emissions*, GM CROPS & FOOD, (2017), https://www.tandfonline.com/action/showCitFormats?doi=10.1080%2F21645698.2017.1309490.

- Improved animal welfare- If GM animals are transformed in a way that improves these qualities, they should be healthier and be able to tolerate some diseases or pests.
- More productive farm animals- Cattle, sheep, and poultry are examples of farm animals that can be genetically modified to improve their output, such as milk, meat, and eggs.

4.4.2 Reduce World Hunger and Improve Global Food Security

The ultimate and targeted users of GM products, including GM foods, are consumers. As a result, clear and convincing facts about the benefits of GM foods must be communicated so that consumers have a complete picture and can make an informed decision about whether or not to consume GM foods.

Supporters of the production and use of GM foods argue that current biotechnology benefits people at present and in the future. Biotechnology's usage in the production of GM foods is predicted to aid in the reduction of hunger and the improvement of global food security. More than three billion people are believed to be undernourished in the globe today[104]. According to the Millennium Development Goal, this number is expected to be zeroed by 2030[105]. The current trend in food availability indicates that this will not be reached. On the contrary, the total number of undernourished people as well as their share has increased. Agricultural biotechnology, in general, and genetically modified crops, in particular, has been hailed as one of the most effective solutions for tackling global hunger and food insecurity. It has the potential to increase output while decreasing costs. The food supply would be increased as a result of GM, resulting in increased food availability at a lower cost, resulting in improved accessibility for the food insecure. This can be accomplished without causing further environmental damage, with a noticeable reduction in non-renewable inputs such as fertilisers and pesticides. GM crops can produce higher yields than conventional crops. One such crop is "Super Rice," which was developed as part of the project "Green Super Rice for the Resource-Poor of Africa and Asia." This is a rice research project funded by the Bill and Melinda Gates Foundation with the goal of developing “Green Super Rice (GSR) varieties that produce high and stable yields under low inputs” and transferring crop management technology to resource-poor rice farmers in 15 African countries and four Asian countries, including China[106]. The major goal of this initiative is to assist the target countries and regions in achieving self-sustaining rice production and food security. Drought, insufficient nutrient input, poor soils, and insect infestations are all factors that put rice production in Sub-Saharan Africa and Asia under persistent strain. Chinese rice experts have made recent scientific breakthroughs that have hastened the production of new types that can tolerate

[104] FOOD AND AGRICULTURAL ORGANIZATION OF THE UNITED NATIONS, http://www.fao.org/state-of-food-security-nutrition (last visited Sept. 28, 2021).

[105] WORLD HEALTH ORGANIZATION, https://www.who.int/news/item/13-07-2020-as-more-go-hungry-and-malnutrition-persists-achieving-zero-hunger-by-2030-in-doubt-un-report-warns (last visited Sept. 28, 2021).

[106] BILL & MELINDA GATES FOUNDATION, https://www.gatesfoundation.org/ideas/media-center/press-releases/2011/04/nutritious-rice-and-cassava-aim-to-help-millions-fight-malnutrition (last visited Sept. 28, 2021).

drought, flooding, freezing temperatures, and harmful elements like salt and high iron. Using biological technology and novel crop management methods, the GSR project intends to breed at least 15 elite cultivars appropriate for growth in the target nations in Africa and Asia. The GSR project also includes the development of a highly efficient genotyping platform for large-scale molecular breeding activities in the target nations as well as the international rice research community.

4.4.3 Nutritious Food to Consumers

Food quality can also be improved through genetic modification to match the demands and preferences of consumers. GM can increase a variety of quality features and factors, including the nutritional, sensory, and storage properties. Golden rice is an example of GM crops that have been changed to boost the nutritional content of foods. Golden Rice is GM rice that has been genetically modified to contain beta-carotene and vitamin A. Rice, a staple grain in many underdeveloped countries, is vitamin A deficient by nature. In the past, a deficiency of vitamin A in rice resulted in the deaths of over one million children and the blindness of 350,000[107]. Golden Rice consumption was one intervention that helped to address the malnutrition problem and resulted in a reduction in malnutrition cases.

Genetically modified food crops with better nutritional characteristics are possible. To treat specific nutritional disorders or to target specific groups in society with special nutritional demands, the natural level of micro- and macronutrients can be enhanced using GM. Wheat with higher amounts of folic acid to prevent spin bifida and higher fibre content to minimise the risk of colon cancer, tomatoes with higher vitamin content, and peanuts with non allergic components are examples of these crops. GM technology can also be used to modify or improve the processing properties of food products, such as increasing the starch content of potatoes to reduce the quantity of oil absorbed during cooking or frying. Food crop shelf life can also be improved through genetic modification, such as changing tomatoes to ripen on the vine for a better and more acceptable taste and a longer shelf life. Sensory qualities such as flavour, texture, and colour can be modified to suit the preferences and tastes of consumers. GM has also been used to alter the functional properties of proteins used in the production of ice cream in order to prevent the creation of ice crystals and keep the smooth texture that consumers demand. Through genetic modification, the level of naturally occurring harmful and toxic substances present in some food crops can be reduced or eliminated, making the foods produced from these crops safer for human consumption[108].

Some foods that include inherent poisons, toxic chemicals, or allergens can be improved through genetic modification. According to International Food Information Council Foundation in 2011, the developments of potatoes that create less acryl amide when heated or cooked, as well as the manufacturing of low-lactose milk utilising biotechnology-derived

[107] *Golden Rice Project*, GOLDEN RICE HUMANITARIAN BOARD, https://www.goldenrice.org/ (last visited Sept. 25 2021).
[108] *GMO Debate*, ALLIANCE FOR SCIENCE, https://allianceforscience.cornell.edu/blog/2018/08/the-gmo-debate/ , (last visited Sept. 28, 2021).

enzymes, are two examples given[109]. Scientists may be able to eliminate proteins that cause allergic reactions to foods like soy, milk, and peanuts in the future, making the food supply safer for allergic people.

Genetically modified foods, which are currently on the market and have been consumed by people for decades, are said to be safe for human consumption, with no evidence of harm seen anywhere in the world. A number of studies undertaken over the last three decades have verified and corroborated this[110]. Children, as well as pregnant and nursing mothers, are said to be safe when eating GM foods. For those with food allergies, the use of biotechnology will not raise the risk of an allergic reaction or the development of a new food allergy.

Food biotechnology has been evaluated by international specialised and professional organisations such as World Health Organization (WHO), the Food and Agriculture Organization (FAO), the British Medical Association (BMA), and the American Medical Association and they all support its responsible use for its current and future positive impacts on addressing food insecurity, malnutrition, and sustenance. According to FDA research, animal products such as meat, eggs, and milk acquired from cloned animals are identical to those obtained from other animals. Animal feed incorporating biotech crops is also said to have the same nutritional value as feed derived from conventionally cultivated crops[111]. The British Medical Association (BMA) considers that there is insufficient evidence to indicate that genetically modified foods are hazardous. However, the organisation believes that, with acceptable risk assessment methods, independent and rigorous testing of novel foods, effective post-marketing surveillance, and correct regulation, GM foods could have long-term benefits for both developed and poor countries[112].

4.4.4 Benefits for the Environment

When compared to traditional methods of food production, GM supporters say that agricultural biotechnology utilised in the production of GM foods has a lot of positive effects and benefits on the environment. Agriculture's environmental sustainability can be improved by employing modern biotechnology. This can be accomplished by making pesticide treatments safer and more effective, lowering the amount of insecticides used on crops, cutting greenhouse gas emissions, preserving and enhancing soil quality, and reducing pre- and post-harvest crop losses.

The application of contemporary biotechnology techniques has resulted in the development of more ecologically friendly herbicides and pesticides. The acceptance and usage of

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[109] Rommens, C.M, Yan, H, Swords. K, Richael. C, Ye. J, *Low-acrylamide French fries and potato chips*. *Plant Biotechnol.* J., 6, 843–853, 2008, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2607532/.

[110] Massengale, R.D, *Biotechnology: Going beyond GMOs. Food Technology*, 64(11):30–5, 2010, https://www.ift.org/news-and-publications/food-technology magazine/issues/2010/november/features/biotechnology.

[111] ISAAA, https://www.isaaa.org/resources/publications/pocketk/11/default.asp (last visited Sept 23, 2021).

[112] *British Medical Association statement on GM foods*, CROPBIOTECH.NET, K Sheet No. 3, 2004, https://www.isaaa.org/kc/Publications/pdfs/ksheets/K%20Sheet%20(BMA).pdf.

herbicide-tolerant crops generated through genetic engineering has proven to be beneficial to both farmers and the environment. Farmers now have additional options for sustainable weed management by utilising herbicides that disintegrate more quickly, resulting in a lower environmental impact when compared to previous herbicides [113] . Biotechnology's development of pest-resistant crops resulted in more precise and targeted pest control, resulting in improved crop protection. B.thuringiensis crops that target only the insects that consume the crops, rather than valuable insects like honey bees or natural crop pest predators, have proven to be beneficial to the ecosystem[114].

The production of genetically modified crops contributes to the reduction of pollution in the environment. To control pests and diseases and protect crops, traditional agricultural production methods rely on the use of various chemicals, such as pesticides and insecticides. These pesticides have been used by farmers for generations, with detrimental consequences for the environment. Genetically modified crops are more pest-, insect-, and disease-resistant than traditional crops, which decreases reliance on chemicals. Reduced pesticide application also reduces the risk of soil or water contamination, which benefits the environment. GMOs may help lower the environmental effect of food production and industrial operations by reducing the quantity of pesticides required for crop protection, according to the FAO[115].

The arguments in support of GM techniques as used in agriculture for the production of GM foods are:

- Reduction of manual labour- Farmers who plant GM crops are expected to spend less time and effort controlling weeds and pests, as well as ploughing. Soil erosion, runoff, machinery fuel use, and greenhouse gas emissions are all reduced when ploughing is reduced. All of these effects contribute to environmental conservation by conserving soil and energy.
- Water conservation- Drought-tolerant GM crops can be changed in such a way that they require less water to grow. As a result, more water will be preserved and accessible for use in other crops or other applications; as a result, GM will conserve water, which is a scarce resource in the environment.
- More food from less land- Due to the increased need for food by the world's growing population, agricultural land utilised for growing food crops is becoming scarce. Historically, some farmers have resolved to use marginal land, which is less fertile and productive. As indicated by the FAO, genetically modified crops have made it feasible to produce higher yields from agricultural land suitable for cropping; as a result, farmers will no longer need to bring marginal area into cultivation.

[113] Graham Brookes & Peter Barfoot, *Global impact of biotech crops*, GM CROPS & FOOD, 3:2, 129-137, 2012, https://www.tandfonline.com/action/showCitFormats?doi=10.4161%2Fgmcr.20061.

[114] *Impact of Genetically Engineered Crops on Farm Sustainability in the United States*, NATIONAL RESEARCH COUNCIL, 2010, https://www.nap.edu/resource/12804/genetically_engineered_crops_report_brief_final.pdf.

[115] FOOD AND AGRICULTURAL ORGANISATION OF THE UNITED NATIONS, 2003, http://www.fao.org/english/newsroom/focus/2003/gmo7.htm (last visited Sept. 28, 2021).

- Rehabilitation of damaged or less fertile land- According to FAO reports, unsustainable irrigation practises used by farmers in developing nations have caused huge areas of crop land in these countries to become saline. Salt-tolerant and drought-resistant crop types and trees could be developed using genetic engineering.
- Bioremediation- Intensive cropping of agricultural land can cause soil structure and/or fertility deterioration. Through the modification and breeding of organisms capable of regenerating plant nutrients in the soil as well as the soil structure, GM has made it feasible to repair damaged land.
- Less deforestation- Food crops that have been genetically modified have produced higher yields. This would aid in closing the global food shortfall and feeding more people. This is expected to reduce the amount of deforestation required to feed the world's growing population. Less deforestation implies environmental conservation.

4.4.5 Benefits for the Economy

Proponents of GM technology and the development of GM foods say that the technique has some economic advantages. Growing GM crops is known to be expensive at first, but it is cheaper and more economically beneficial in the long term. Extra inputs, such as research, laboratory testing, field trials, and related inputs, must be employed at first. This entails additional costs, which are larger than those incurred when non-GM crops are grown. Because of the high expenses of bringing this agricultural technology to market, companies that are adopting GM technology have originally concentrated on creating crops with high economic returns and benefits. The use of herbicides and insecticides was reduced, lowering average agricultural production costs. Revenue increased as a result of improved and higher crop yields, as well as an improvement in produce quality. Growing GM crops provides economic benefits not only to developed countries, but also to developing regions around the world. Bennett et al. (2006) report that adopters of B. thuringiensis cotton have benefited from higher yields, lower pesticide use, less labour for pesticide application, and higher gross margins per hectare, based on the results of a large-scale survey of resource-poor farmers in South Africa[116]. They concluded that these benefits observed were clearly related to the GM technology used and not to preferential adoption by farmers.

4.4.6 Other Arguments

Prior to the introduction of genetically modified organisms, foods were traditionally produced using traditional plant and animal production methods. When compared to GM methods, conventional breeding methods are thought to be slow.

A new or modified plant or animal product takes years to develop using traditional production methods, whereas the desired GM organisms can be bred in a single generation. In that sense, developing GM foods would be faster and thus more cost-effective. Conventional

[116] Richard Bennett, Stephen Morse & Yousouf Ismael, *The economic impact of genetically modified cotton on South African smallholders: Yield, profit and health effects*, THE JOURNAL OF DEVELOPMENT STUDIES, 42:4, 662-677, 2006, https://www.tandfonline.com/doi/abs/10.1080/00220380600682215.

breeding techniques, on the other hand, involve unpredictable processes that can result in unpredictable results. GM has processes that are more precise, faster, and efficient, resulting in the desired results.

Human ingestion of GM foods is considered safe. Various tests undertaken for them and legally required to have them authorised as safe have confirmed this. The safety of currently available GM foods has been evaluated, and the results reveal that no health issues or risks have been detected or recorded. "Foods are regarded safe unless proven unsafe," is the main premise guiding the approval of foods as safe.

The conclusions drawn from the work of many scientists on the safety of GM foods and the broad scientific consensus (e.g., FAO 2004; European Commission 2010; Ronald 2011; American Association for the Advancement of Science (AAAS), Board of Directors 2012; American Medical Association, 2012) give enough evidence that the currently available transgenic crops and foods derived from them pose no greater risks to human health than foods developed through conventional methods. GM foods have been judged safe to eat, and the methods used to test their safety have been deemed appropriate[117].

Supporters of the GM technology and GM food production accept the fact that this modern technology, similar to any other technology used to produce foods, has some problems and possible drawbacks. They believe that it is important to weigh the benefits against the problems and to make the final judgment based on which outweigh the other. They believe that the benefits of the GM technology used to produce GM foods by far outweigh the problems.

4.5 GMOs AND HUMAN RIGHTS

4.5.1 Right to Adequate Food

The right to adequate food, which is drawn from the Universal Declaration of Human Rights, covers certain ethical implications of GMOs. The Rome Declaration on World Food Security and the World Food Summit Plan of Action, adopted during the 1996 World Food Summit, underlined everyone's right to adequate food. In the aftermath of the World Food Summit, the UN Committee of Economic, Social, and Cultural Rights and the UN Commission on Human Rights both addressed the right to food. The following comments about the right to adequate food, in particular, are thought to be quite pertinent to the GMO analyses presented in this work.

One of the most fundamental human rights, the right to food is inextricably related to the right to life. The right to food is part of the right to an adequate standard of living, which includes a minimum level of nutrition and other essentials. There can be no official practise or action that denies people this right. The human right to food evolved from the greater human right to an acceptable standard of living enshrined in the 1948 Universal Declaration of Human Rights (UDHR). Article 25 (1) of the UDHR asserts that 'everyone has the right to

[117] *supra* note 14

a standard of living adequate for the health and well-being of himself and his family including food, clothing, and housing..'. The right to food is recognised as part of the right to an adequate standard of life in a number of other international agreements, with a particular emphasis on the requirement for hunger relief. The Preamble to the Food and Agricultural Organization's (FAO) Constitution of 1965 stated that one of the organization's fundamental aims is to "ensure humanity's independence from hunger."

The International Covenant on Economic, Social, and Cultural Rights (ICESCR) addresses the Right to Food more comprehensively than any other treaty. Article 11 of the International Covenant on Economic, Social, and Cultural Rights envisions two concepts of the Right to Food: "adequate food" (para.1) and "freedom from hunger" (para.2) (para.2). While the former is a broader concept, the latter is more focused and could be achieved by enacting policies that mandate a minimum daily nutritional intake." According to the Committee on Economic, Social, and Cultural Rights, the core content of the right to adequate food entails: "Food that is available in sufficient quantity and quality to meet individual dietary needs, is free of harmful substances, and is acceptable within a given culture; Food that is accessible in ways that are sustainable and do not interfere with the enjoyment of other human rights."

Work on the human right to adequate food at the global level began in the late 1990s, after a mandate from the World Food Summit (WFS) in Rome in 1996, which approved a Plan of Action aimed at halving the number of undernourished people by 2015. Food security exists when all people, at all times, have physical and economic access to sufficient, safe, and nutritious food to meet their dietary needs and food preferences for an active and healthy life, according to the FAO's operational concept of right to food.

"In his report, the Special Rapporteur uses the following comprehensive definition derived from Article 11 of the ICESCR and GC 12: "the Right to Food is the right to have regular, permanent and free access, either directly or by means of financial purchases, to quantitatively and qualitatively adequate and sufficient food corresponding to the cultural traditions of the people to which the consumer belongs, and which ensures a physical and mental, individual and collective, fulfilling and dignified life free of fear."

4.5.2 Right to Food in India

India has a number of international commitments to respect the right to food of both children and adults. The International Covenant on Economic, Social, and Cultural Rights, as well as the Convention on the Rights of the Child, were both signed by India in 1986. In 1990, the Indian government ratified the United Nations Convention on the Rights of the Child.

The legislations which protects and ensures food security and safe food includes, Prevention of Food adulteration Act, 1954 and Rules, Essential Commodities Act, 1955, Food Corporation Act, 1964, Child Nutrition Act of 1966, Consumer Protection At, 1986, Food safety and standards Act 2006, National Food Security Act, 2013. The Food Safety and Standards Authority of India was established by the Food Safety and Standards Act 2006, which consolidates the laws relating to food and establishes the Food Safety and Standards

Authority of India to lay down science-based standards for articles of food and to regulate their manufacture, storage, distribution, sale, and import in order to ensure the availability of safe and wholesome food for human consumption.

The National Food Security Act, 2013, was passed by Parliament in 2013, with the goal of providing subsidised food grains to around two-thirds of India's 1.2 billion population. The National Food Security Act of 2013 (NFSA 2013) converts existing government of India food security programmes into legal entitlements.

4.5.2.1 Constitutional Perspective

Part III of the Indian Constitution contains a number of fundamental rights, which are divided into seven categories. The right to food, for example, can be included under the notions of equality and right to life, which are both enshrined in Articles 14 and 21 of the Indian Constitution, respectively. This right can be described as both fundamental and justifiable. The term "life" in this article has been construed by the courts to indicate "human dignity" rather than "survival" or "animal existence." In light of this, Article 21 should be read in conjunction with Articles 39(a) and 47, which are stated as directive principles of state policy, in order to comprehend the nature of the State's obligations in order to enable the effective realisation of this right. Article 39(a) establishes the state's obligation to direct its policies toward ensuring that all people, men and women alike, have access to appropriate means of subsistence. As a primary responsibility, Article 47 compels the state to enhance the level of nutrition and living standards of its citizens[118].

4.5.2.2 Judicial Interpretations

By transforming government food security initiatives into constitutionally protected legal entitlements, the judiciary has always worked to establish and fulfil a constitutional right to food[119]. The case of Krishna *Pattnayer v State of Orissa*[120] was the first to address the subject of hunger and malnutrition. In this case, the petitioner sent a letter to the Supreme Court informing the court of the acute poverty of the people of Kalahandi, Orissa, where hundreds of people were dying of starvation and others were forced to sell their children to survive. This court stated that no one in this country should be subjected to such deprivation and exploitation, especially since social justice is the watchdog of our Constitution. It is the state's responsibility to ensure that everyone has access to the basic essentials of life and that no one is forced to sell his sweat and labour for a pittance.

The most important case in which the right to food was established as a basic right is *PUCL v Union of India*[121]. The People's Union for Civil Liberties (PUCL) filed a writ petition on behalf of the underprivileged who were denied the needed employment and food relief mandated by the Rajasthan Famine Code of 1962 following a number of famine deaths in the state of Rajasthan. They brought up two points of disagreement. To begin, whether Article 21

[118] INDIA CONST. art 39(a)& 47.
[119] Ahmedabad Muncipal Corporation v. Nawab Khan Gulab Khan and Others, AIR 1997 SC 152.
[120] Pattnayer v State of Orissa, AIR 1989 SC 677.
[121] PUCL v Union of India, WP No. 196 of 2001.

protects the right to food, entrusting the government with this responsibility, and why, while people were dying due to drought, the government did not distribute the food, instead left it to rot in the godowns. The Supreme Court had to deal with a number of other topics in order to address these concerns, including the National Food Security Act, the Public Distribution System, the Integrated Child Development Scheme, and the Mid-day Meal Scheme.

The Delhi High Court granted the writ petition in *Harit Recyclers Association v Union of India*[122], in which the petitioners contended that the right to life of children to live with dignity had been seriously jeopardised due to the supply of contaminated food, and that this had eventually affected the enrolment and attendance of the children, the right to education as engrafted under Article 21A of the Constitution and further, the stoppage of the Mid Day Meal for a period of two months tantamount to deprivation and denial of food which fossilizes the right to food, a basic human right.

4.5.3 Genetic Engineering does not violate Right to Health

All genetically modified foods currently on the international market have passed safety tests, and no adverse effects on human health have been demonstrated as a result of eating GM foods. Three major safety concerns are examined while discussing and creating GM foods. The first is allergenicity, which refers to a gene's or a food's ability to trigger an allergic reaction. There have been no reported allergy reactions to GM foods currently on the market. The second is gene transfer from GM foods to the human gastrointestinal tract. Although the likelihood of transmission is low, use of gene transfer technology that does not incorporate antibiotic resistant genes is advised. Third is out crossing, meaning the transfer of genes from GM organisms to other species. Cases have been reported where GM crops approved for animal feed or industrial use were detected at low levels in the products intended for human consumption. Several countries have developed preventative strategies, including clear separation of GM and non-GM food crops.

4.5.4 Biotechnology and the Right to Health

The application of biotechnology in medicine aims to ensure the right to health. Biopharmaceuticals, biological remedies through genetic engineering, cure of hereditary disorders through gene therapy, and other biotechnological R&D achievements hold potential for improving public health. The four interconnected and fundamental characteristics of the right to health are availability, accessibility, quality, and acceptability. The right is protected by the Indian Constitution as well as a few international treaties. Every human being has the right to freely share scientific advancement and its advantages, according to the Universal Declaration of Human Rights. It is particularly pertinent in the case of biotechnology, due to its promising breakthroughs in meeting the community's food, health, and other related demands. Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), states that everyone has the right to access the highest standard of physical and mental health. It enumerates non-exhaustive obligations of states parties, including the

[122] Harit Recyclers Association v Union of India, WP(C) No. 2714/2010

creation of conditions that would ensure that all people have access to medical services and attention.

Article 21 of the Indian Constitution ensures protection for life and personal liberty, unless otherwise specified by law. The courts have construed this right to encompass the right to health. The Supreme Court held in *People's Union for Democratic Rights v. Union of India*[123] that the state has an obligation to protect and improve public health as stated in the Constitution's Directive Principles of State Policy; it should introduce and implement various international instruments that are consistent with fundamental rights and in harmony with the spirit of the Constitution, including the fundamental right to health. The right to health is enshrined in the constitution as part of the right to life. Furthermore, the state is responsible for creating an environment that protects people's right to health. It was held in *M.K. Sharma v. Bharat Electronics Ltd*[124] that Article 21 of the Constitution includes the right to health.

In *Vincent Panikulangara v. Union of India*[125], the Supreme Court of India stated that maintaining and improving public health should be prioritised because these are essential to the community's very physical existence, and the composition of the society as envisaged by the constitution is dependent on the improvement of these factors. Furthermore, the Supreme Court of India held in *Vishaka v. State of Rajasthan*[126] that the state is bound under the constitution to follow international law and treaty obligations. In view of international conventions establishing the right to health and medical help, this conclusion was taken. The Supreme Court of India, in *M.C. Mehta v. Union of India*[127], declared that Articles 47 and 48A, individually and combined, impose a duty on the state to safeguard and promote people's health, as well as to protect and improve the environment. As a result, Indian policymakers must consider the Directive Principles articulated in Articles 47 and 48A to guarantee that every law is consistent with the Constitution's state goals. In fact, the state is required to uphold human rights in general, and the right to health in particular, as outlined in the International Covenant on Economic, Social, and Cultural Rights, which was adopted in 1966.

The right to health is on the verge of being guaranteed in the field of biotechnology, due to the use of genetic technology and genetic engineering. However, certain negative consequences of genetic technology and related advancements, such as gene patenting, may put significant innovations that could meet health needs in the hands of a few people.

4.6 ACCEPTABILITY OF GM FOODS: UK SET TO DIVERGE FROM EU RULES

The United Kingdom recently launched an industry consultation on gene editing as it seeks to depart from EU regulations on genetically modified organisms (GMOs). Boris Johnson, the Prime Minister, has previously pledged to abandon European environmental rules that have

[123] People's Union for Democratic Rights v. Union of India, AIR 1982 SC 1473.
[124] M.K. Sharma v. Bharat Electronics Ltd, WP (C) No. 761 of 1986.
[125] Vincent Panikulangara v. Union of India, W.P.C. No. 23900 of 2009.
[126] Vishaka v. State of Rajasthan, AIR 1997 SC 3011.
[127] M.C. Mehta v. Union of India, 1987 SCR (1) 819.

stifled the development of genetically modified crop plants and farm animals in the United Kingdom. “Let us free the United Kingdom's extraordinary bioscience sector from anti-genetic-modification regulations. Let us work together to develop blight-resistant crops that will feed the world,” Johnson said in his inaugural speech as Prime Minister in 2019. Plant breeders and researchers applaud the government's promise to loosen restrictive gene editing regulations. According to Denis Murphy, professor of biotechnology and head of Genomics & Computational Biology at the University of South Wales, "the consultation is a welcome move that will be broadly welcomed by UK farmers and crop experts." “Genome editing is already being utilised in medicine, and it has enormous potential to address fundamental agricultural concerns such as food security, climate change, and sustainability,” he said.

The European Court of Justice's restriction on genome editing in agriculture in 2018 sparked significant outrage and was contrary to mainstream scientific opinion in both Europe and the rest of the globe, according to Murphy[128]. “It's worth noting that EU agriculture ministers have now requested that the ECJ prohibition be revisited by 2021, and new developments may have occurred by then. Meanwhile, it is critical that the UK develops an independent, evidence-based policy on genome editing and other genetic technologies as soon as possible for the benefit of farmers and society.” Only one variety of GM agricultural seed has received commercial authorisation in Europe, Monsanto's 810 maize, in keeping with the EU's traditionally cautious approach to biotechnology in food and agriculture. Imports of genetically modified organisms are subject to stringent safety assessments on a case-by-case basis.

A reduction in the use of agrochemicals, which would reduce the carbon footprint, is one of the potential benefits of genetic technologies. According to the researchers, the consultation allows policymakers to put this theory to the test. Other potential advantages of gene editing include the ability to remove allergens from food and reduce waste, such as by extending the shelf life of fruits and vegetables. While scientists have been critical of Brexit, Jonathan Jones, a plant scientist at Cambridge University's Sainsbury Laboratory, believes that gene editing is one area where it could improve. “Excessive regulation obstructs safe methods of reducing agriculture's environmental impact, and Brexit allows for regulatory flexibility,” he said.

Gene-edited plants and animals may not require thorough applications and evaluations before field testing and commercial authorisation under the new policy in the United Kingdom. In Europe, however, each commercialised genetically modified organism (GMO) must undergo a rigorous risk assessment by the European Food Safety Authority and must be approved by a majority of member nations before it may be planted, regardless of how it was generated.

[128] SCIENCE BUSINESS, https://sciencebusiness.net/news/uk-sets-out-diverge-eu-rules-genetically-modified-organisms , (last visited Sep. 5, 2021).

4.7 CONCLUSION

The discussion is still going on. It will, and it really should. It will go on because some people on both sides of the issue refuse to see the entire picture of genetically modified foods and technologies. Some proponents of genetically modified foods focus solely on the benefits of GM technology and the positive elements of GM foods, ignoring the potential hazards. On the other hand, critics of GM technology and GM foods emphasise and attempt to magnify the possible risks to human health, the environment, and the entire ecosystem, while ignoring the technology's good elements. The discussion will continue until both sides have a clear knowledge of the benefits and risks associated with GM technology and GM foods. It will also continue until researchers and scientists give reliable results and interpretations of their work, free of external demands to distort results or emphasise aspects that serve the research sponsors' objectives. The argument will continue, and topics will stay controversial until consumers have access to the information and can make informed decisions about whether or not to support or oppose them. The argument over the release of GM foods and crops will continue until more studies establish that they do not pose severe hazards to human and animal health, the environment, or the world's ecosystems.

The introduction of genetically modified organisms (GMOs) into the environment and the marketing of GM foods have sparked public discussion in many regions of the world. This issue is expected to continue, most likely in the context of other biotechnology applications (such as human medicine) and their consequences for human societies. Despite the fact that the issues under discussion are usually relatively similar (costs and advantages, safety concerns), the debate's outcome varies from country to country. There is currently no global consensus on topics such as GM food labelling and traceability as a strategy to address consumer preferences. Despite the lack of agreement on these issues, the Codex Alimentarius Commission made significant progress in 2011 by developing Codex texts relevant to the labelling of foods derived from modern biotechnology to ensure consistency in any labelling approach implemented by Codex members who have already adopted Codex provisions.

The argument should go on for the sake of the confused consumers, who are thought to be the majority. Large segments of the public are perplexed because they are constantly bombarded with contradictory information and reports about genetically modified foods. Each side of the debate strives to persuade customers that their claims are true and accurate representations of reality. Supporters of the technology strive to paint a bright picture without emphasising the concerns, whereas opponents discuss the GM technology's risks and threats. The majority of consumers are perplexed and unsure of whom to trust. The debate should be conducted in a professional and objective manner, with the welfare of consumers at the forefront of the agenda.

WHO has been taking an active role in relation to GM foods for two reasons: first, because public health could benefit from the potential of biotechnology, such as increased nutrient content of foods, decreased allergenicity, and more efficient and/or sustainable food production; and second, because there is a need to investigate the potential negative effects

on GM foods on human health. If modern technologies are to truly improve the way food is produced, they must be thoroughly evaluated. WHO and FAO collaborated on multiple expert discussions on GM food evaluation and gave technical advice to the Codex Alimentarius Commission, which was incorporated into the Codex Guidelines on GM food safety assessment. In close collaboration with FAO and other international organisations, WHO will continue to pay special attention to the safety of GM foods from the standpoint of public health protection.

Both parties must recognise and express potential benefits as well as potential risks, hazards, and threats associated with GM foods. It should be emphasised that no human activity is completely risk-free, and certainly no food, whether produced using GM or traditional methods, is. This is not to say that we should blindly believe in or fully trust modern technologies like GM without first conducting extensive research. Potential risks should be identified, evaluated, and reduced to a safe level as much as possible. It is critical to underline that scientific discoveries are not expected to provide definitive answers to significant questions about GM technology and GM foods, and should not be viewed as the ultimate aim for resolving the GM food controversy.

CHAPTER V

CONCLUSION AND RECOMMENDATIONS

GM technologies have been established for about 15 years and are used in countries all over the world, including Brazil and China. Manmohan Singh, the former Prime Minister, recognised biotechnology as a path to food security and warned against falling prey to "unscientific biases[129]." "Concerns about the perceived hazards of their (GM crops) should be addressed by using internationally established techniques for establishing safety parameters. Former President Pranab Mukerjee said, "ICAR, which is involved in producing valuable products and technology in this field, must contribute to the public dialogue and provide clarification on this sensitive issue[130]." Anti-GM organisations such as Greenpeace India and Gene Campaign are among the many foreign-funded NGOs obstructing India's economic progress, according to the Indian intelligence service. Agriculture scientists from research institutes such as IARI, ICAR, and universities have called for "field trials" for GM crops, claiming that "confined field trials are required for the evaluation of productivity performance as well as food and environmental safety assessment." A group of distinguished academics gathered at the National Academy of Agricultural Sciences (NASA) under the leadership of MS Swaminathan, the "father of the green revolution," and released a 15-point resolution in support of GM crops.

According to S.S. Gosal, Punjab Agriculture University Director of Research, a brinjal crop typically necessitates up to 30 insecticide sprays[131]. Indirectly, this enters the human food supply. We will ingest some of the genes that have been incorporated into the seeds to make the crop pest- and herbicide-resistant if we cultivate and eat Bt brinjal. Finally, we must determine which of the two is less dangerous to human consumption." In India, Bt cotton is the only GM crop that can be grown commercially. Following a Public Interest Litigation (PIL) on the environmental release of such crops, the fate of other new GM crops is pending in the Supreme Court. In India, approximately 75% of pesticides used are insecticides, posing major dangers to humans, animals, and the environment due to a lack of regulatory oversight over the sale and distribution of highly hazardous pesticides. Recently, 18 organophosphate pesticides were discovered in common vegetables collected from marketplaces, with brinjal having the highest pesticide concentration[132]. The field trial of Bt-brinjal, which was

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[129] LIVE MINT, https://www.livemint.com/Politics/jUYRmnHqK5WEX7p55VWlPK/Dont-succumb-to-unscientific-prejudices-against-Bt-crops.html, (last visited Sept. 30 2021).

[130] SPEECH BY THE PRESIDENT OF INDIA, SHRI PRANAB MUKHERJEE ON THE OCCASSION OF THE 85TH FOUNDATION DAY OF INDIAN COUNCIL OF AGRICULTURAL RESEARCH (ICAR), https://presidentofindia.nic.in/speeches-detail.htm?103, (last visited Sept. 30, 2021).

[131] *Two decades after global launch, GM crops remain controversial*, BUSINESSTODAY.IN, https://www.businesstoday.in/magazine/features/story/genetically-modified-crops-controversial-challenges-ahead-47515-2014-04-12, (last visited Sept.30, 2021).

[132] Shashi Kumar, Raj K. Bhatnagar, Keshab R. Kranthi & Swapan K. Datta, *The legal battle over field trials of GM crops*, https://www.natureasia.com/en/nindia/article/10.1038/nindia.2014.14?WT.ec_id=NINDIA-20140212.

genetically engineered to reduce pesticide use by eliminating the primary infestation caused by fruit and shoot borer larvae, has been halted.

India is the world's largest importer of edible oil, with imports accounting for over half of its domestic use[133]. At Delhi University, a genetically modified hybrid mustard DMH-11 with a greater oil production was produced to minimise reliance on oil imports. Since March 2012, field trials of mustard DMH-11 have been anticipated. Golden rice has been genetically modified to offer a pro-vitamin-A supplement that could significantly reduce blindness caused by vitamin-A deficiency in India, which has the world's highest percentage of Vitamin A deficient (VAD) children. The field evaluation of transgenic rice with high iron/zinc levels has yet to be completed. Several indigenous transgenic lines of crops with insect resistance/agronomic features, such as cauliflower, cabbage, chickpea, groundnut, maize, okra, pigeon pea, potato, tomato, and sorghum, are also awaiting field trials.

The legal battle in India for GM crop field trials is very similar to the legal battle in the United States over the GM herbicide-tolerant sugar beet, which was approved for outdoor cultivation in 2005 by the USDA but was banned in 2010 by a Californian district court due to lawsuits by various NGOs. USDA deregulated it for commercial production again in June 2012. The USDA's deregulation decision has prompted the European Food Safety Authority (EFSA) to look into science-based recommendations for growing GMHT sugar beet in the European Union. The World Health Organization, the American Medical Association, the National Academy of Sciences, and the American Association for the Advancement of Science have all stated that there is no convincing evidence that genetically modified organisms are dangerous. That finding is supported by hundreds of investigations. However, many of us do not believe these assurances. We're drawn to doubters who argue that there's more to the tale, that certain studies have discovered GMO hazards, and that Monsanto is concealing it up.

It's true that the situation is complex. However, the more you look into the evidence against GMOs, the more you discover fraud. It's riddled with errors, fallacies, misunderstandings, misrepresentations, and outright lies. People who claim Monsanto is concealing the truth are concealing evidence that their own claims concerning GMOs are wrong. They're counting on you to be overwhelmed by the science and adopt their message of scepticism as a gut instinct. The anti-GMO movement's primary argument—that caution and prudence are grounds to shun genetically engineered, or GE, food—is a sham. Activists who advise you to avoid GMOs take no such precautions when weighing the alternatives. They condemn GE agricultural proteins as hazardous while defending pharmaceuticals, herbicides, and non-GMO crops that contain the same proteins. Even while studies show that other crop development technologies, including some favoured by the same campaigners, are more disruptive to plant genomes, they portray genetic engineering as chaotic and unpredictable.

[133] *Id.*

Some aspects of GE agriculture, such as herbicides, monocultures, and patents, raise legitimate concerns. However, none of these issues are directly related to genetic engineering. There is no such thing as genetic engineering. It's a method that may be applied in a variety of ways to produce various results. To think properly about GMOs, separate the applications and concentrate on the substance of each situation. If pesticides and transparency are important to you, you should be aware of the toxins to which your food has been exposed. That isn't something a GMO label will inform you. It can also persuade you to purchase a non-GMO product even if the GE counterpart is safer.

The Environmental Protection Agency (EPA) approved Bt potatoes, corn, and cotton in 1995. The toxin produced by these crops was "similar to that produced naturally in the bacteria" and "affects insects when swallowed, but not mammals," according to the agency." Opponents, however, were unconvinced. Greenpeace, the Center for Food Safety, the Pesticide Action Network, and the International Federation of Organic Agriculture Movements led a coalition that sued the EPA in 1999 to have its approvals revoked. According to the lawsuit, Bt crops may produce insecticide-resistant insects and cause "direct harm to non-target organisms." Greenpeace and its allies were not opposing the Bt industry. They were guarding it. They were attempting to persuade the public that the Bt protein was harmful when produced by plants but completely safe when produced by bacteria and sprayed by farmers.

Most people don't realise that food regulation is significantly more complicated and thorough than they think. It's the complete process of monitoring your food from the moment it's created until it hits your lips. This includes the growing or manufacturing process, trade (where your food originates from and how it gets to where it's going), quality (ensuring that your food is unadulterated), labelling, and more. The purpose of food regulation is to ensure that the food we eat is safe and of sufficient quality. Every country in the globe has its own set of food restrictions, although not all of these regulations are equal.

Although labelling is only a small aspect of food regulation, it receives a lot of attention since it allows people to determine what's in their food and make judgments about what they want to eat. Food sold beyond state boundaries is required by law to have labels (thus the food at your local farmer's market, as long as it's grown in-state, doesn't need one until the state mandates it). Food labelling is regulated by the Food and Drug Administration and the United States Department of Agriculture. Labels must be accurate and not deceptive. Foods that fail to meet government standards are mislabelled and recalled.

Soybeans and corn are the two most common GM crops in the United States. In the United States, genetically modified corn, canola, soybean, and beet sugar crops account for more than 90% of all corn, canola, soybean, and beet sugar crops produced. The United States produces over half of the world's genetically modified organisms. This dominance can be attributed to the fact that plant biotechnology as a science and a business was essentially invented there, with strong support from government institutions that promote technological change through a strong intellectual property system and a science-based approach to risk

assessment. The US regulatory approach differs significantly from that of the EU in that the US government regulates only the product itself, not the manufacturing process. In other words, the process of genetic engineering is not evaluated separately from other plant engineering techniques in risk assessments. As long as the GM product passes the criteria of substantial equivalence, it is anticipated to follow the same stages as products obtained from prior approaches when it comes to risk assessment. After commercial approval, expost monitoring can reveal discrepancies or new risks in the field, leading to improvements in risk management and risk control. In this context, industry self-regulation has shown to be an effective tool for assuring the safety of genetically modified foods. Science, consumer, and producer organisations, for the most part, did not join the opposition since they had concrete experience with the technology that contradicted the public claims. Many of them believe that genetic engineering has the potential to improve food quality and the environment, and that it is compatible with organic farming.

The EU has a more stringent and formal regulatory structure in place for genetically modified organisms (GMOs) and GM food, while also ensuring that its population have access to healthy food and food security. In Europe, a number of restrictions have been enacted, including particular regulations on genetically modified foods, as well as a regulation on the tracing and labelling of GMOs and a directive against the deliberate release of GMOs into the environment. A rule was passed requiring the mandatory labelling of all foods containing GM ingredients in amounts greater than 1%. Pre-market authorisation for novel foods, including GM foods, was implemented in Europe in 1997, requiring a manufacturer or importer to demonstrate that commercialization of the GM foods does not pose a risk to human health or the environment. In Europe, unlike in the United States, the process of food production is taken seriously. Consumers' rights to select between ordinary food and GM food are protected by separate rules for GM foods. Countries like Japan, Australia, and New Zealand are following Europe's lead by adopting similar GM food regulatory policies. The EU's GM food policy is thought to be based on the precautionary principle that people should know what they're ingesting.

Nobody should be critical of civil society campaigns as long as they originate in the societies that will suffer the brunt of the repercussions. Unfortunately, most anti-GMO agricultural NGO campaigns come from wealthy countries, with poor countries bearing the brunt of the consequences. GMOs are obviously unappealing to well-fed citizens in Europe and North America, where agriculture is already highly productive. Most citizens in these countries do not require this technology to improve their well-being; farmers reap the majority of the benefits, and farmers today account for only about 1–2% of all citizens in these countries[134]. Even for farmers in wealthy countries like the United States, where so much agricultural production is now diverted to industrial (e.g., maize for ethanol) or animal feed (e.g., soybean meal), avoiding GMO food staple crops is relatively painless.

[134] Robert Paarlberg, *A dubious success: The NGO campaign against GMOs*, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5033189/, (last visited Sept. 30, 2021).

However, moral clarity is lost when residents from these wealthy countries transfer their negative attitudes regarding GMOs onto underdeveloped countries, where up to 60% of the population is poor farmers who could profit from this technology. Farmers in poor nations rely nearly completely on food crops, not animal feed or industrial crops, therefore the de facto prohibition on GMO foods today is particularly harmful to them.

It's even more shameful when anti-GMO campaigners from developed countries deliberately hide from citizens in developing countries the published conclusions of their own national science academies, which continue to show that no convincing evidence of new risks to human health or the environment has yet been discovered from this technology. It would be bad enough to use scare tactics to prevent the planting of GMO foods; using deliberate deception cannot be acceptable.

International non-governmental organisation (NGO) campaigns against GMO foods have been successful in the developing world in part because they were first successful in Europe. This achievement was fueled in part by a perfectly reasonable food safety concern that had nothing to do with GMOs. The UK government officially admitted in March 1996 that consuming the meat of animals infected with bovine spongiform encephalopathy (BSE), also known as "mad cow disease," posed a potentially lethal human food safety concern. The government had previously informed consumers that eating this meat was entirely safe. By coincidence, the first shipment of a GMO food, herbicide-tolerant soybeans from the United States, was allowed by European officials in March 1996. Activist NGOs in Europe, such as Greenpeace, Friends of the Earth, and the European Consumers' Organization (BEUC), found no consumer benefit from GM foods that would warrant even a hypothetical safety risk, therefore they began advising individuals to avoid GM foods and crops on "precautionary" grounds. Efforts by European officials to reassure customers about soybeans were ineffective since the BSE outbreak had tarnished their reputation as food safety watchdogs. Activists from non-governmental organisations (NGOs) rejected the assurances and instead staged street protests and organised efforts to prevent ships carrying GMO soybeans from unloading. To avoid being targeted by activist demonstrations, European grocery chains began removing identified GM items from their shelves.

Anxiety arose, therefore the EU agreed in June 1997, in response to citizen and activist pressure, to mandate that all GM food marketed in Europe be labelled. Rather than calming customers, this move appeared to confirm the growing belief that GM foods are truly unsafe. By 1998, political fears had grown so high that EU officials were compelled to impose an informal halt on any further case-by-case GM crop licences.

Once the European victory was secured, the NGO campaign shifted its focus to the global arena, focusing on a UN-led effort to negotiate an international protocol (the Cartagena Protocol) governing the trans-boundary movement of living GMOs, which was underway at the time under the 1992 Convention on Biological Diversity (CBD). Anti-GM groups like Greenpeace, Friends of the Earth International, and the Third World Network used their access to the protocol negotiation process to spread fear about the dangers of GMOs and

advocated for the new Protocol to be modelled after the 1989 Basel Convention on the Control of Transboundary Movements of Hazardous Wastes. GMOs, which had been produced at great expenditure and had been authorised for safe use by regulators, were therefore equated to hazardous wastes. This was an odd and inappropriate framing, but it was accepted by the European environmentalists who controlled the protocol negotiations, and it was presented to Africans and other developing-country delegates as something the UN had to do to conserve their rich biodiversity.

India permits the import of genetically modified soybeans and canola oil. Cotton (bt) is the only crop that has been permitted for cultivation. For a long time, India has had an effective ban on other GM seeds. Importers must produce a non-gm certification under the new rules. The authorisation of field testing of new genetically modified (GM) crops in India has come to a halt. The impasse is caused by the Genetic Engineering Appraisal Committee (GEAC) of India's Ministry of Forests and Environment (MoEF) taking too long to make a decision on the topic). In India, Bt cotton is the only GM crop permitted for commercial production. Following a Public Interest Litigation (PIL) on the environmental release of such crops, the fate of other new GM crops is pending in the Supreme Court. India could take the example of China as both countries have similar exponential population and face food security challenges. China has already been using GM crops for the last two decades. China with its 7% of the global arable land feeds 22% of the world's population. Such a boost is necessary for India. By 2050 India's population will reach 1.8 billion and GM foods are the only way to feed them all[135].

India has the world's biggest number of hungry people. In order to significantly reduce the suffering caused by hunger and malnutrition in India, progress must be made on both the supply and demand sides. Food must be supplied in adequate quantities while retaining nutritional quality to feed a population of over a billion people on the supply side. On the demand side, it's important to ensure that everyone has access to food, as well as (cultural) acceptance and consumption of it, not just at the national level, but also at the home and individual level. India is now discussing whether to allow new technologies, such as genetically modified (GM) crops, into the agricultural industry. GM crops are thought to have a role in raising output and consequently increasing food supply in order to end hunger. Food security at the national and global level, according to Pinstrup-Andersen, tends to focus on the supply side, or food availability, but fails to consider that food availability does not guarantee access or sufficient calories. 4 The latter is known as nutritional diet bt brinjal, and it is predicted to reduce pesticide use by 42 percent while doubling productivity. Smallholder farmers' ability to engage in biotechnology agricultural crops, which demands large capital commitment, adaption of new skills, affordability, marketing strategy, and cultural acceptance, is an issue raised by the social dimension of the Bt brinjal debate. The cash crop promises more rewards, but it also comes with more risks. Cotton cultivation necessitates a lot of money and a lot of water; it also necessitates a lot of fertilisers and insecticides. The

[135] QUARTZ INDIA, https://qz.com/india/740532/there-will-be-1-8-billion-indians-by-2050-gm-crops-are-the-only-way-to-feed-them-all/, (last visited Sept. 30, 2021).

marginal farmers in tribal areas are enticed to grow cotton crops for quick income, but they are plagued by droughts and the inability to repay debts owed to local merchants[136].

While genetically modified brinjal, India's first transgenic food crop, is nearing the end of field trials, scientists at the Centre for Cellular and Molecular Biology (CCMB), a prominent Hyderabad-based research institution, have taken the first steps toward bringing genetically modified (GM) fish, which are currently confined to labs, to Indian plates. Despite the fact that the genetic engineering approval committee has extensive criteria and process for testing the safety of genetically engineered crops, no such rules or protocol exist for genetically modified animals.

RECOMMENDATIONS

1. **PUBLIC AWARENESS:**

   Several surveys conducted in the country have revealed a serious lack of awareness and knowledge about biotechnology. Because public acceptability is so important in the development and implementation of laws in India, it is critical to gain the public's trust via raising awareness. Given the wide range of opinions on the impact and risks of biotechnology, as well as the costs and advantages, it's not surprising that agreement is difficult to come by when debates turn no policy. Lack of public acceptance is a major impediment to policy development and execution. It has been discovered that half-truths and deliberate propaganda by interested parties are substantially to blame for India's low popular acceptability. As a result, research institutes should make their findings public and communicate them to the general public and policymakers in order to increase public trust in biotechnology. The number of bioinformatics networks already operating in India must be increased to cover the whole population of each district. Local awareness initiatives, in combination with increased regulatory transparency, will help to build public trust.

2. On a case-by-case basis, bio safety concerns should be addressed at all stages of GM crop research and release. Strong bio safety rules are important for evaluating GM crops, and they must be addressed at all stages of development and release of transgenic crops. Since then, many transgenic crops have been produced and released for open field testing and commercial production on a regular basis, raising concerns about the potential consequences to the environment, biological diversity, and human health. To preserve biodiversity and reap the benefits of genetically modified crops, well-planned, systematic research, development, exchange, and commercialization of transgenic crops after addressing all environmental concerns, followed by regular post-release monitoring to assess long-term impacts, would be required.

3. To maximise the benefits of revolutionary new genetics while minimising risks, a number of policy and regulatory steps must be taken, either to restore the current

[136] Purabi Bose & Bernd Van Der Meulen, *The Law to End Hunger Now: Food Sovereignty and Genetically Modified Crops in Tribal India - A Socio-Legal Analysis*, 118 PENN St. L. REV. 893 (2014).

regulatory system's functionality or to establish a new regulatory framework that can provide smallholder farmers with access to genetically enhanced crops. Both regulation choices appear to be a difficult task for India's government. This requires the government to reverse a number of policy decisions, including the Bt brinjal moratorium, the renaming of GEAC, and the imposition of NOC criteria prior to awarding licences - all of which were described in detail in the previous section.

4. **NEW BIOSAFETY LEGISLATION:**

With legislation spanning the disciplines of science and technology, environment and preservation, agriculture and advancement, food and health, and GMO trading, India's existing legislative framework on genetically modified organisms is arguably comprehensive. A Bio safety Protection Legislation is required in India. Any GMO regulatory regime should prioritise protecting people's health and the environment from the risks of modern biotechnology, while simultaneously acknowledging that transgenic technology is actively opposed by citizens and governments around the world and is not a foregone conclusion.

To gain public trust, it is necessary to ensure that there are strong rules in place to ensure that companies producing GM foods adhere to the regulations and so protect consumers. For this reason, legislation should be drafted specifically for biotechnology. The following elements must be included as cornerstones of the legislation:

- Non political, that is, approvals are given by an intergovernmental body, of which the members are experts in relevant fields, nominated by the ministries involved and other relevant government bodies.
- Separating the phases of contained research and deliberate release, as well as distinct regulatory mechanisms for both, in a sequential manner.
- There must be no conflicts of interest in regulation or decision-making.
- Transparent operation requires information disclosure as well as public/independent scrutiny.
- Participation of the public in democratic processes is essential.
- Risk assessment –prescribing rigorous, scientific protocols and requesting that the crop developer conduct studies, followed by independent analysis of the crop developer's dossier and evaluation of the same; to conduct independent testing, with all necessary facilities and institutional structures in place, and to evaluate the results.
- Monitoring, reviewing, and revoking approvals are all part of risk management.
- Liability - including monetary penalties, redress, and remediation; Liability Regime must cover both crop developers and regulators.
- Affected parties and those who can approach in the public interest should have access to easy, affordable, and accessible oversight and appellate methods.

- Special clauses to allow state governments to develop their own regulatory systems and methods; similarly, protection of the constitutional authority of Gram Sabhas over their natural resources, given India's federal structure with Agriculture as a state subject.
- There must be provisions for regulating genetically modified animals also.

5. However, there is need to be cautious and move slowly. GMO product creation, testing, and release must all be properly regulated. This need regulatory institution to ensure that humans, animals, and the environment are not harmed. The current systems are insufficient and incapable of performing these vital functions.
6. The country's regulatory, clinical trial, and post-marketing monitoring and surveillance capabilities should all be improved. As a result, biotechnology should be promoted and equipped in universities and research institutions.

7. **IMPROVE RISK ASSESSMENT PROCESSES:**
   The following recommendations were made on opportunities to improve the risk assessment processes:
   - Risk assessors should be professional, well-trained, and able to convey their findings to authorities and the general public in a clear and concise manner.
   - Given that traditional plant breeding is supposed to serve as a baseline for evaluating transgenic crops as outlined in the original Codex texts, more plant breeding and genetics experts should be included in the expert panels and regulatory institutions charged with determining GMO safety.
   - A procedure should be devised in which countries collaborate to reach an agreement on the safety of transgenic proteins and crops. Regional or sub-regional approaches should be taken.
   - After several years of use, criteria are needed to establish when a GM event becomes "conventional," so that it can be used as a benchmark for future events.
   - Criteria should be devised to identify solid, relevant evidence that may be utilised to assist decision-making, as well as to reject studies that are irrelevant, of poor quality, or that are misrepresented.
   - To give greater access to information, data, and decisions from other regulatory agencies and relevant entities, online databases must be developed/improved. These should, at the very least, have ties to each other.
   - Resources should be established to assist local developers in generating data for regulatory investigations while adhering to high quality requirements. While such data does not have to meet GLP criteria, it should be subjected to rigorous Quality Assurance testing.
   - Increase the number of GM crops and regions represented in compositional databases.
   - Harmonization of breeding stack evaluation criteria; this is the area with the most possibility for consensus.

8. It is impossible to overstate the importance of making every effort feasible to achieve better integrated and harmonised regulatory oversight for GMOs. However, in order to facilitate regulatory collaboration and cooperative effort, the fundamental challenges that have been identified must be addressed in the near future.

9. **PATENT OF GM PLANTS:** Patenting has positive impacts. It should also be emphasised that genetic editing is a costly and time-consuming operation. As a result, if the producers of genetically modified products are not allowed to profit from their work, they will lack the motivation and financial resources to continue their research, causing the industry to stagnate. Patents have a positive impact on attracting more funding for agricultural research.

   To gain a market position, the manufacturer must first research the population of the market in which he wishes to release his GM plant. Rice is India's main crop, while corn is in the United States and sugar beets are in the European Union. Due to the diverse population in Indian markets, demand varies from state to state. And apart from that, the manufacturer should identify the problems that a specific plant is experiencing and the methods needed to rectify the problem by genetically modifying it. Issues may arise during the growth phase or only after the product has been completed. Though farmers and cultivators are increasingly relying on GM plants due to their ease of use and abundance of defect-free end products, GM plants remain unaffordable to another group due to high prices and restrictions on re-using. There is also a negative impact on researchers, as patented GM plants restrict their ability to conduct further research. The patented GM plant can be useful to the entire society if the creator readily accepts measures to reduce the harmful impact of these patents, such as lowering prices, allowing licences for future research, reducing the number of exclusive rights for production, and so on. A patentable GM plant can currently gain a strong market position if the inventor thoroughly researches the industry and is prepared to incorporate societal needs.

10. **SUBSTANTIAL EQUIVALENCE:** Substantial equivalence is not a replacement for a risk assessment. It is a guiding principle that can be used by regulatory scientists conducting safety assessments. It emphasises that an evaluation should show that a GM variety is as safe as its conventional counterparts. Differences in this approach may be identified for further investigation, which may include nutritional, toxicological, and immunological testing. The approach enables regulators to concentrate on the differences in a new variety, and thus on critical safety concerns.

11. **LABELLING:** The introduction of GMO-containing or GMO-derived food products into the market must respect the consumer's right to be informed about specific characteristics while also ensuring freedom of choice. State governments are responsible for meeting these standards; one simple way would be to include rules for labelling GM items. To avoid claims of discrimination, the labelling system should be applied to all food products, as limiting the labelling obligation to GM foods only contributes to stigmatisation of these products**.** When there are existing 'GMO-free'

items on the market, inserting information labels about a product's GMO content implies that the latter is somehow unsafe. Obviously, information on a product's composition, chemical content, and method of manufacture or origin is important for consumer health protection. As a result, it may be appropriate to keep the requirement to include information regarding GMO content on labels while prohibiting the possibility of labelling other items as 'GMO-free.'

BIBLIOGRAPHY

BOOKS

- DAVIDE E. NEWTON, GMO FOOD, 246-247, ABC CLIO (2014)
- Genetically Engineered Foods, Handbook of Food Bioengineering, Volume 6, 2018, Academic Press
- Ronald Rose Watson & Victor R. Preedy, Genetically Modified Organisms in Food Production, Safety, Regulation and Public Health, 2016, Academic Press
- SALAH E.O. MAHGOUB, GENETICALLY MODIFIED FOODS, BASICS, APPLICATIONS AND CONTROVERSY, CRC PRESS, (2016)
- SREENIVASULU, LAW RELATING TO BIOTECHNOLOGY, 1ST Edition, OXFORD, (2016)

ARTICLES

- A. Snow, D. A. Andow, P. Gepts, E. M. Hallerman, A. Power, J. M. Tiedje & L. L. Wolfenbarger, *Genetically Engineered Organisms and the Environment: Current Status and Recommendation,* (2005).
- Alexandrova, K. Georgieva & A. Antanassov, *Biosafety Regulations of GMOS: National and International Aspects and Regional Cooperation*, TAYLOR AND FRANCIS GROUP, 19:sup3, 153-172 (2005).
- Amit Khurana, Sonam Taneja & Bhavya Khullar, *Genetically Modified Processed Food in India*, CSE India, 6 (2018)
- Cheng Zang, Robert Wohlhueter & Han Zang, *Genetically Modified Foods: A critical review of their promise and problems*, 5 Food Science and Human Wellness, 116-123 (2016)
- Dhan Prakash, Sonika Verma, Ranjana Bhatia, B. N. Tiwary, Risks *and Precautions of Genetically Modified Organisms*, INTERNATIONAL SCHOLARLY RESEARCH NOTICES, vol. 2011
- *Graham Brookes & Peter Barfoot, Environmental impacts of genetically modified (GM) crop use 1996–2015: Impacts on pesticide use and carbon emissions*, GM CROPS & FOOD, (2017),
- Brookes G & Barfoot P, *Global impact of biotech crops: environmental effects,* 1996-2010. GM Crops Food. 2012 Apr-Jun;3(2):129-37
- Godfray HC, Beddington JR, Crute IR, Haddad L, Lawrence D, Muir JF, Pretty J, Robinson S, Thomas SM & Toulmin C, Food security: the challenge of feeding 9 billion people. Science. 2010.
- Guillaume P. Gruere & S.R.Rao, AgBioForum, *A Review of International Labeling Policies of Genetically Modified Food to Evaluate India's Proposed Rule*, Volume 10, No.1, 2007, AgBioForum
- Ians, *Labelling Required if GM content over 1%: FSSAI chief*, BUSINESS STANDARD
- Davison J & Ammann K, *New GMO regulations for old: Determining a new future for EU crop biotechnology*, GM Crops Food. 2017 Jan 2;8(1):13-34

- Kanchana Kariyawasam, *Legal Liability, Intellectual Property and Genetically Modified Crops: Their Impact on World Agriculture*, 19 PAC. RIM L & POL'Y J. 459 (2010).
- Louis-Marie Houdebine, *Impacts of genetically modified animals on the ecosystem and human activities*, Global Bioethics, 25:1, 3-18 (2014).
- Manish Shukla, Khair Tuwair Al-Busaidi, Mala Trivedi & Rajesh K. Tiwari, *Status of research, regulations and challenges for genetically modified crops in India*, GM Crops & Food, 9:4, 173-188 (2018)
- Massengale. R.D, *Biotechnology: Going beyond GMOs. Food Technolog*, 64 FOOD TECH, (2010).
- P. Byrne, D. Pendell, & G. Graff, Colarado, *Labeling of Genetically Modified Food*, STATE UNIVERSITY EXTENSION.
- Perez. J, Bond. C, Buhl. K. & Stone. D, *Bacillus thuringiensis (Bt) General Fact Sheet*; National Pesticide Information Center, Oregon State University Extension Services, (2015)
- Priyanka Rastogi & Anshul Bansal, *India: Patenting of Genetically Modified Crops In India Vis-A-Vis International Decisions*, MONDAQ, (2017).
- Purabi Bose & Bernd Van Der Meulen, *The Law to End Hunger Now: Food Sovereignty and Genetically Modified Crops in Tribal India - A Socio-Legal Analysis*, 118 PENN St. L. REV. 893 (2014).
- Richard Bennett, Stephen Morse & Yousouf Ismael, *The economic impact of genetically modified cotton on South African smallholders: Yield, profit and health effects*, The Journal of Development Studies, 42:4, 662-677, (2006)
- Robert Paarlberg, *A dubious success: the NGO campaign against GMOs*, GM CROPS & FOOD vol. 5,3 (2014)
- Rommens, Caius M et al, *Low-acrylamide French fries and potato chips*, Plant biotechnology journal, vol. 6, 843-53, (2008)
- Setsuko Yasuda, *GMO Foods Labeling in India*, IATP, (1999).
- Shashi Kumar, Raj K. Bhatnagar, Keshab R. Kranthi & Swapan K. Datta, *The legal battle over field trials of GM crops*, (2014).
- Stephanie Storm, *Connecticut Approves Labeling Genetically Modified Foods*, THE NEW YORK TIMES, (2013).
- T. M. Manjunath, *Safety and Benefits of Bt and Bt- Cotton: Facts Refute Allegations*, RESEARCHGATE, (2009).
- Ahuja, V, *Regulation of emerging gene technologies in India*, *BMC Proc* 12, 14 (2018)

WEB SOURCES

- *Adoption of Technologies for Sustainable Farming Systems Wageningen Workshop Proceedings*, OECD, (2001), https://www.oecd.org/greengrowth/sustainable-agriculture/2739771.pdf.

- *An Investigation of Labelling Genetically Modified Food*, DEPARTMENT OF AGRICULTURE AND FOOD GOVERNMENT OF WESTERN AUSTRALIA, 2011, https://www.parliament.wa.gov.au/publications/tabledpapers.nsf/displaypaper/3814485c74d13040d2558f9e482579f4000e72b6/$file/4485.pdf.
- BILL & MELINDA GATES FOUNDATION, (2011), https://www.gatesfoundation.org/ideas/media-center/press-releases/2011/04/nutritious-rice-and-cassava-aim-to-help-millions-fight-malnutrition
- *British Medical Association statement on GM foods*, CROPBIOTECH.NET, (2004), https://www.isaaa.org/kc/Publications/pdfs/ksheets/K%20Sheet%20(BMA).pdf.
- *Cultivation of Genetically Modified Crops- Prospects and Effects*, MINISTRY OF AGRICULTURE (DEPARTMENT OF AGRICULTURE AND COOPERATION, 2012, https://www.thehindu.com/multimedia/archive/01189/Cultivation_of_gen_1189244a.pdf.
- Food, Genetically Modified, WHO, 2014, https://www.who.int/news-room/q-a-detail/food-genetically-modified
- *Food Genetically Modified(GM),* BETTER HEALTH CHANEL,
- FOOD SAFETY AND STANDARD AUTHORITY, https://fssai.gov.in/cms/about-fssai.php
- *Food Safety Management System, Guidance Document, 2019*, FSSAI, https://www.fssai.gov.in/upload/uploadfiles/files/FSMS_Guidance_Document_Fruits Vegetable_15_03_2019.pdf
- *Functional Foods and Natural Health Products Regulations in Canada and Around the World: Nutrition Labels and Health Claims*, CAIRN, 2013, http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.500.3804&rep=rep1&type=pdf
- FOOD AND AGRICULTURAL ORGANISATION OF THE UNITED NATIONS, 2003, http://www.fao.org/state-of-food-security-nutrition.
- *Genetically Modified Crops Issues and Challenges in the Context of India*), RESEARCH UNIT (LARRDIS) RAJYA SABHA SECRETARIAT NEW DELHI, https://rajyasabha.nic.in/rsnew/publication_electronic/gen_modify_crops.pdf
- *Genetically Modified Foods in China and the United States: A Primer of regulation and Intellectual Property Protection,* https://www.sciencedirect.com/science/article/pii/S2213453016300076#sec0110
- *Genetically Modified Crops: the Ethical and Social Issues*, NUTFIELD COUNCIL ON BIOETHICS, 2014, https://www.nuffieldbioethics.org/wp-content/uploads/2014/07/GM-crops-full-report.pdf
- *Genetic Modification and Food*, INSTITUTE OF FOOD SCIENCE AND TECHNOLOGY, 2008, http://ucbiotech.org/resources/reports/IFST_gm.pdf
- *Golden Rice Project*, GOLDEN RICE HUMANITARIAN BOARD, https://www.goldenrice.org/
- *GMO Debate*, ALLIANCE FOR SCIENCE, https://allianceforscience.cornell.edu/blog/2018/08/the-gmo-debate/
- *Handbook for Genetically Modified Foods Safety Assessment and Regulations*, MINISTRY OF ENVIRONMENT FORESTS AND CLIMATE CHANGE, 2019,

https://www.biotech.co.in/sites/default/files/2020-01/2019%20Handbook%20for%20Food%20Safety%20Officials%20%E2%80%93%20Genetically%20Modified%20Foods%20Safety%20Assessment%20and%20Regulations.pdf

- *Health Risk Information about Bacillus Thurigiensis (B.t.),* MINNESOTA DEPARTMENT OF HEALTH, https://www.health.state.mn.us/communities/environment/pesticide/bt.html#:~:text=B.t.%20is%20considered%20safe%20for,by%20staying%20indoors%20during%20applications
- *Impact of Genetically Engineered Crops on Farm Sustainability in the United States*, NATIONAL RESEARCH COUNCIL, https://www.nap.edu/resource/12804/genetically_engineered_crops_report_brief_final.
- JSA, https://www.jsalaw.com/covid-19/right-to-health-as-a-fundamental-right-guaranteed-by-the-constitution-of-india
- JOINT FAO/WHO EXPERT CONSULTATION ON BIOTECHNOLOGY AND FOOD SAFETY, 1996, http://www.fao.org/ag/agn/food/pdf/biotechnology.pdf
- Modern Food Biotechnology, *Human Health and Development: an evidence-based study*, Food Safety Department WHO, https://www.who.int/foodsafety/publications/biotech/biotech_en.pdf
- *Preventing GMO Contamination- An Overview of National Coexistence measures in the EU*, IFOAM EU GROUP, https://www.organicseurope.bio/content/uploads/2020/06/ifoameu_policy_gmos_dossier_201412.pdf?dd
- *Pocket K No. 16: Biotech Crop Highlights in 2019*, ISAAA, 2019, https://www.isaaa.org/resources/publications/pocketk/16/
- Report on Council on Science and Public Health, CSAPH Report 2- A- 12, https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/about-ama/councils/Council%20Reports/council-on-science-public-health/a12-csaph2-bioengineeredfoods.pdf
- *Revised Guidelines for Research in Transgenic Plants and Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants And Plant Parts*, 1998, https://biosafety.icar.gov.in/wp-content/uploads/2015/11/Rev_Guidelines_Research1998.pdf.
- *Regulation of Current and Future Genetically Engineered Crops*, THE NATIONAL ACADEMIES, https://www.scconline.com/blog/wp-content/uploads/2020/07/20th-Harvard-bluebook.pdf
- *Safety Evaluation of Foods Derived by Modern Biotechnology Concepts and Principles*, OECD 1993, https://www.oecd.org/science/biotrack/41036698.pdf
- *Statement of Policy- Foods Derived from New Plant Varieties*, U.S. FOOD AND DRUG ADMINISTRATION, May 1992, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/statement-policy-foods-derived-new-plant-varieties

- *Safety Assessment of Genetically Modified Food*, FOODS STANDARDS AUSTRALIA NEW ZEALAND, 2005, https://www.foodstandards.gov.au/consumer/gmfood/safety/documents/GM%20Foods_text_pp_final.pdf
- *Sustainable Development Goals*, UNITED NATIONS, https://www.un.org/sustainabledevelopment/hunger/
- *Safety aspects of genetically modified foods of plant origin*, Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology, WHO 2001, http://www.fao.org/fileadmin/templates/agns/pdf/topics/ec_june2000_en.pdf
- SCIENCE BUSINESS, https://sciencebusiness.net/news/uk-sets-out-diverge-eu-rules-genetically-modified-organisms
- SPEECH BY THE PRESIDENT OF INDIA, SHRI PRANAB MUKHERJEE ON THE OCCASSION OF THE 85TH FOUNDATION DAY OF INDIAN COUNCIL OF AGRICULTURAL RESEARCH (ICAR), https://presidentofindia.nic.in/speeches-detail.htm?103
- *Two decades after global launch, GM crops remain controversial*, BUSINESSTODAY.IN, https://www.businesstoday.in/magazine/features/story/genetically-modified-crops-controversial-challenges-ahead-47515-2014-04-12
- THE ORGANIC AND NON- GMO REPORT, 2014, https://non-gmoreport.com/articles/millenium/japanlegislationlabelinggmfoods.php
- Vidya Venkat, *All you need to know about the GM food controversy*, THE HINDU, https://www.thehindu.com/sci-tech/All-you-need-to-know-about-the-GM-food-controversy/article14483330.ece
- WORLD HEALTH ORGANIZATION, *As more go hungry and malnutrition persists, achieving Zero Hunger by 2030 in doubt, UN report warns* , 2020, https://www.who.int/news/item/13-07-2020-as-more-go-hungry-and-malnutrition-persists-achieving-zero-hunger-by-2030-in-doubt-un-report-warns

STATUTES/ CONSTITUTION

- The Constitution of India
- Food Safety and Standards Act, 2006
- Prevention of Food Adulteration Act, 1954
- The Patents Act, 1970
- The Protection of Plant Varieties and Farmers' Rights Act 2001
- The Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-Organisms/Genetically Engineered Organisms or Cells, 1989