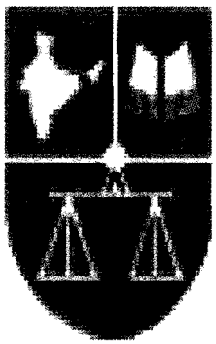
"Field Trials, Genetically Modified Food Crops & Consumerism"

DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF LL.M.



NATIONAL LAW SCHOOL OF INDIA UNIVERSITY

Bangalore

UNDER THE GUIDANCE OF

DR. ASHOK. R. PATIL,

ASSOCIATIVE PROFESSOR, NLSIU, BANGALORE

SUBMITTED BY

G Hariharabalan

I.D. No. 313

CERTIFICATE

This is to certify that the dissertation entitled ***"Field Trials, Genetically Modified Food Crops & Consumerism"*** submitted by **G.Hariharabalan**, (ID No. 313) in partial fulfillment of the requirements for the award of degree **LL.M**, is a product of the student's own work, carried out by him under my guidance and supervision. The matter embodied in this dissertation is original and has not been submitted for the award of any other degree in any other University.

(Dr. Ashok. R. Patil)

Date: Supervisor

Place: NLSIU, Bangalore

DECLARATION

I, G.Hariharabalan, do hereby declare that this dissertation titled "Field Trials, Genetically Modified Food Crops & Consumerism", is the result of the research undertaken by me in the course of my LL.M. Programme at the National Law School of India University (NLSIU), Bangalore, under the guidance and supervision of Dr. Ashok. R. Patil.

This work is my original work, except for such help taken from such authorities as have been referred to at the respective places for which necessary acknowledgements have been made.

I further declare that this work has not been submitted either in part or in whole, for any degree or diploma at any other University or institution.

(G.Hariharabalan)

I.D. No. – 313

LL.M. – Final Year

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G.Hariharabalan

LIST OF ABBREVIATIONS

BT	Bacillus Thuringiensis
BRAI	Biotechnology Regulatory Authority of India
DLC	District Level Committee
DNA	Deoxyribo Nucleic Acid
EU	European Union
FAO	Food and Agricultural Organisation
GE	Genetic Engineering
GEAC	Genetic Engineering Approval Committee
GM	Genetically Modified
GMO	Genetically Modified Organism
IBSC	Institutional Biosafety Committee
LMO	Living Modified Organism
RCGM	Review Committee on Genetic Manipulation
RDAC	Recombinant DNA Advisory Committee
SBCC	State Biotechnology Co-Ordination Committee
USA	United States of America
WHO	World Health Organisation

TABLE OF CONTENTS

Bibliography

Annexure

"Operationalizing the Regulation of Genetically Modified Foods in India' – Report of Food Safety and Standards Authority of India, New Delhi.

SYNOPSIS

- The title of the paper is "**Field Trials, Genetically Modified Food Crops & Consumerism**".

- The paper is divided in to eight chapters.

- In the first chapter, the concept of consumerism is dealt with elaborately. The various rights available to the consumer, as spelt out the former American president Mr. Kennedy, and the four rights added subsequently, are also dealt in this chapter. The relationship between the concepts of 'consumerism' and 'GM Food Products' is traced, and the basics of genetic engineering are also briefly given in the first chapter.

- Consumerism - "The movement seeking to protect and inform consumers by requiring such practices as honest packaging and advertising, product guarantees, and improved safety standards.

- Right of consumers – to Safety, Information, Choice, remedy, satisfaction of basic needs, Redress, Education and healthy environment.

- In the second chapter the concept of consumerism is dealt with briefly. The various rights available to the consumer, as spelt out the former American president Mr. Kennedy, and the four rights added subsequently, are also dealt in this chapter. The relationship

between the concepts of 'consumerism' and 'GM Food Products', is also traced at the concluding part of this chapter.

- In the third chapter the definitions of environmental concepts such as 'sustainable development', 'polluter pays principle', 'precautionary principle' and 'inter-generational equity', in light of land-mark Supreme Court decisions, are dealt with. The environment principles such as 'sustainable development', 'polluter pays', 'precautionary principle' and 'inter-generational equity', are also applied to the issue, in the third chapter.

- In the fourth chapter international legal mechanism(Cartagena Protocol & Codex Alimentarius) that regulates the trials / production of GM food is traced. The state practices and their domestic Laws, confirming their international obligations in this regards, are discussed briefly.

- In fifth and sixth chapters a survey of important statutes, which deal with the GM Food Crops, is carried out. The Ministries, institution dealing with GM Food crops is also discussed. The Labelling of the GM food products, the pros-cons of making GM labelling mandatory, etc are also dealt with in the above chapters.

- In seventh chapter the GM Food issue is analyzed through constitutional rights perspective. The rights of various groups and which right has to be given primacy are also discussed.

- The eighth chapter is concluding chapter and as such it would summarize the whole discussion and the research hypotheses would be tested, and the paper would conclude with few suggestions.

Chapter- I

Introduction

"The bottom line of our national agricultural biotechnology policy should be economic well being of farm families, food security of the nation, health security of consumers, biosecurity of agriculture and health, protection of environment and the security of national and international trade in farm commodities."

- **M.S.Swaminathan**[1]

There cannot be a much better statement than the above, to describe about the trends and issues concerning the field trials, production and commercialization of GM food crops, in our country.

GM Food Issue : Multiple Stake Holders

It is no longer considered to be issue only concerning only the agriculturist and the seed manufacturers. The GM crop issue concerns many stake holders such as the farming families which willingly consent for the field trials involving GM seeds, the farming families whose lands are situated adjacent to the lands of the farming

[1] *From the recommendations of the task force setup by the Ministry of Science and Technology for formulation of National Bio-technology, under the Chairmanship of Dr.M.S.Swaminathan, in the year 2004.:*

families who carry on GM trials, the consumers who may consume the GM food both knowingly / unknowingly and the GM seed manufacturers.

Apart from the above as there are unverified allegations[2] that the GM Food crops damage the environment and also affect the human health, the Government has a greater stake in the issue than anybody else. The Non Governmental Organizations and the Agricultural Scientist allege that due to pollination of GM food crops, the agricultural fields in the neighbouring areas where GM crops field trials / cultivation takes place and in the worst case even the eco-balance of the neighbouring areas, may be affected.

One research paper goes on to state that[3],

"There are a lot of apprehensions associated with GM foods chiefly relating to the safety aspects, both for the environment and for human health. It is feared that novel genes and genetic constructs could escape into the environment and create monster

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[2] *For full discussions pertaining to the environmental/health impacts refer, 'Introduction: What Are the Issues in Addressing the Allergenic Potential of Genetically Modified Foods?', by Dean D. Metcalfe.*

Source: Environmental Health Perspectives, Vol. 111, No. 8 (Jun., 2003), pp. 1110-1113 Published by: Brogan & Partners, URL : http://www.jstor.org/stable/3435426, Accessed on 28th May, 2010

[3] *World Trade Organisation : India should block trade in GM foods – by Suman Sahai, source : http://www.genecampaign.org/Publication/Article/Trade-WTO/WTOIndia, Accessed on 28th, May , 2010*

plants like weeds that cannot be destroyed or new, recombinant pathogens like bacteria and virus for which there are no cures. There are fears that antibiotic genes used as markers in GM crops could have adverse effects on human health Scientific evidence at present is thin that such side effects have actually happened or are likely to happen. However, there is a consensus in the scientific community and the informed public that the precautionary principle must be applied to GM food. It is felt that the technology needs improvement and that the safety aspect will have to be tested far more rigorously before it can be declared that GM crops are indeed a safe source of food."

Furthermore, the constitution casts an obligation on the state as under[4],

" The state shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties and, in particular, the state shall endeavor to bring about prohibition of the consumption except for medicinal purposes of intoxicating drinks and of drugs which are injurious to health."

In many decisions including the decisions in Kirloskar Brothers Ltd. v. Employees State Insurance Corporation[5], Paschim Bangla Khet Mazdoor Samity v. State of West

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[4] *Article – 47, the Constitution of India*

[5] *1996 (2) SCC 682*

Bengal[6], Punjab v. Ram Lubhaya Bagga[7], the apex court by reading articles 47 and 21 together, has culled out therefrom the obligation of the state to provide better health and environment conditions, to the public. The apex court in Vincent Panikur Langara v. Union of India[8] observed as follows : -

" the maintenance and improvement of public health have to rank high as these are indispensable to the very physical existence of the community and on the betterment of these depends the building the society of which the constitution makers envisaged. Attending the public health, in our opinion, therefore, is of high priority – perhaps the one at the top".

The constitution places the right to health of the general public at a higher pedestal, than any other right. Thus the issues concerning the GM food crops and the field trials of GM crops are multi-dimensional in nature and there are also multiple stakeholders including concerned ministries, universities, research institutes, private sector, civil society, consumer groups, non-government and voluntary organizations and international bodies.

History of GM Organisms and Entry into India

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[6] *1996 (4) SCC 37 : AIR 1996 SC 2426*

[7] *AIR 1998 SC 1703 : 1998 4 SCC 117*

[8] *AIR 1987 SC 990 : (1987) 2 SCC 165*

On attainment of independence and immediately after becoming a Democratic Sovereign Republic, during the mid of the last century, the political leadership of our country resolved to work for the attainment self sufficiency in agricultural production[9], and thereby to eliminate poverty and hunger. Accordingly, huge sums were allocated, in the first two five year plans, for agriculture, irrigation and other allied activities[10]. Green revolution, pioneered by Dr.M.S.Swaminathan in late 1960s, considerably increased our gross food produce[11] and as of now, except for certain food products such as pulses, our country has achieved food self sufficiency.

Though the quantum of our food produce increased in arithmetic progression, our population figures increased in geometric progression, resulting in the breach of one billion mark long back[12]. Our country is one among the only two countries[13] to share such distinction. The population explosion has adversely affected the food security of

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[9] *In the first five year plan 44.6 % of the total outlay was allocated for Agriculture and Irrigation.Source : http://www.planningcommission.nic.in/plans/planrel/fiveyr/welcome.html, Accessed on 22nd May, 2010*

[10] *Ibid*

[11] *Green Revolution in India, by A. K. Chakravarti, Annals of the Association of American eographers, Vol. 63, No. 3 (Sep., 1973), pp. 319-330, Published by: Taylor & Francis, Ltd. on behalf of the Association of American Geographers*
Source URL: http://www.jstor.org/stable/2561997, Accessed on 12th May, 2010

[12] *As per 2001 Census, India's total population is 1.0287 billion, Source URL : http://www.censusindia.gov.in/Census_Data_2001/National_Summary/National_Summary, Accessed on 14th May, 2010*

[13] *China & India are the only two countries to having more than a billion population.*

our country. Despite technological advancement and economic development in the past six decades, the cruel reality is that, a whopping 30 % of this country is still living below poverty line.[14]

It is in the above circumstances, due to bio-technological advancement, Genetic Engineering developed and certain gene characteristics are changed in the seed, so as to get desired results such as high yield and effective pests/insects resistant[15].

Agricultural scientist Mr. K P Prabhakaran Nair, in one of his articles[16] traces the growth of genetic engineering in the following words,

"In the early 1980s, Monsanto scientists had noticed that certain bacteria inhabiting the waste outflows from the company's glyphosate manufacturing plants were impervious to the chemical. Ernie Jaworski and some of his colleagues reasoned that they could dramatically enhance Roundup's commercial value if they could introduce the genes responsible for this resistance to glyphosate into crop plants. Farmers would then be able to spray Roundup onto their fields even during the growing season, killing unwanted weeds without harming the crop. This would significantly expand the market for Roundup and, more importantly, help Monsanto to negotiate the expiry

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[14] *National Poverty Line: Rs.12 per capita/day for rural and Rs.18 per. At this rate, 27.5 % of the population lives under poverty line. Source URL, Accessed on 31st May, 2010 : http://www.undp.org.in/content/mdg/india-situational-analysis.pdf.*

[15] *For detailed discussions refer discussion at page nos. – 7 to 11*

[16] *Made by Monsanto, Published on 24 May 2010, The New Indian Express*

of its glyphosate patents. With glyphosate-tolerant GM crops, Monsanto would be able to preserve its dominant share of the glyphosate market through a marketing strategy that would couple proprietary 'Roundup Ready' seeds, priced at a level high enough to recoup the company's substantial investment in R&D. Thus was born the idea of the 'Bt crops', because, the bacteria is the ubiquitous Bacillus thuringiensis, known popularly as Bt. The fact that Monsanto's strength lay primarily in herbicides rather than insecticides meant that GM insect-resistance technology opened up a new market segment without conflicting with or undermining any significant 'pesticide interest' within the company.

Thus the green revolution gave way to a 'gene revolution', with a promise of wiping out the hunger of starving masses, in the 21st century. GM technology arrived in India in 1995[17] when the USA biotech giant Monsanto made a venture into the Indian agricultural market, jointly with India's Mahyco to import Bt cotton seeds, which would be crossed and repeatedly backcrossed with local varieties to ensure they could adapt to local conditions[18].

Bio-Technology and Genetic Engineering - Basics

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[17] *GM in India: the battle over Bt cotton. 20 December 2006, the Economic News, Source URL : http://www.scidev.net/en/features/gm-in-india-the-battle-over-bt-cotton.html, Accessed on 27th May, 2010,*

[18] *Ibid*

Genetic Engineering is a technique by which direct manipulation of an organism's genes was made possible, so as to get desired result. It is also known by various names such as recombinant DNA technology, genetic modification, genetic manipulation (GM), and gene splicing. It is said to differ from traditional breeding, where the organism's genes are manipulated indirectly. Genetic engineering finds its application in agriculture, industries such as medicine and healthcare. Genetic modification involves altering an organism's DNA. This can be done by altering an existing section of DNA, or by adding a new gene altogether.

Modern Biotechnology superior to traditional processing - Claims Agricultural Scientists

Biotechnology, claims the agricultural scientist, is an evolution of traditional agricultural methods. They further claim that, over the past 10,000 years, people have routinely used their knowledge of plants to improve food production. Biotechnology is the latest development in the evolution of agricultural methods. Farmers used to rely on plant breeding to add or eliminate specific genetic traits in a plant. Those with desirable characteristics are selected over several generations. The crops and livestock we see today are a result of traditional processing. Because of plant breeding, corn today looks nothing like it did one hundred years ago. Although it typically took several growing seasons to produce a plant that expressed a desired trait, farmers were eventually able to produce crops that were resistant to drought, insect pests or diseases. The modified crops also possess stronger stalks to withstand strong winds and thereby giving higher yields.

Genetic modification is a more efficient and precise way to achieve the benefits of crop improvement. With the advent of modern bio-technology, it is now possible, to pinpoint the specific gene responsible for a particular trait and then extract or add that gene to a specific plant. Genetic modification is a more precise technique, where one can be exact in transferring the desired characteristics. In traditional processing one cannot avoid the possibility that other characteristics may also be transferred. Genetic modification is less time consuming than traditional processing. In traditional processing, characteristics can only be exchanged between species which are the same or very similar. It might be maize and nave or a horse and a donkey. In genetic modification, it's possible to transfer genes from one species to another from plant to plant, from animal to plant, from plant to animal or from animal to animal. This is because all genes, no matter where they come from, are made of the same material DNA.

The Ministry of Environment & Forests, by way of powers conferred under the Environment Protection Act, 1986, framed rules for the manufacture, use, import, export and storage of hazardous micro organisms genetically engineered organisms or cells. It contains the following among various other definitions, which would enable us to understand the subject.

(i) "Biotechnology" means the application of scientific and engineering principles to the processing of materials by biological agents to produce goods and services;

(ii) "Cell hybridisation" means the formation of live cells with new combinations of genetic material through the fusion of two or more cells by means of methods which do not occur naturally;

(iii) "Gene Technology" means the application of the gene technique called genetic engineering, include self-cloning and deletion as well as cell hybridisation;

(iv) "Genetic engineering" means the technique by which heritable material, which does not usually occur or will not occur naturally in the organism or cell concerned, generated outside the organism or the cell is inserted into said cell or organism. It shall also mean the formation of new combinations of genetic material by incorporation of a cell into a host cell, where they occur naturally (self cloning) as well as modification of an organism or in a cell by deletion and removal of parts of the heritable material;

(v) "Microorganisms" shall include all the bacteria, viruses, fungi, mycoplasma, cells lines, algae, protodones and nematotes indicated in the schedule and those that have not been presently known to exist in the country or not have been discovered so far.

The proposed National Biotechnology Regulatory Bill, 2008 contains certain definitions including the definition for terms such as 'Modern Bio-technology', Genetic Engineering, and Genetically Engineered Organism etc. It states that 'Modern Bio-Technology means the application of in-vitro nucleic acid techniques, including

recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection. It excludes: in vitro fertilisation; natural processes such as conjugation, transduction, transformation; polyploidy induction; and accelerated mutagenesis'.

Furthermore the secretariat of Rajyasabha has published a report[19] in December'2009, titled as Genetically Modified crops - Issues and Challenges in the context of India, It clearly the explains the basics of Genetic Engineering. The excerpts of the report is as follows:-

Report of Rajyasabha Research Unit : 'Genetically Modified crops - Issues and Challenges in the context of India'[20].

"Genetically Modified Organisms (GMOs)—the definition

Genetically Modified Organisms, are the ones in which the genetic material (DNA) has been altered in such a way as to get the required quality. This technology is often called 'gene technology', or 'recombinant DNA technology' or 'genetic engineering' and the resulting organism is said to be 'genetically modified', 'genetically

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[19] *Research Unit (Larrdis) Rajya Sabha Secretariat New Delhi, December'2009.*

[20] *Genetically Modified crops issues and challenges in the context of India research unit (Larrdis) Rajya Sabha Secretariat New Delhi, Page Nos: 1 &2*

Source : http://rajyasabha.nic.in/rsnew/publication_electronic/gen_modify_crops.pdf, Accessed on 12th, May 2010

engineered' or 'transgenic'. GM products (current or those in development) include medicines and vaccines, foods and food ingredients, feeds and fibre.

"Genetic Engineering - the process

All living organisms, from viruses to human beings, are made up of cells, with a nucleus at the centre, which contains a unique set of instructions regarding their size, strength and other qualities. These instructions are found on a long molecule called DNA (Deoxyribonucleic Acid), which is divided into small sections called genes. It is the sequencing of genes on DNA that determines an organism's characteristics. Very simple organisms such as bacteria may have fewer genes than the more complicated ones. In simple terms, the complete set of genetic material of an organism, i.e., all the DNA contained in an organism, is called a genome.

Thus the process of isolating gene(s) from the genome of one organism and inserting the same into the genome of another organism is known as Genetic Engineering. In nature, exchange of genes happens only between compatible or closely related species. However, the modern technique of genetic engineering facilitates the removal of group of genes from one species and insertion into another, there being no need for compatibility.

The transfer process involves shifting the desired gene from the chromosome of a particular plant or animal or any other organism into a cell. This genetically modified cell is then regenerated to produce a 'genetically modified organism' (GMOs). The modified organism passes the new gene onto its progeny. Such methods are now being used to create GM plants, of desired quality, growth and strength. Basic idea is to have plant varieties with high yield, pest/ disease resistant, or other such qualities

mainly for better marketability and durability. This is different from the processes of modifying crops/plants from their wild ancestors through selective breeding or mutation breeding, which have been practiced by farmers as part of their regular farming activity. "

Whether or not to go for Genetically Modified Foods – The Dilemma ?

On the one hand the agricultural scientist claim that Biotechnology can help alleviate hunger worldwide.[21] They contend that, in the next 50 years the global population is expected to double, reaching more than 8 billion people by 2050, and therefore the massive population growth and diet upgrading will require the world food supply to increase at least 250 percent from its current quantity. The amount of land currently committed to food production, approximately 36 percent of the earth's cumulative land area, cannot yield the amount of food needed by this increased population. Although forests could be cleared to obtain needed acreage, a better approach is to find ways of getting greater crop yield from existing land. Biotechnology can increase the quantity of the harvest by addressing the factors that traditionally deplete crops such as pests, weeds, drought and wind. Plants from biotechnology can deal with

[21] *GM crops are banned in most parts of the world; they are largely confined to four countries: the US, Canada, Argentina and Brazil. They are banned in most countries of the European Union and in the UK. Countries such as Greece, Austria, Germany, Switzerland and even small states such as Tasmania have banned them specially.*
Source : http://www.tribuneindia.com/2009/20091101/edit.htm#1, Accessed on 31st May,2010
Tribuneindia, "Food without choice ? We must know what we are eating" Dr Pushpa M. Bhargava

these hardships and dramatically increase the percentage of crops that survive and are harvested each year.

On the other hand the agricultural scientists, NGOs, Agricultural bodies, Farmer cooperatives, other independent Scientists, claim[22] that the rampant growth of illegal Bt cotton in the country is already proof of serious regulatory failure. They also argue that the field trials have already resulted in contamination of the supply chain. They question the biosafety regime of our country and stresses for looking at larger issues beyond, including whether GM technology is needed at all.

There are also unverified allegations of the civic bodies that large bt cotton has resulted in mass suicide of farmers. The instant dilemma in the country as to whether or not we should go for GM technology has, recently, resulted in a public spat between pro-anti GM lobbies in Bangalore.

"Union Minister of state for Environment and Forest Jairam Ramesh on Sunday said the final decision on the question of allowing Bt Brinjal in the country would be taken by February 10. Six public hearings have been held at various cities across the country so far and the seventh is scheduled to be held in Bangalore on February 6. The final decision would be taken on the issue by February 10, he told reporters here.

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[22] *For instance refer the discussion in the article written by Prof.Kavitha Kuruntagi's, titled "Biosafety and Beyond -GM Crops in India,*

Asked about the possibility of postponing the decision in the wake of demands for more consultations on the matter, he said, "Wait till February 10".[23]

The renowned agriculturist scientist Mr.M.S.Swaminathan too expressed his concern and advised that the government should not be in hurry to introduce Bt brinjal until fundamental issues were addressed. He further adds that, 'every technology has its benefits and risks, but it all depends on our capacity to analyze risks and benefits. We must analyze whether risks are more or benefits are more. There should be an authority to analyze the risks and benefits in a transparent way'. India lacks such authority is fact both admitted by the minister Mr.Jairam Ramesh and the agricultural scientist Mr.Swaminathan. The union government has already taken decision against bt brijal on 9th February, 2010, when it officially announced that it needs some more time to release Bt brinjal. Indian Environment Minister Jairam Ramesh added that there is no overriding urgency to introduce Bt brinjal in India.

Again on 17th February, 2010, the centre government reiterated that it had only suspended the release of transgenic brinjal hybrid, and not a permanent ban was imposed on it. On the same day the Genetic Engineering Approval Committee (GEAC)-Govt. of India , made it mandatory for companies with any seeds of Bt brinjal to register the details with the government, to ensure none of it is sowed or otherwise gets into the market . In order to effectively enforce the moratorium on Bt

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[23] *News article titled, 'Protests mar debate on Bt brinjal", The Hindu, Bangalore Edition, Dated 31st January 2010,*
Source : http://beta.thehindu.com/news/states/andhra-pradesh/article98024.ece, Accessed on 28th May, 2010

brinjal, it was further communicated that the National Bureau of Plant Genetic Resources (NBPGR) shall be responsible to store all the Bt brinjal seeds in India.

Thus the temporary ban on bt brinjal may be or not be revoked, and it is an admitted fact that bt cotton is already rampant in India, most particularly in the black soils of the Deccan plateau, comprising the states of Gujarat, Maharashtra and parts Andhra Pradesh also. In this scenario, this paper aims to investigate the legal mechanisms and the effectiveness present in our country, the legal mechanism present at the international level and its effectiveness, to deal with the issue in hand. An attempt is made, at the conclusion part of this paper, to suggest a solution to the issue in hand, within a legal frame work.

Research Methodology

Project Title Field Trials, Genetically Modified Crops, and Consumerism

Objectives of the Study

1. To investigate as to whether any legal mechanism is present at domestic / international level(s), to regulate the production of GM food crops and conducting field trials.

2. And, if such legal mechanisms are found to be present, to ascertain the effectiveness of the same.

3. To find out which of the various rights amon the following namely,

   (i) Right to health / clean environment of general public who may consume GM Food crops, or

   (ii) Right to food / food security of starving mass, or

   (iii) Right to carry on any trade / business of GM food producers, or

   (iv) Right to development of farmers willing to cultivate GM crops,

has to be given primacy, in case of conflict between those rights.

4. To ascertain the prevalence / effectiveness of legal mechanisms to control prices of GM seeds, and other related aspects, assuming that GM Food crops is the only way out for ensuring food security,

Research Hypotheses

1. **Indian legal mechanism is effective enough to handle GMOs & Field Trials / Cultivation.**

   Our country has legislations such as Environment Protection act, Seeds Act, Prevention of Food Adulteration Act etc, which may be applied for GMOs & Field Trials / Cultivation, as well. Therefore it is presumed that the Indian legal mechanism is effective enough to deal with issue in hand.

2. **No legal mechanism is available at international level to deal with GMOs & Field Trials / Cultivation.**

   Except for Codex Alimentarius, there is no legal mechanism present at international level to deal with the Issue and as such it is presumed that no effective legal mechanisms are present at international level.

Research Questions

1. Whether any legal mechanism is present at domestic / international level(s), for regulation of Genetically Modified Organisms (GMOs) ?

2. Whether any legal mechanism is present at domestic level, for regulation of field trials involving GM Crops and GM seeds ?

3. If the legal mechanisms are found to be present, are they effective to deal with the GMO issue ?

4. Which fundamental right has to be given primacy in case of conflict between them, and are there any decision of the apex court spelling out the rule of interpretation / construction in case of conflict between various fundamental rights ?.

Research Method The Method adopted is Descriptive and Analytical

Source of Data

Primary Data

1. Constitution of India, Essential Commodities (control) Act / Orders, Environment Protection Act, , Seeds Act and other relevant statues/rules/regulations.
2. International Conventions.

Secondary Data

1. Articles, Books, Previous Studies, Government official websites and other relevant sources.

Mode of Citation Uniform mode of citation is used throughout the paper.

Limitations of the study

1. The study is limited only to the legal aspects concerning the GM crops / Field Trials of GM Crops./

2. Modern Bio-technology finds its application not only in food production, but also in other sectors such as health care etc. This study is limited to the consumers who are using / may use Genetically Modified Food Products.

2. Literatures written by many agricultural scientists / technical persons, is relied upon for matters concerning technical aspects such as veracity of lab tests conducted, the reports of GM manufacturers etc.

Chapter II

Consumerism & GM Food Products

In this chapter the concept of consumerism is dealt with briefly. The various rights available to the consumer, as spelt out the former American president Mr. Kennedy, and the four rights added subsequently, are also dealt in this chapter. The relationship between the concepts of 'consumerism' and 'GM Food Products', is also traced at the concluding part of this chapter.

Consumerism – Definition & Growth in Twentieth Century

Webster's dictionary defines Consumerism[24] as, "The movement seeking to protect and inform consumers by requiring such practices as honest packaging and advertising, product guarantees, and improved safety standards".

In simple words consumerism intends that the consuming public should have the entire knowledge of the products/services and should get products/services worthy of the money they spend. Thus the primary concern of consumerism is to fulfill and protect the rights of consumers as articulated by President Kennedy some five decades ago.

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[24] *source: http://www.merriam-webster.com/dictionary/consumerism, Accessed on 26th April, 2010*

Though the industrial revolution took place in 16th and 17th century, resulting in increase of industrial goods, consumerism was taking back stage for about three centuries. The governmental policies then were leaning towards Laissez-Faire or non intervention in private business affairs. The rigidity of the doctrine of privy of contract also did not allow the government to intervene in private affairs.

In the mid of 20th century, changes in domestic demographics and advances in industrialization, manufacturing, transportation, and communication took place, contributing to the growth of consumerism. Consumerism contributed greatly to the liberal thrust of the Progressive Era and spawned a long-running trend of consumer advocacy and consumer protection legislation. Consumerism is thus, may be defined as the shift in the market culture from a producer-oriented society in the nineteenth century to a "consumerist" society in the twentieth century.

When the 'police state' gave way to 'welfare state', consumerism gained strength. The 1960s and '70s saw consumer activism under the leadership Ralph Nader, in United States of America, on whose request the government enacted consumer laws, setting safety standards for products. Consumerism also ensured the passage of laws obliging advertisers to represent their goods truthfully and preventing sales representatives from using deceptive sales tactics. It is carried on worldwide by the International Organization of Consumers Unions (IOCU).

Rights of Consumer

As stated supra, public concern over the rights of consumers, the quality of consumer goods, and the honesty of advertising increased. Consumerism came into full focus in the 1960s when former President of USA John F. Kennedy introduced the Consumer Bill of Rights, in the US Congress. It stated that the consuming public has a right to be safe, to be informed, to choose, and to be heard.

In 1962 the then President of United States of America, John F. Kennedy, while addressing a gathering said, 'Consumers by definition include us all. They are the largest economic group, affecting and affected by almost every public and private economic decision. Yet they are the only important group... whose views are often not heard.'

He went on to add that every consumer has four basic rights namely,

i. Right to Safety

ii. Right to Information

iii. Right to Choice

iv. Right to remedy.

The Consumers International added four more rights namely, Right to

v. The satisfaction of basic needs

vi. Redress

vii. Education

viii. A healthy environment.

Thus the first and foremost 'right' of a consumer is 'right to safety'. It must be stated that the consumers using GM food products may be risking their health, as most of the studies[25], as to safe-worthiness of the GM products point otherwise.

The consumer has both the right to information and the right to choice, which would mean that the consumer has a right to informed choice. In the instant case the consumers do not have either right to information or right to choice. Most of the GM food consumers are using the same, even without knowing that they are GM Food products. The GM manufacturers have, in the past thwarted attempts to label the GM products. It is needless to add that the consumers, in the instant case, do not have right to healthy environment also.

Is GM Food a 'Credence Commodity'?

In economics there is a class of commodity known as credence goods, whose utility impact is difficult or impossible for the consumer to ascertain and the manufacturer of the commodity alone knows the utility impact of the good, creating a situation of asymmetric information. The GM food consumers neither have information nor choice. There may be health impacts for the GM food consumers. The above stated

[25] *Refer discussions at Pages 11 - 13*

two points would suffice for bringing the GM food products under the category of Credence Goods[26]. Credence goods, as the definition itself suggests, requires more 'proactive consumerism' to deal with. Thus 'GM Food products' are one of those categories of products which require the attention of 'consumer activists'.

[26] *"GM foods fall into the category of credence goods, products that have certain characteristics that are not apparent to consumers before or even after consumption". Authors(s) Chris MacDonald & Melissa Whellams, in their article, 'Corporate Decisions about Labelling Genetically Modified Foods.*
Source : Journal of Business Ethics (2007) 75:181–189 Springer 2007DOI 10.1007/s10551-006-9245-8

Chapter III

Impact of GM Food Products on Environment – Is Consumerism answer for Environment Degradation?

In this chapter the definitions of environmental concepts such as 'sustainable development', 'polluter pays principle', 'precautionary principle' and 'inter-generational equity', in light of land-mark Supreme Court decisions, are dealt with. There may be difference of opinion as to the degree of impact of the GM crops on environment and human health, but there is unanimity among the agricultural scientist that field trials / cultivation, involving GM crops, do certainly affect the neighbouring environment and also has considerable impact on human health. An attempt is made in this chapter, to apply the environment principles such as 'sustainable development', 'polluter pays', 'precautionary principle' and 'inter-generational equity', to the issue in hand.

Sustainable Development

'Sustainable development' is term coined by the Brundtland Report in the year 1987. The Brundtland Report defines Sustainable Development[27] as ' the development that

[27] *Report of the World Commission on Environment and Development: Our Common Future Source is commonly known to be called as Brundtland Report, as it functioned under the chairmanship of Mr. Gro Harlem Brundtland.*

meets the needs of the present without compromising the ability of the future generations to meet their own needs'.

Sustainable development is thus a pattern of resource utilization whose objectives are to meet human needs of the current generations, while preserving the environment so that these needs can be met not only in the present, but also for future generations. The term was used by the Brundtland Commission which coined what has become the most often-quoted definition of sustainable development as development that "meets the needs of the present without compromising the ability of future generations to meet their own needs.

Though the Stockholm Declaration of 1972[28] fell short of explicitly spelling out the principle of 'sustainable development', it did spelt against[29] the reckless exhaustion of renewable natural resources.

Source : http://www.un-documents.net/wced-ocf.htm, Accessed on 28th, May, 2010

[28] *Declaration of the United Nations Conference on the Human Environment, 1972, is commonly known as 'the Stockholm Declaration, 1972'.*
Full text can be Accessed at, http://www.unep.org/Documents, Accessed on 28th May, 2010

[29] *Principle 5, Declaration of the United Nations Conference on the Human Environment, 1972, Source : http://www.unep.org/Documents, Accessed on 27th May, 2010*
"The non-renewable resources of the earth must be employed in such a way as to guard against the danger of their future exhaustion and to ensure that benefits from such employment are shared by all mankind.

The highest court of appeal of this country too, in many of its classic judgements, has dealt with the principle of 'Sustainable Development'.

In Reliance Natural Resources Limited Vs. Reliance Industries Limited[30], the apex court observed that,

"The ambit and sweep of our egalitarian ideal inheres within itself the necessity of inter-generational equity. Our Constitutional jurisprudence recognizes this and makes sustainable development and protection of the environment a pre-condition for the use of nature. The concept of people as a nation does not include just the living; it includes those who are unborn and waiting to be instantiated. Conservation of resources, especially scarce ones, is both a matter of efficient use to alleviate the suffering of the living and also of ensuring that such use does not lead to diminishment of the prospects of their use by future generations."[31]

In the Vellore Citizens Welfare Forum Vs. Union of India and others[32], the Supreme Court of India dealt with the concept of sustainable development elaborately. It held that,

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[30] *MANU (2010) SC 0341*

[31] *Para-94, Reliance Natural Resources Limited Vs. Reliance Industries Limited, MANU (2010) SC 0341*

[32] *AIR 1996 SC 2715 : 1995 (5) SCALE 592 :: (1996) 5 SCC 647*

'Some of the salient principles of "Sustainable Development", are Inter-Generational Equity, Use and Conservation of Natural Resources, Environmental Protection, the Precautionary Principle, Polluter Pays principle, Obligation to assist and cooperate, Eradication of Poverty and Financial Assistance to the developing countries. We are, however, of the view that "The Precautionary Principle" and "The Polluter Pays" principle are essential features of "Sustainable Development".[33]

In the objectives National Biotechnology Regulatory Bill, 2008[34], itself it is stated that it recognises that modern biotechnology offers opportunities to address important needs related to health, agriculture and food production, environmental protection, climate change and sustainable development that will have profound impact on society and the economy, and that modern biotechnology should be developed in a responsible way in harmony with ecological and ethical values and goals, indirectly advocating to adopt a sustainable approach in the matters of GM Food.

Aruna Rodrigues, a well known Green Activists, in the response to the environment ministry invitation to submit a document on safety testing of GM crops in India, also advocated for a sustainable and enviro-friendly approach to the issue.

Polluter Pays Principle

The polluter pays principle makes the party liable for causing pollution and environmental damage to pay for the E-damage caused'. The Polluter pays principle

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[33] *Vellore Citizens Welfare Forum Vs. Union of India and others, AIR 1996 SC 2715*

[34] *For detailed discussions about the bill refer discussion infra at Pages -*

(PPP) requires that the cost of the pollution should be borne by the person responsible for causing the pollution and the cost of consequential environmental damage. The practical applicability of the principle can be found in allocation of economic obligations which have the potential the damaging the environment.

The Rio Declaration of 1972 states[35] that, 'National authorities should endeavour to promote the internalization of environmental costs and the use of economic instruments, taking into account the approach that the polluter should, in principle, bear the cost of pollution, with due regard to the public interest and without distorting international trade and investment.

The Supreme Court of India has, in many of its judgement, applied the polluter pays principle, wherein the damage caused to the environment was proved. Recent application of the polluter pays principle may be found in the judgment given in State of Uttaranchal Vs. Balwant Singh Chaufal and Others.[36]

In the above case the apex court traced the entire jurisprudence of polluter pays principle. It relooked at the famous 'Vellore Citizens Welfare Forum v. Union of India and others,[37] wherein the Court held that precautionary principle and the polluter pays principle are part of the environmental law of the country and declared

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[35] *Principle 16, Declaration of the United Nations Conference on the Human Environment, 1972, Source: http://www.unep.org/Documents, Accessed on 28th May, 2010*

[36] *MANU SC 0050 2010 : JT 2010(1) SC 329 : : 2010(1)SCALE492*

[37] *MANU SC 0686 1996 : AIR 1996 SC 2715*

that Articles 47, 48A and 51A(g) to be part of the constitutional mandate to protect and improve the environment.

Referring to an equally important decision in the case of M.C. Mehta v. Kamal Nath and others,[38] wherein the court held that Articles 48A and 51A(g) have to be considered in the light of Article 21 of the Constitution. Further the court added that, 'any disturbance of the basic environment elements, namely air, water and soil, which are necessary for "life", would be hazardous to "life" within the meaning of Article 21, and in the matter of enforcement of rights under Article 21, this Court, besides enforcing the provisions of the Acts referred to above, has also given effect to Fundamental Rights under Articles 14 and 21 and has held that if those rights are violated by disturbing the environment, it can award damages not only for the restoration of the ecological balance, but also for the victims who have suffered due to that disturbance. In order to protect the "life", in order to protect "environment" and in order to protect "air, water and soil" from pollution, this Court, through its various judgments has given effect to the rights available, to the citizens and persons alike, under Article 21. The court held that pollution is a civil wrong and it is a tort committed against the community as a whole. A person, therefore, who is guilty of causing pollution, has to pay damages or compensation for restoration of the environment and ecology.

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[38] *MANU SC 0416 2000 : 2000 (6) SCC 213*

Precautionary Principle

Principle 15, of the rio declaration states that, "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

The precautionary principle requires that if there is a suspected risk of harm being caused to the environment or to the public health, in the absence of any conclusive scientific proof that it is not harmful, the burden of proof that it is not harmful lies on the persons causing risk to the environment. The principle confers the Government with discretionary powers to make decisions in situations where there is the possibility of harm from taking a particular course or making a certain decision when extensive scientific knowledge on the matter is lacking. The principle implies that there is a social responsibility to protect the public from exposure to harm, when scientific investigation has found a plausible risk.

The Supreme Court of India, applied the principle for the first time in Vellore Citizens Welfare Forum Vs. Union of India and others[39], and held as follows,

[39] *MANU SC 0686 1996 : AIR 1996 SC 2715*

The "Precautionary Principle" - in the context of the municipal law - means :

(i) Environmental measures - by the State Government and the statutory authorities - must anticipate, prevent and attack the causes of environmental degradation.

(ii) Where there are threats of serious and irreversible damage, lack of scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation.

(iii) The "Onus of proof is on the actor or the developer/industrialist to show that his action is environmentally benign."[40]

The above decision was followed in many decisions including the following, S.Jagannath Vs. Union of India and others[41], M.C. Mehta Vs. Kamal Nath and others[42], and also recently in M.C. Mehta Vs. Union of India (UOI) and others[43]

It would be interesting to note that the polluter pays principle may be traced even before the Rio-declaration of 1972, in the international instruments such as the Convention of Civil Liability for Nuclear Damage, the 1960 Paris Convention and the 1603 IAEA liability Convention etc.

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[40] *Vellore Citizens Welfare Forum Vs. Union of India and others, AIR 1996 SC 2715*

[41] *MANU SC 0188 1997 : AIR 1997 SC 811 :: 1997 (5) SCALE 406*

[42] *MANU SC 1007 1997 : 1996 (9) SCALE 141 :: 1997 (1) SCC 388*

[43] *MANU SC 0768 2009 : 2009 (7) SCALE 650 :: 2009 (6) SCC 142*

Inter-generational Equity

Principle 3 of the Rio-Declaration, 1972, speaks about intergenerational equity. The idea of inter-generational equity is that as "members of the present generation, we hold the earth in trust for future generations, so Edith Brown Weiss.[44] The Charter of the United Nations also advocates for saving future generations.[45] Many other conventions including the International Convention on the Regulation of Whaling, 1946,[46] the Convention on the Protection and Use of Transboundary Water Courses and International Lakes, 1992,[47] speak about saving the future generations.

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[44] *'Our Rights and Obligations to future Generations", 84 AJIL 198, 199 (1990)*

[45] *The Preamble, United Nations Charter, 'We the peoples of the United Nations determined to save succeeding generations from the scourge of war, which twice in our lifetime has brought untold sorrow to mankind, and....'.*
Source : http://www.un.org/en/documents/charter/preamble.shtml, Accessed on 28th May, 2010

[46] *The Preamble, the International Convention on the Regulation of Whaling, 1946, "The Governments whose duly authorised representatives have subscribed hereto, Recognizing the interest of the nations of the world in safeguarding for future generations the great natural resources represented by the whale stocks...".*
Source : http://iwcoffice.org/commission/convention.htm#convention, Accessed on 28th May, 2010

[47] *Article 2 (5) (c), the Convention on the Protection and Use of Transboundary Water Courses and International Lakes, 1992, "Water resources shall be managed so that the needs of the present generation are met without compromising the ability of future generations to meet their own needs".*
Source : http://www.unece.org/env/water/pdf/watercon.pdf, Accessed on 28th May, 2010

The Supreme Court of India for the first time mentioned about the principle of inter-generational equity in S. Jagannath Vs Union of India and others[48], in the following words.

"We are of the view that before any shrimp industry or shrimp pond is permitted to be installed in the ecology fragile coastal area it must pass through a strict environmental test. There has to be a high powered "Authority" under the Act to scrutinise each and every case from the environmental point of view, there must be an environmental impact assessment before permission is granted to install commercial shrimp farms. The conceptual framework of the assessment must be broad-based primarily concerning environmental degradation linked with shrimp farming. The assessment must also include the social impact on different population strata in the area. The quality of the assessment must be analytically based on superior technology. It must take into consideration the inter-generation equity and the compensation for those who are affected and prejudiced".

The Supreme Court of India reiterated the principle in M.C. Mehta Vs. Union of India (UOI) and others[49], in the following words,

"Time has now come, therefore, to suspend mining in the above Area till statutory provisions for restoration and reclamation are duly complied with, particularly in

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[48] *MANU SC 0188 1997 : AIR 1997 SC 811 :: 1997 (2) SCC 87*

[49] *MANU SC 0768 2009 : 2009 (7) SCALE 650 :: 2009 (6) SCC 142*

cases where pits/quarries have been left abandoned. Environment and ecology are national assets. They are subject to inter-generational equity. Time has now come to suspend all mining in the above Area on Sustainable Development Principle which is part of Articles 21, 48A and 51A(g) of the Constitution of India. In fact, these Articles have been extensively discussed in the judgment in M.C. Mehta's case (supra) which keeps the option of imposing a ban in future open. Mining within the Principle of Sustainable Development comes within the concept of "balancing" whereas mining beyond the Principle of Sustainable Development comes within the concept of "banning". It is a matter of degree. Balancing of the mining activity with environment protection and banning such activity are two sides of the same principle of sustainable development. They are parts of Precautionary Principle".

Applying the Environmental Principles for GM Field Trials / Cultivation

Authors George S. Day and David A. Aaker in their article[50] 'A Guide to Consumerism', argue that there is a high probability that the scope of consumerism will eventually subsume, or be subsumed by two other areas of social concern; distortions and inequities in the economic environment and the declining quality of the physical environment.

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[50] *The Journal of Marketing, Vol. 34, No. 3 (Jul., 1970), pp. 12-19, Published by: American Marketing Association, Source: http://www.jstor.org/stable/1249814, Accessed on 28th May, 2010*

The term 'Consumerism', in the above passage, is used in a general context, if we look into the 'GM Foods Consumerism', we would come to know that 'environmental activism' and GM Foods Consumerism' are intertwined.

Prof.Kavitha Kurunthangi in her article[51] stresses for applying precautionary principle in dealing with GMOs. She states that 'biosafety is an important consideration with transgenic crops since they have known environmental and health hazards as scientific evidence from all over the world shows. What is worse, unlike in the case of other agricultural technologies, these transgenic seeds and plants, once released into the environment are irreversible and are living. That is the reason why critics advocate a precautionary approach to this technology.

Environmental activist Aruna Rodrigues, who filed a public interest litigation in the Supreme Court, praying for a permanent ban on BT brinjal field trials & cultivation, in the submission in response to the environment ministry's invitation to submit a report on safety testing of GM crops in India, and Bt brinjal, advocates for applying precautionary principle. In the Public Interest Litigation filed against GM Food, Aruna Rodrigues and the other petitioners, the Supreme Court, in an interim order dated 22nd Sep, 2006, banned all field trials of genetically modified (GM) crops in the country, as there were evidences of environmental damage, and the court came down heavily on the regulatory mechanism, the Genetic Engineering Approval Committee. The court also suggested forming an independent experts committee to look into the regulatory aspects for release of GM crops.

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[51] *Biosafety and Beyond-GM Crops in India, by Prof. Kavitha Kuruntagi*

It is pertinent to note that by way of various decisions discussed above, the apex court has time and again held that, the environmental principles such as 'Sustainable Development', 'Polluter pays', 'Precautionary Principle' and 'inter-generational equity', have become the part of law of this land. Furthermore by way of application of Article 141[52] of the Constitution of India, the Governmental agencies dealing with GM Crops in India are mandated to follow the decision of Supreme Court.

As stated supra, as there seems evidence of substantial damage being caused to environment owing to the carrying of field trials and cultivation of GM Crops, it is legally mandated for the government to apply the environment principles in case of dealing with 'GM Crops issue'.

Though it may be difficult to apply principle of 'polluter pays' to the issue in hand, as it would be difficult to estimate the cost of environmental damage caused so far by the GM Field trials & Cultivation, the government should apply atleast 'precautionary approach', in dealing with the GM Crops.

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[52] *Article 141, Constitution of India, Law declared by Supreme Court to be binding on all courts .- The law declared by the Supreme Court shall be binding on all courts within the territory of India.*

Chapter IV

International Regulations: An Overview

In this chapter international legal mechanism that regulates the trials / production of GM food is traced. The state practices are also discussed briefly and their domestic Laws, confirming their international obligations in this regards, is also discussed briefly.

State Practice

Governments around the world are hard at work to establish a regulatory process to monitor the effects of and approve new varieties of GM plants. Yet depending on the political, social and economic climate within a region or country, different governments are responding in different ways.

In Japan, the Ministry of Health and Welfare has announced that health testing of GM foods will be mandatory as of April 2001. Currently, testing of GM foods is voluntary. Japanese supermarkets are offering both GM foods and unmodified foods, and customers are beginning to show a strong preference for unmodified fruits and vegetables.

Some states[53] in Brazil have banned GM crops entirely, and the Brazilian Institute for the Defense of Consumers, in collaboration with Greenpeace, has filed suit to prevent the importation of GM crops. Brazilian farmers, however, have resorted to smuggling GM soybean seeds into the country because they fear economic harm if they are unable to compete in the global marketplace with other grain-exporting countries.

In Europe, anti-GM food protestors have been especially active[54]. In the last few years Europe has experienced two major foods scares: bovine spongiform encephalopathy (mad cow disease) in Great Britain and dioxin-tainted foods originating from Belgium.

These food scares have undermined consumer confidence about the European food supply, and citizens are disinclined to trust government information about GM foods. In response to the public outcry, Europe now requires mandatory food labeling of GM foods in stores, and the European Commission (EC) has established a 1% threshold for contamination of unmodified foods with GM food products.

In the United States, the regulatory process is confused because there are three different government agencies that have jurisdiction over GM foods. To put it very

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[53] *It would be interesting to note that recently in India also, many states banned cultivation and field trials of Bt. Brinjal variety, as agriculture falls under List III, of Schedule VII of the Indian Constitution.*

[54] *In Europe, public opposition to GM food is stronger. According to the Eurobarometer 2000, 69% held that genetic engineering should not be encouraged in food production.*

Source : The Genetically Modified (GM) Food Labelling Controversy: Ideological and EpistemicCrossovers, by Mikael Klintman, Social Studies of Science, Vol. 32, No. 1 (Feb., 2002), pp. 71-91, http://www.jstor.org/stable/3182978, Accessed on 28th May, 2010

simply, the EPA evaluates GM plants for environmental safety, the USDA evaluates whether the plant is safe to grow, and the FDA evaluates whether the plant is safe to eat.

The EPA (Environmental Protection Agency) is responsible for regulating substances such as pesticides or toxins that may cause harm to the environment. GM crops such as Bt. pesticide-laced corn or herbicide-tolerant crops but not foods modified for their nutritional value fall under the purview of the EPA. The USDA is responsible for GM crops that do not fall under the umbrella of the EPA such as drought-tolerant or disease-tolerant crops, crops grown for animal feeds, or whole fruits, vegetables and grains for human consumption.

The FDA historically has been concerned with pharmaceuticals, cosmetics and food products and additives, not whole foods. Under current guidelines, a genetically-modified ear of corn sold at a produce stand is not regulated by the FDA because it is a whole food, but a box of cornflakes is regulated because it is a food product. The FDA's stance is that GM foods are substantially equivalent to unmodified, "natural" foods, and therefore not subject to FDA regulation.

The EPA conducts risk assessment studies on pesticides that could potentially cause harm to human health and the environment, and establishes tolerance and residue levels for pesticides. There are strict limits on the amount of pesticides that may be applied to crops during growth and production, as well as the amount that remains in the food after processing.

Growers using pesticides must have a license for each pesticide and must follow the directions on the label to accord with the EPA's safety standards. Government

inspectors may periodically visit farms and conduct investigations to ensure compliance. Violation of government regulations may result in steep fines, loss of license and even jail sentences.

In Australia, manufacturing, research, commercial release, production and import of GMOs are regulated under the Gene Technology Act 2000 by the Gene Technology Regulator (GTR). Every dealing with a GMO needs to be licensed by GTR, unless the dealing is an Exempt Dealing, a Notifiable Low Risk Dealing or on the Register of GMOs. There are three advisory committees, the Gene Technology Technical Advisory Committee (GTTAC), the Gene Technology Community Consultative Committee (GTCCC) and the Gene Technology Ethics Committee (GTEC), provide advice to GTR and the Ministerial Council.

In Canada, the regulations of the biotechnology products are coordinated by Canadian Food Inspection Agency (CFIA), Health Canada and Environment Canada. The CFIA is in charge of regulating the import, variety registration, environmental release and use in livestock feeds of plants with novel traits. Health Canada is solely responsible for assessing the human health safety of foods.

Environment Canada is responsible for administering the new substances notifications regulations and for performing environmental risk assessment of toxic substances, including organisms and microorganisms that may have been derived from biotechnology. These agencies regulate biotechnology products under the authority derived from atleast ten pieces of preexisting legislation that have been amended time to time to deal with new products.

International Legal Entities - Cartagena Protocol

The Protocol promotes biosafety by establishing rules and procedures for the safe transfer, handling, and use of LMOs, with specific focus on transboundary movements of LMOs. It features a set of procedures including one for LMOs that are to be intentionally introduced into the environment called the advance informed agreement procedure, and one for LMOs that are intended to be used directly as food or feed or for processing. Parties to the Protocol must ensure that LMOs are handled, packaged and transported under conditions of safety.

Furthermore, the shipment of LMOs subject to transboundary movement must be accompanied by appropriate documentation specifying, among other things, identity of LMOs and contact point for further information. These procedures and requirements are designed to provide importing Parties with the necessary information needed for making informed decisions about whether or not to accept LMO imports and for handling them in a safe manner.

The Party of import makes its decisions in accordance with scientifically sound risk assessments. The Protocol sets out principles and methodologies on how to conduct a risk assessment. In case of insufficient relevant scientific information and knowledge, the Party of import may use precaution in making their decisions on import. Parties may also take into account, consistent with their international obligations, socio-economic considerations in reaching decisions on import of LMOs.

Parties must also adopt measures for managing any risks identified by the risk assessment, and they must take necessary steps in the event of accidental release of LMOs.

It's objective is also facilitate its implementation, the Protocol establishes a Biosafety Clearing-House for Parties to exchange information, and contains a number of important provisions, including capacity-building, a financial mechanism, compliance procedures, and requirements for public awareness and participation.

Codex Alimentarius

The Codex Alimentarius is a set of internationally recognized standards, codes of practice, guidelines and other recommendations relating to foods, food safety and food production. Its name derives from the Codex Alimentarius Austriacus. Its texts are developed and maintained by the Codex Alimentarius Commission, a body that was established in 1963 by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO).

The Commission's main aims are stated as being to protect the health of consumers and ensure fair practices in the international food trade. The Codex Alimentarius is recognized by the World Trade Organization as an international reference point for the resolution of disputes concerning food safety and consumer protection.

The Codex Alimentarius officially covers all foods, whether processed, semi-processed or raw, but far more attention has been given to foods that are marketed

directly to consumers. In addition to standards for specific foods, the Codex Alimentarius contains general standards covering matters such as food labeling, food hygiene, food additives and pesticide residues, and procedures for assessing the safety of foods derived from modern biotechnology. It also contains guidelines for the management of official (i.e., governmental) import and export inspection and certification systems for foods.

The controversy over the Codex Alimentarius relates to a perception that it is a mandatory standard for food - including vitamin and mineral supplement - safety. Supporters of the Codex Alimentarius say that it is a voluntary reference standard for food and that there is no obligation on countries to adopt Codex standards as a member of either Codex or any other international trade organization.

From the point of view of its opponents, however, one of the main causes of concern is that the Codex Alimentarius is recognized by the World Trade Organization as an international reference standard for the resolution of disputes concerning food safety and consumer protection. Proponents argue that the use of Codex Alimentarius during international disputes does not exclude the use of other references or scientific studies as evidence of food safety and consumer protection.

Additional controversy has been expressed by proponents of ecologically and socially sustainable agriculture and food systems, such as the Slow Food movement , who view the Codex Alimentarius as antithetical to this goal. According to the Manifesto on the Future of Food, the Codex Alimentarius has "codified policies designed to serve the interest of global agribusiness above all others, while actively undermining the rights of farmers and consumers"

Conflicts over Trade Regimes

The European Union and the United States have strong disagreements over the EU's regulation of genetically modified food. The US claims these regulations violate free trade agreements, the EU counter-position is that free trade is not truly free without informed consent.

In Europe, a series of unrelated food crises during the 1990s created consumer apprehension about food safety in general, eroded public trust in government oversight of the food industry.

This has further fueled widespread public concern about genetically modified organisms (GMO), in terms of potential environmental protection (in particular biodiversity), health, and safety of consumers. Critics of GM foods contend that there is evidence that the cultivation of genetically modified plants may lead to environmental changes. Directives such as directive 2001/18/EC were designed to require authorisation for the placing GMO on the market, in accordance with the precautionary principle.

Many European consumers are demanding the right to be informed whether food that they have consumed had been genetically modified. Some polls indicate that some Americans would also like labeling, but it has not become a major issue. New EU regulations are expected to require strict labeling and traceability of all food and

animal feed containing more than 0.5 percent GM ingredients. Also Codex Alimentarius published a document to safe guard the GM food in 2003 and further compliances need to be made if the GM food is for the purpose of exporting and importing.

A 2003 survey by the Pew Research Center found that a majority of people in all countries surveyed felt that GM foods were "bad". The lowest scores were in the US and Canada, where 55% and 63% were against it, while the highest were in Germany and France with 81% and 89% disapproving. The survey also showed a strong tendency for women to be more opposed to GM foods than men.

In 2002, Oregon Ballot measures gave voters in that state one of the first opportunities in the United States to directly address that issue. The measure, which would have required the labeling of genetically engineered foods, failed to pass by a ratio of 7-3.

Friedrich-Wilhelm Graefe zu Baringdorf, member of the German Green Party and vice president of the Landwirtschaftsausschuss (committee of agriculture) of the European Commission said on the 1 July 2003: "In America 55% of the consumers are against GM food and 90% in favor of a clear labeling."

Thus there are regulations and guidelines at international level for regulation of GM Field Trials and mass cultivation. The states who are parties to the international convention / protocols have incorporated the same in their domestic legislations.

Chapter V

Indian Legal Mechanisms to regulate GM Crops Field Trials and GM Food Production

In this chapter a survey of important statutes, which deal with the GM Food Crops, is carried out. The Ministries which deal with GM Food Crops and the institutionalized regulation of GM Food crops is also discussed in this chapter. At the concluding part of this chapter, application of such rules by the Supreme Court in the 'Aruna Rodrigues PIL' case is also briefly discussed.

GM Food Crop Governing Statutes / Rules

The following are the Biotechnology laws in India.

The Environment Protection Act, 1986

The Environment Protection Act was enacted in 1986 with the objective of protecting and improving the environment. It was enacted pursuant to the decisions taken at the United Nations Conference on the Human Environment held at Stockholm in June, 1972, in which India actively participated. Yet another important objective of the act is the protection and improvement of environment and the prevention of hazards to human beings, other living creatures, plants and property.

Important provisions of the Environment Protection Act, 1986[55] :-

Among other provision of the Environment Protection Act, 1986, the following are most relevant to the subject in hand.

Definitions -Sec. 2,

a) "**Environment**" includes water, air and land and the inter- relationship which exists among and between water, air and land, and human beings, other living creatures, plants, micro-organism and property;

(b) **"Environmental Pollutant"** means any solid, liquid or gaseous substance present in such concentration as may be, or tend to be, injurious to environment;

(c) **"Environmental Pollution"** means the presence in the environment of any environmental pollutant;

(e) **"Hazardous Substance"** means any substance or preparation which, by reason of its chemical or physico-chemical properties or handling, is liable to cause harm to human beings, other living creatures, plant, micro-organism, property or the environment;

Sec. 3, Power of Central Government to take measures to protect and improve Environment

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[55] *Source : http://moef.nic.in/downloads/rules-and-regulations/eprotect_act_1986.pdf, Accessed on 28th May, 2010*

(1) Subject to the provisions of this Act, the Central Government, shall have the power to take all such measures as it deems necessary or expedient for the purpose of protecting and improving the quality of the environment and preventing controlling and abating environmental pollution.

(2) In particular, and without prejudice to the generality of the provisions of sub-section (1), such measures may include measures with respect to all or any of the following matters, namely:--

(vii) laying down procedures and safeguards for the handling of hazardous substances;

Sec. 6, Rules to regulate environmental pollution

(1) The Central Government may, by notification in the Official Gazette, make rules in respect of all or any of the matters referred to in section 3.

(2) In particular, and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely:--

(c) the procedures and safeguards for the handling of hazardous substances.

In exercise of the powers conferred by sections 6 and 25 of the Environment Protection Act, 1986, the Central Government enacted the Environment Protection Rules, 1986[56].

[56] *Source : http://www.envfor.nic.in/legis/env/env4.html, Accessed on 26th May, 2010*

Further under the power conferred under the Environment Protection Act,1986 and under the Rule.13 of the Environment Protection Rules, 1986, the central government enacted the 'Rules for the Manufacture, Use / Import / Export and Storage of Hazardous Micro Organisms/Genetically Engineered Organisms or Cells,1989, which was notified by Ministry of Environment & Forests on December 5, 1989.

Rules for the Manufacture, Use / Import / Export and Storage of Hazardous Micro Organisms/Genetically Engineered Organisms or Cells, 1989.

As discussed supra[57] the above rules provides for many definitions such as bio-technology, micro-organism, genetic-engineering etc.

Rule 4 provides for the constitution of the following committees,

Recombinant DNA Advisory Committee (RDAC)[58]: For reviewing developments in Biotechnology at national and international levels and to recommend suitable and appropriate safety regulations for India in recombinant research, use and applications. It functions in the Department of Biotechnology. The committee has come up with many guidelines to regulate the GM Food sector, such as,

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[57] *Chapter I , at pages 8,9*

[58] *Official Website : http://dbtbiosafety.nic.in/committee/rdac.htm, Accessed on 28th May, 2010*

- Recombinant DNA Safety Guidelines – 1990,
- Recombinant DNA Safety Guidelines and Regulations – 1990,
- Revised Guidelines for Safety in Biotechnology – 1994,
- Revised Guidelines for Research in Transgenic Plants & Guidelines for
- Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant parts – 1998,
- Guidelines for Generating Pre-clinical and Clinical Data for r-DNA Based Vaccines, Diagnostics and other Biologicals – 1999,
- Guidelines and Standard Operating Procedures (SOPs) for Confined Field Trials of Regulated,Genetically Engineered (GE) Plants – 2008,
- Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants – 2008,
- Protocols for Food and Feed Safety Assessment of GE crops – 2008, etc.

Review Committee on Genetic Manipulation (RCGM)[59]: Its main objective is monitoring the safety related aspects in respect of on-going research projects and activities involving genetically engineered organisms/hazardous microorganisms. It functions under the department of biotechnology and it is empowered to constitute sub groups. It brings out manuals of guidelines specifying procedure for regulatory process with respect to activities involving genetically engineered organisms in

[59] *Official Website : http://dbtbiosafety.nic.in/committee/rcgm.htm, Accessed on 28th May, 2010*

research, use and applications including industry with a view to ensure environmental safety. It also lays down procedures restricting or prohibiting production, sale, importation and use of such genetically engineered organism of cells.

Institutional Biosafety Committee (IBSC)[60] **:** The institutions handling GMOs are required to constitute a domestic committee namely the IBSC. It shall prepare an up to date on site emergency plan according to the manuals/guidelines of the RCGM and make available copies to the District Level Committee/State Biotechnology Co-ordination Committee and the Genetic Engineering Approval Committee.

Genetic Engineering Approval Committee (GEAC)

It functions under the Department of Environment, Forest and Wildlife for approval of activities involving large scale use of hazardous microorganisms and recombinants in research and industrial production from the environmental angle. It is also responsible for approval of proposals relating to release of genetically engineered organisms and products into the environment including experimental field trials.

Rule 7 states that 'no person shall import, export, transport, manufacture, process, use or sell any hazardous microorganisms or genetically engineered organisms/substances or cells except with the approval of the Genetic Engineering Approval Committee'.

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[60] *Official Website : http://dbtbiosafety.nic.in/committee/ibsc.htm, Accessed on 28th May, 2010*

The Genetic Engineering Approval Committee publishes the biosafety[61] data including comparative toxicity, allergencity and feeding studies of GM Crops, which are approved by it. The GEAC is empowered to appoint 'Expert Committees' for approval of any particular case.

GEAC came under the severe criticism of the Supreme Court. The Supreme Court of India on September 22, 2006, issued an interim verdict banning all field trials of GM crops in the country and slammed the regulatory mechanism. GEAC was injuncted from giving permission to any further GM Crop till the court delivers its final judgment. The order was issued in response to a public interest petition filed by Social Activists Aruna Rodrigues and other experts.

The court directed GEAC to form an independent experts committee to look into the regulatory aspects for release of GM crops. Following the directive, GEAC formed a committee, headed by geneticist Deepak Pental, the vice-chancellor of Delhi University. GEAC approved field trials for 'Bt brinjal'. 'Bt Cotton', as of now, is the only approved and commercially cultivated GM crop in the country. There are more crops, including GM brinjal, awaiting GEAC approval.

In an earlier judgment given on May 1, 2006, the court had ordered that GEAC would be the only regulatory authority. Citing conflict of interests in field trials, the court found RCGM, which conducts field trials, is the same establishment that also has

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[61] *Bio-Safety data is available at : http://www.igmoris.nic.in/major_developments1.asp, Accessed on 28th May, 2010*

biotechnology interests. "This ensures conflict of interests, as RCGM could easily be biased towards ensuring easy passage of GM crops,' says Kuruganthi. She brands GEAC as nothing but a rubber stamp. "Previously, RCGM used to call the shots by conducting the field trials and bio-safety regulations. GEAC was a rubber stamp when it came to releasing the variety,' she adds.

RCGM was formed to provide technical support to GEAC. All the 28 members of RCGM are thorough experts and come from premier institutes in the country. There are other two committees namely the State Biotechnology Co-Ordination Committee (SBCC) and District Level Committee (DLC).

National Seed Policy, 2002[62]

The national seed policy is formulated with an objective to achieve food and nutritional security at the household level[63]. It also aims at sustained increase in agriculture production and productivity, by development of new and improved varieties of crops and an efficient system for timely supply of quality seeds to farmer.

In the objectives of the Seeds Policy, 2002 it is stated that, "...biotechnology will be a key factor in agricultural development in the coming decades. Genetic engineering/modification techniques hold enormous promise in developing crop varieties with a higher level of tolerance to biotic and abiotic stresses. A conducive

[62] *Source : http://dbtbiosafety.nic.in/default.asp, Accessed on 28th May, 2010*

[63] *Ibid*

atmosphere for application of frontier sciences in varietal development and for enhanced investments in research and development is a pressing requirement. At the same time, concerns relating to possible harm to human and animal health and bio-safety, as well as interests of farmers, must be addressed...". Thus the policy itself expresses concern about the possible effects of transgenic seeds over environment and human health.

More particularly policy no.6 states about 'Transgenic Plant Varieties'. It states that, 'biotechnology will play a vital role in the development of the agriculture sector and this technology can be used not only to develop new crops/varieties, which are tolerant to disease, pests and abiotic stresses, but also to improve productivity and nutritional quality of food'. Furthermore it states that, '..all genetically engineered crops/varieties will be tested for environment and bio-safety before their commercial release, as per the regulations and guidelines of the Environment Protection Act (EPA), 1986', and, 'Seeds of transgenic plant varieties for research purposes will be imported only through the National Bureau of Plant Genetic Resources (NBPGR) as per the EPA, 1986'.

The Prevention of Food Adulteration Act, 1955 and The Food Safety and Standards Act, 2006

The important objectives of the prevention of food adulteration act, 1955 is to protect the public from harmful foods, to prevent the sale of substandard foods and to protect the interests of the consumers by eliminating fraudulent practices. The act was

amended many times[64], so as to keep in pace with time. Under the act [65] GM food products are required to be mandatorily labeled.

Biotechnology Regulatory Authority of India (BRAI) Bill, 2009

Two reports were commissioned by the Ministry of Agriculture and the Ministry of Environment & Forests to evaluate the regulatory framework for products of agricultural biotechnology and recombinant pharmaceuticals, respectively. The 2004 Report of the Task Force on the Application of Agricultural Biotechnology chaired by Prof. M.S. Swaminathan, recommended the establishment of an "autonomous, statutory and professionally-led National Biotechnology Regulatory Authority" (NBRA) that would have "two separate wings, one dealing with food and agricultural biotechnology, and the other with medical and pharmaceutical biotechnology. The Report recommended that the "NBRA is essential for generating the necessary public, political, professional and commercial confidence in the science based regulatory mechanism in place in the country".

The 2005 Report of the Task Force on Recombinant Pharma chaired by Dr. R.A. Mashelkar also supported the establishment of a National Biotechnology Regulatory Authority/Commission "providing a professionally managed single window mechanism for giving various clearances including biosafety issues."

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[64] *The Prevention of Food Adulteration (Amendment) Act, 1964 (49 of 1964),*
The Prevention of Food Adulteration (Amendment) Act, 1971 (41 of 1971),
The Prevention of Food Adulteration (Amendment) Act, 1976 (34 of 1976),
The Prevention of Food Adulteration (Amendment) Act, 1986 (70 of 1986).
Source URL : http://mohfw.nic.in/pfa , Accessed on 23rd May, 2010

[65] *Refer discussions infra at Pages -*

A model for the NBRA was proposed that "would comprise of four wings namely,

a) Agricultural products / Transgenic Crops;

b) Pharmaceutical/ Drugs and Industrial Products;

c) Transgenic Foods/Feed; and

d) Transgenic Animals/ Aquaculture.

The NBRA will be established as an independent, autonomous and professionally led body to provide a single window mechanism for biosafety clearance of genetically modified products and processes.

Criticisms against BRAI Bill

The biotech regulatory Bill gags dissent and takes away the power of states without providing any safeguards to farmers and consumers, opines, Ms.Latha Jishnu. She adds that 'shortcuts always lead to problems, and nowhere is this more evident than in the biotechnology sector. Research in genetically modified organisms (GMOs) crops was permitted, both in the public and private sectors, even before a clear policy was in place and before any guidelines had been formulated on the priority areas for Indian agriculture.'

The regulatory system is mostly manned by bureaucrats. The proposed apex regulatory body with representation from several ministries is a three-member regulator that will act as single-window clearing house for all GM commercial applications. The processing of applications is its primary mandate under the Bill.

This was first articulated by the 2004 Task Force Report on Agricultural Biotechnology, which was accepted by the Union government in 2005. The task force was headed by M S Swaminathan, the agricultural scientist.

In keeping with his guiding principle, the task force had recommended a statutory and autonomous National Biotechnology Regulatory Authority (NBRA) with two wings: One for agricultural and food biotechnology and the other for medical and pharmaceutical biotechnology. The setting up of National Biotechnology Regulatory Authority was delayed for some reasons and it ultimately morphed into Biotechnology Regulatory Authority of India (BRAI). While the GEAC, which the BRAI replaces, is under the jurisdiction of the Ministry of Environment and Forests (MoEF), the Department of Biotechnology (DBT), which come under the Ministry of Science and Technology, has formulated the Bill.

Certain activist points out that there would be a serious conflict of interest, between the ministries, if BRAI is housed under the Ministry of Science and Technology. Plant geneticist Suman Sahai, who was on the Planning Commission's Task Force on Biodiversity and Genetically Modified Organisms (GMOs) for the XIth Plan, says the problem with the regulatory system is that "it lacks technical competence, transparency and stringency" and that new Bill does nothing to set right these shortcomings. The proposed act provides for imprisonment and hefty fines for persons who, without any evidence or scientific record, mislead the public about the safety of the organisms and products in Schedule I of the Act.

Besides, the proposed law will override other statutes like the Right to Information (RTI) Act and the Environment Protection Act. In sum, details of BRAI's decisions

cannot be sought by the public, nor can these be legally challenged. In all other spheres of government and regulatory activity, it is the Central Information Commission that decides what information can or cannot be disclosed, and even its ruling can be challenged in the courts. In fact, there is no provision for public participation in the regulatory process, which is expressly mandated under the Cartagena Protocol on Biosafety to which India is a signatory under the Convention on Biosafety. The bill is also violative of the Constitution of India as agriculture and health falls under List-II, or under the state subject. The Bill envisages only an advisory role through the State Biotechnology Regulatory Advisory Committee. Apart from hitting at the federal structure on agriculture and health issues, the BRAI will impinge on, if not override, other laws like the better designed Biological Diversity Act which gives equal play to the states and Union government.

It is also not clear whether the Product Rulings Committee will be the final arbiter of risk assessment or whether its reports will form the basis for such evaluation by the risk assessment unit. But, of more concern is the fact that independence, impartiality or autonomy of this three-member body can be easily undermined. Under the proposed act the Central government is allowed to give directions to the regulatory authority, allowing it to "interfere with matters that are scientific and technical in nature." Sahai, the convener of farmers' rights group Gene Campaign, has been fighting a long battle in the Supreme Court. Her PIL was filed in 2004 so as to ensure stringent and transparent regulations for GM crops, and she says it's high time a credible authority was in place.

The larger issue with the BRAI is that risk management is almost absent from its agenda. Not only is there is no stipulation for revocation of approval by the authority

to prevent any possible harm to the environment or public health, there is also no strong provisions for liability. Missing here are express clauses for redressal or compensation and measures for remediation and clean up in the event of an ecological disaster, says Kavitha Kuruganti of the Kheti Virasat Mission, a civil society organisation working for sustainable agriculture.

Thus the Biotechnology Regulatory Authority of India, if constituted, with the modifications suggested by the academicians, social activist, NGOs etc, then, no doubt it would be one of the most stringent legal mechanism to regulate GM Food crops.

Chapter VI

Labelling of Genetically Modified Food – The Indian perspective

This chapter would deal with the Labelling of the GM food products[66]. The pros-cons of making GM labelling mandatory, is also dealt with. Though the subject matter of this chapter and the preceding chapter are similar, as Labelling of GM Food products falls under the Indian Legal Mechanisms to regulate GM Field Trials and Production, still considering the importance of the subject matter, it is given as a separate chapter.

Labelling – Definitions

Section 3(z), of the Food Safety and Standards Act, 2006, defines 'Label in the following words,[67]

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[66] *'In recent years, an increasing number of countries have adopted labeling policies for genetically modified (GM) food. The first labeling policies were introduced by the European Union (EU) in 1997, but since then many other countries, including all developed countries, have adopted some type of labeling policy for GM food'.*
Source : A Review of International Labeling Policies of Genetically Modified Food to Evaluate India's Proposed Rule, by Guillaume P. Gruère, International Food Policy Research Institute and S.R. Rao
Ministry of Science and Technology, http://www.agbioforum.org/v10n1/v10n1a06-gruere.htm, Accessed on 28th May, 2010

[67] *Source : http://www.fssai.gov.in/FOOD%20ACT.pdf, Accessed on 28th May, 2010*

"Label means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed, and graphic, perforated, stamped or impressed on or attached to container, cover, lid or crown of any food package and includes a product insert".

"Labelling means any written, printed or graphic matter that is present on the label, accompanies the food, or is displayed near the food, including that for the purpose of promoting its sale or disposal".[68]

Food labelling may be defined as the process of writing on the food products, in any form such as written, electronic, graphic, etc, so as to inform the consumer about the manufacturer, ingredients of the products, statutory warnings etc. Though labelling serves other purposes such as protection from physical damage, preservation from external agents such as moist, air, better marketing, etc., still the main objective is to pass on right information about the product to the consumer.

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[68] *Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods, given by The Codex Committee on Food Labelling.*
Source : http://www.codexalimentarius.net/web/index_en.jsp, Accessed on 28th May, 2010

Views on Labelling the GM Food Products – For & Against

The Labelling of GM Food products have, over the last few years, become a hotly contested issue. On the one hand the manufacturers of GM Food, argue that they can't be discriminated and called to label their products, in the absence of any conclusive proof as to the 'after-impacts' of GM Food, as against a non-GM Product Manufacturers. Whether and how GM Food manufacturers should convey to consumers, information regarding various characteristics of their products, is also a question in consideration.

A strong GM Crops proponent Henry Miller states[69] that, "Even a message that is accurate, in the narrowest sense, can mislead and confuse consumers if it is irrelevant, unintelligible, or so craftily selected that it provides inadequate or biased information. In the same article, biotechnology labelling is also said to be as irrelevant as a label that assures consumers that 'no uranium' or 'no rattlesnake venom' is contained in the produce",

As discussed in the preceding chapters[70], the two important rights of a consumer are right to information and right to choice. Accordingly the GM Food consumers have

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[69] *Henry I. Miller and Suzanne L. Huttner, 'Food Produced with New Biotechnology: Can Labeling Be Anti-Consumer?', Journal of Public Policy & Marketing, Vol. 14, No. 2 (Fall 1995), 330-33, at pg-330.*

[70] *Chapter II, at Page(s)- 24, 25*

every right to know the 'after-impacts' of the GM Food. To the least, the GM Food consumers should know that they are consuming GM Food.

Authors(s) Chris MacDonald & Melissa Whellams, in their article, 'Corporate Decisions about Labelling Genetically Modified Foods',[71]

"....whether, in such a situation, individual corporations can be ethically required to take such unilateral action. We argue that they cannot. Given the lack of solid evidence for any risk to human health, and the serious market disadvantage almost surely associated with costly unilateral action, no individual company has an ethical obligation to label its GM foods".

On the other hand, "We must pass labelling laws according to which any product that contains more than 0.01 per cent of GM food material must be labelled as GM", so argues[72] the former Director, Centre for Cellular and Molecular Biology, Hyderabad, and Vice-Chairman, National Knowledge Commission, Dr Pushpa M. Bhargava.

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[71] *Source : Journal of Business Ethics (2007) 75:181–189 Springer 2007 DOI 10.1007/s10551-006-9245-8*

[72] *Source : http://www.tribuneindia.com/2009/20091101/edit.htm#1, Tribuneindia, "Food without choice ? We must know what we are eating", Accessed on 28th May, 2010*

Does GM Food deny right to choice to consumer?

How does a consumer know a food product contains genetically modified organisms or not?

As discussed supra,[73] GM Food falls under the category of credence goods and as such, only the manufacturers and not the consumers, would be in a position to know whether a food product contains Genetically Modified Organisms or not. For this Bio-Scientist, Paras Chopra, answers as follows, -

"Only rarely can one see whether a plant or animal has been genetically modified, with the naked eye. Scientists have therefore developed some techniques to assist them. For example a special colour test can identify whether a plant is genetically modified or not. At the time when the plant is genetically modified, the scientist inserts an extra marker gene into the plant. The marker gene can have different characteristics, for example, it can make the plant change colour when exposed to a chemical test. In this way, scientists can identify whether the plant has been genetically modified or not by performing a chemical test and noting the colour of the plant".[74]

In Food products that are considered substantially equivalent to their conventional counterparts, which include products derived from all transgenic crops such as GM

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[73] *Refer Chapter II, at page 25*

[74] *Extracted from 'Genetically modified crops in India - The current status of GM crops in India', by Paras Chopra*

products, there is a large international heterogeneity in labeling regulations. For instance countries Canada, Hong Kong & South Africa, leaves the labelling issue to the GM manufacturers. In contrast, in countries like Australia, the EU, Japan, Brazil, & China, it is made mandatory.

Voluntary labeling guidelines dictate rules that define what food can be called GM or non–GM, and let the food companies decide if they want to use such information on their products. In contrast, mandatory labeling requires GM Food manufacturers to display whether their product contains or is derived from genetically engineered materials. A certain number of countries with mandatory labeling for GM ingredients also have voluntary guidelines for the labeling of non–GM food, like Japan and the EU. This mixed mandatory & voluntary system is in place in countries with mandatory labeling for which consumers are willing to pay a premium to completely avoid GM ingredients, even at a residual level.

The above discussion would make clear that for an ordinary consumer, it would not be possible to know as to whether a Food product contains GM Organisms or not. Therefore the consumer has to look into the 'Label', to have the above information.

GM Labelling – Indian Legal Requirements

On March 10, 2006, the Central Government of India, after consultation with the Central Committee for Food Standards, published two draft rules to amend the Prevention of Food Adulteration Rules, 1955, introducing labeling and approval requirements for GM food and the products derived thereof.

Rule 37E[75] states about Labeling of Genetically Modified Food require that all primary or processed foods, food ingredients, or food additives derived from a GM food, be labeled accordingly, and that imported GM foods indicate the status of approval in the country of origin.

The Prevention of Food Adulteration Rules, 1955, in addition to the above labeling provision, also requires the GM Food manufacturers to conform to the following labeling requirements:

a. GM food, derived there from, whether it is primary or processed or any ingredient of food, food additives or any food product that may contain GM material shall be compulsorily labeled, without any exceptions;

b. the label of all package(s) of GM food(s) or foods containing ingredients, derived from biotechnology or bioengineering or food additives or any food product that may contain GM material shall indicate that they have been subject to genetic

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[75] *Rule - 37E, Prevention of Food Adulteration Rules, 1955,was inserted by a notification dated 10 th March 2006 of the Ministry of Health and Family Welfare, Government of India, Nirman Bhavan, New Delhi - 110 011 ,*

Rule -37E 'Labeling of Genetically Modified Food— Genetically engineered or modified foods means food and food ingredients composed of or containing genetically modified or engineered organisms obtained through modern biotechnology, or food and food ingredients produced, from but not containing, genetically modified or engineered organisms obtained through modern biotechnology.

Source : http://mohfw.nic.in, Accessed on 28th May, 2010

modification. These provisions will be applicable to all such products both imported or domestically produced; and

c. the label of imported GM food or derived there from, whether it is primary or processed or any ingredient of food, food additives or any food product that may contain GM material shall also indicate that the product has been cleared for marketing and use in the country of origin so that the verification, if needed can be taken up with that country without having to resort to testing."

Furthermore, Rule 48F[76] provides for the restriction on Sale of Genetically Modified Food in the following words,

"No person shall except with approval of and subject to the conditions that may be imposed by the Genetic Engineering Approval Committee (GEAC) constituted under the Environment Protection Act, 1986, manufacture, import, transport, store, distribute or sell raw or processed food or any ingredient of food, food additives or any food product that may contain GM material in the country. Provided that in case of imported genetically modified foods, the importer shall submit documents supporting the purported clearance at the time of import."

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[76] *Rule – 48F, Prevention of Food Adulteration Rules, 1955, was inserted by a notification dated 10th March 2006 of the Ministry of Health and Family Welfare, Government of India, Nirman Bhavan, New Delhi - 110 011, Source : http://mohfw.nic.in, Accessed on 28th May, 2010*

First, draft rule 37–E proposes labeling requirements with very comprehensive product coverage. The proposed standard would rank India's regulation among the most stringent GM food labeling policies in the world, states Guillaume P. Gruère & S.R. Rao.[77]

Further they state that, in view of the requirements under clause (a) of Rule37E, GM Food products would include ingredients derived from GM and/or that may contain GM material.

They also find fault with the drafting of clause (b) of Rule-37E. They state that the labeling specification of clause (b) only refers to the displaying of the words 'genetically modified,' not to the fact that the GM material has been approved by the governing body. They say that, this is arguably regrettable, because the information content remains limited and might act as a hazard warning signal to uninformed or partially informed consumers, such a situation might occur for India's packaged food products, thus resulting in a 'no GM' versus 'non–GM' choice for consumers, imprecise information, and likely higher food prices.

GM Labelling under International Law

The Codex Alimentarius, the Biosafety Protocol, and the World Trade Organization (WTO) are the three international institutions directly involved in discussions over

[77] *A Review of International Labeling Policies of Genetically Modified Food to Evaluate India's Proposed Rule, by Guillaume P. Gruère, International Food Policy Research Institute & S.R. Rao, Ministry of Science and Technology.*

labeling of GM food. India is a member of the WTO[78], a ratifying member of the Biosafety Protocol, and an active member of the Codex Alimentarius negotiations.

The Codex Committee on Labelling[79] came up with guidelines for the labeling of food and food ingredients obtained through certain techniques of genetic modifications/genetic engineering, which included the following recommendations,

(a) Labeling should be required for GM food that is not substantially equivalent to its conventional equivalent,

(b) Labeling should be required for GM food that contains allergens,

(c) Labeling should be required for substances with physiological or metabolic impacts,

(d) Where label indicates the presence of production process, GM food (food containing GM and food with ingredients derived from GM food) should be labeled,

(e) For GM food products for which there are religious or dietary concerns, labeling should be required.

Thus, the arguments in favour of and against Labelling GM Food products apart, the parliamentary wisdom calls upon the manufacturers, who market their products

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[78] *Source : http://www.wto.org/english/thewto_e/countries_e/india_e.htm, Accessed on 28th May, 2010*

[79] *India is also a member of Codex Commission,*
Source : http://www.codexalimentarius.net/web/member_info.jsp?iso3=IND, Accessed on 28th May, 2010

containing GMOs either produced in our country or imported, to label their products. Added to the above domestic legal requirement, the international law also calls upon the manufacturers to label their GM Food products.

Chapter VII

The Sustainable solution : Harmonizing the Conflicting Rights

In this chapter the GM Food issue is analyzed through constitutional rights perspective. The rights of various groups and which right has to be given primacy are also discussed in this chapter.

GM Food Issue –Constitutional Rights perspective

The GM Food crops issue, as stated supra[80], has multiple dimensions and multiple stake-holders. The biggest group in terms of numbers would be the GM Food consuming public, followed by the farmers who willingly permit field trials or cultivation of GM Food Crops at commercial scale, in their lands. The other groups such as the manufacturers, both international/domestic, the NGOs, the academicians, environmentalists are small in numbers.

[80] *Refer discussions at Pages 1 & 2*

The fundamental law of the land namely the constitution confers various rights on persons under part III of the constitution. The constitution guarantees right to life[81] to all persons. The Supreme Court of India, since the late seventies from when it delivered the decision in Maneka Gandhi V. Union of India[82], has made Article.21 a reservoir of many rights. The apex has in many decisions held that right to life includes, 'right to healthy life and environment. Notably in B.L.Wadhera Vs Union of India,[83] and in Indian Council for Enviro-Legal Action vs Union of India[84], held that right to life would not mean a mere vegetative life, but a right to health and clean environment. Furthermore the apex court came down heavily on the polluters, in Vellore Citizens Welfare Forum Vs Union of India[85] and held that right to health and clean environment is part and parcel of right to life under article 21.

The domestic[86] GM food manufacturers and the agriculturists who willingly consent for carrying on cultivation & field trials in their land have a fundamental right to practice any profession, or to carry on any occupation, trade or business[87]. The above

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[81] *Article 21, Constitution of India, 'No person shall be deprived of his life or liberty except according to procedure established by law*

[82] *AIR 1978 SC 597*

[83] *AIR 1996 SC 2969 : 1996 (2) SCC 594*

[84] *AIR 1996 SC 1446*

[85] *AIR 1996 SC 2715 : 1996 (5) SCC 647*

[86] *Article 19(1) of Constitution of India confers rights on for citizens.*

[87] *Article 19(1)(g), Constitution of India, ' All citizens shall have the right to practice any profession, or to carry on any occupation, trade or business.*

right is not absolute, but may be subjected to reasonable restrictions[88] in the interest of general public.

Right to food security can also be brought under right to life. The GM Food crops are being launched with a promise of wiping out the hunger of starving people in 21st century.

The farmers, who, as in case of Brazil[89], willingly consent for GM Food crops, have also right to development. The right to development is neither a fundamental nor even a statutory right.

Harmonious Construction of Conflicting Rights

Even if the right to development is not taken into account, the other rights namely,

(i) Right to health consumers who may consume GM Food crops,

(ii) Right to life (food / food security) of poor people,

(iii) Right to carry on trade or business of GM food producers and farmers who willingly consents for GM crops field trials / cultivation in their field, and

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[88] *Article 19(5), Constitution of India, ' Nothing in sub-clauses (d) and (e) of the said clause shall affect the operation of any existing law in so far as it imposes, or prevents the state from making any law imposing, reasonable restrictions on the exercise of any of the rights conferred by the said sub clauses either in the interests of general public or for the protection of the interests of any scheduled tribes.*

[89] *Refer discussions at Page 39*

(iv) Right to clean environment of farmers having lands adjacent to fields where GM Crops are sown,

are in conflict with each other. The apex in A.K.Gopalan Vs Union of India[90], explaining the principles of harmonious interpretation, stated that,' the constitution should be so interpreted as to give effect to all its parts. The presumption is that no conflict or repugnancy was intended by the framers between the various provisions of the constitution. Accordingly, it has been laid down that if certain provisions should be interpreted so as to effect reconciliation between them so that, if possible, effect could be given to all'.

Again in Venkataramana Vs. State of Mysore[91], the apex court applied the principle to resolve the conflict between two fundamental rights namely freedom of religion and freedom of managing religious affairs. The substantial question of law, which arose for decision in the appeal, was whether the right of a religious denomination to manage its own affairs in matters of religion guaranteed under Art. 26(b), is subject to, and can be controlled by, a law protected by Art. 25(2)(b), throwing open a Hindu public temple to all classes and sections of Hindus.

The apex court replied[92] as follows,

"The question is how the apparent conflict between them is to be resolved. The rule of construction is well settled that when there are in an enactment two provisions which

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[90] *AIR 1950 SC 27*

[91] *AIR 1958 SC 255*

[92] *Ibid*

cannot be reconciled with each other, they should be so interpreted that, if possible, effect could be given to both. This is what is known as the rule of harmonious construction. Applying this rule, if the contention of the appellants is to be accepted, then Art. 25(2)(b) will become wholly nugatory in its application to denominational temples, though, as stated above, the language of that Article includes them. On the other hand, if the contention of the respondents is accepted, then full effect can be given to Art. 26(b) in all matters of religion, subject only to this that as regards one aspect of them, entry into a temple for worship, the rights declared under Art. 25(2)(b) will prevail. While, in the former case, Art. 25(2)(b) will be put wholly out of operation, in the latter, effect can be given to both that provision and Art. 26(b). We must accordingly hold that Art. 26(b) must be read subject to Art. 25(2)(b)."

Not only the apex court but also the high courts' at times give classic judgements. One such judgment is delivered by the Allahabad High Court in Moinuddin Vs. State of Uttar Pradesh[93]. The High Court traced the entire case jurisprudence and stated that[94],

"The choice between two alternative constructions should be made in accordance with well-recognised canons of interpretation. I may summarise some of them very briefly. Firstly, if two constructions are possible, the Court must, as reiterated by the Supreme Court in State of Punjab v. Ajaib Singh[95], adopt the one which will ensure smooth, and harmonious working of the Constitution and eschew the other which will lead to

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[93] *AIR 1960 All 484*

[94] *Ibid*

[95] *AIR 1953 SC 10 at Page 14*

absurdity or gave rise to practical inconvenience or make well-established provisions of existing law nugatory. Secondly, as was observed by P. B. Mukerji, J. in Ram Hari v. Nilomani Das[96], constitutional provisions are not to be interpreted and crippled by narrow technicalities but as embodying the working principles for practical Government. Thirdly, as laid down by the U. S. Supreme Court in Gompers v. United States,[97] the provisions of a Constitution are not to be regarded as mathematical formulae and that their significance is not formal but vital. I take this observation to mean that practical considerations rather than formal logic must govern the interpretation of those parts of a Constitution which are obscure or capable of two alternative meanings. Fourthly, as was observed by the Madras High Court in Champakam Dorairaja v. State of Madras,[98] in a choice of two alternative constructions, the one which avoids a result unjust or injurious to the nation should be preferred. Fifthly, before making its choice between two alternative meanings, the Court must read the Constitution as a whole, take into consideration its different parts and try to harmonise them. Lastly, and above all, was observed by the Supreme Court in Gopalan v. State of Madras,[99] the Court should proceed on the presumption that "no conflict or repugnancy (between the different parts) was intended by the framers of the Constitution. The last principle was laid down in slightly different language by the Privy Council in James v. Commonwealth of Australia[100], in which Lord Wright observed that the question then is one of construction and in the ultimate result must

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[96] *AIR 1952 Cal 184*

[97] *(1913) 233 US 604 (610): 58 Law Ed. 1115 at page 1120*

[98] *AIR 1951 Mad 120 at Page 130*

[99] *AIR 1950 SC 27 at Page 93*

[100] *1936 AC 578*

be determined upon the actual words used, read not in vacuo but as occurring in a single complex instrument in which one part may throw light on another."

As stated supra[101] Article 47 also obligates the state to improve standard of living and public health. Part IV of the constitution is no longer a dead letter of law, after the decision of the apex court in Re Kerala Education Bill[102], wherein reversing its own judgment in State of Madras Vs. Champakam Dorairajan[103], wherein it was held that 'while the fundamental rights were enforceable , the directive principles of state policy were not', it held as follows[104],

" Nevertheless, in determining the scope and ambit of the fundamental rights relied upon by or on behalf of any person or body, the court may not entirely ignore these Directive Principles of State Policy laid down in Part IV of the constitution but should adopt the principles of harmonious construction and should attempt to give effect to both as much as possible".

The above decision was followed in a catena of judgements, including the decisions in Kesavananda Bharathi Vs State of Kerala[105] and State of Kerala Vs N.M.Thomas[106].

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[101] *Refer discussions at Pages 3 & 4*

[102] *AIR 1958 SC 956*

[103] *AIR 1951 SC 226*

[104] In Re Kerala Education Bill, AIR 1958 SC 956

[105] AIR 1973 SC 1461 : 1967 (2) SCR 762

[106] AIR 1976 SC 490

The apex court in Minerva Mills Vs Union of India [107] said that the fundamental rights are not an end in themselves but are means to an end, the end is specified in the Directive Principles.

Even while delivering the judgement in Venkataramana Vs. State of Mysore[108], the Supreme Court gave the verdict in favour of the larger interest. If the dicta of the above said case if applied to the issue in hand, it should be concluded that the larger public interest, namely the interest of consumer shall prevail and a moratorium be imposed on all GM Food crops, till a conclusive scientific proof, guaranteeing the 'Environment Safety' and 'Health Safety', arrives.

[107] AIR 1980 SC 1789

[108] *AIR 1958 SC 255*

Chapter VIII

Conclusion

The whole study would also be summarily discussed, with suggestions and concluding note. The two research hypotheses would also be tested.

Summary of the discussions

Genetic Engineering is a technique by which direct manipulation of an organism's genes was made possible, so as to get desired result. It is also known by various names such as recombinant DNA technology, genetic modification, genetic manipulation (GM), and gene splicing. It is said to differ from traditional breeding, where the organism's genes are manipulated indirectly. Genetic engineering finds its application in agriculture, industries such as medicine and healthcare. Genetic modification involves altering an organism's DNA. This can be done by altering an existing section of DNA, or by adding a new gene altogether. Genetic Engineering is claimed to be done so as to provide the crop with better 'pests control', 'insects control' and ultimately better yield.

'Consumerism is a movement seeking to protect and inform consumers by requiring such practices as honest packaging and advertising, product guarantees, and improved safety standards'. The former American president Mr. Kennedy gave four consumer

rights and subsequently four other were added, namely, Right to (i) Safety, (ii) Information, (iii) Choice, (iv) Remedy, (v) Satisfaction of basic Needs, (vi) Redress, (vii) Education and (viii) healthy Environment. As 'GM Food Crops' fall I the category of 'Credence Goods' it requires 'proactive consumerism'.

Thus far the environment principles such as, 'sustainable development', 'inter-generational equity', 'precautionary principle' and 'polluter pays principle' have been applied in cases where there were environmental violations. Social Activists, Environmentalist, NGOs and other civic bodies are calling upon to apply the 'Precautionary Principle' to the issue in hand. The decisions of the apex court, under Article.141 of Constitution of India, shall be applicable throughout the territory of India and as such the decision of the apex discussed in chapter III would also be applicable in the instant case. As there seems evidence of substantial damage being caused to environment owing to the carrying of field trials and cultivation of GM Crops, it is legally mandated for the government to apply the environment principles in case of dealing with 'GM Crops issue'.

International instruments such as the Cartagena Protocol and the Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods, etc provide for regulation of GM Food crops at international level. As seen in the fourth chapter, most of the countries have their own legal regime to regulate GM Food Crops.

In our country, the legislature amended the acts such Environment Protection Act, Prevention of Food Adulteration Act, Seeds Act from time to time, so as to make the

acts more relevant with time. As such there are legal mechanisms, in fact one of stringent of its class, to regulate the GM Food Crops from research & field trials to full pledged marketing and commercialization. The proposed successor of GEAC namely the BRAI, would be able to contribute more to consumerism, if the changes proposed by the interested civic bodies, are incorporated in the Biotechnology Regulatory Authority of India Bill.

The survey of legislations pertaining to the Labelling requirement of GM Food products showed that, it is mandatory for the persons dealing with GM Food Product to ensure that the GM Food products are labeled. From consumerism point of view also, it is desirable to have Labels.

If the principles of the decisions discussed supra are applied to the issue in hand, it should be concluded that the larger public interest, namely the interest of consumer shall prevail and a moratorium be imposed on all GM Food crops, till a conclusive scientific proof, guaranteeing the 'Environment Safety' and 'Health Safety', arrives.

Study Findings – Testing of Hypotheses

1. Indian legal mechanism is effective enough to handle GMOs & Field Trials / Cultivation.

2. No legal mechanism is available at international level to deal with GMOs & Field Trials / Cultivation.

In view of the discussions contained from pages 1 to 83, it is concluded that the **First Hypothesis** namely 'Indian legal mechanism is effective enough to handle GMOs & Field Trials / Cultivation', **STANDS PROVED,** and

The **Second Hypothesis** namely, 'No legal mechanism is available at international level to deal with GMOs & Field Trials / Cultivation', **STANDS DISPROVED.**

Suggestions & Concluding Note

In light of the study and discussion from pages 1 to 83, it is suggested as follows,

(i) It is suggested that the Government shall impose a moratorium on all type GM Food Crops, till conclusive scientific evidence, guaranteeing the safety of Environment & Human / Animal Health, is published.

(ii) It is suggested that the Government shall apply the 'precautionary principle' and other environmental principles to GM Food Crops issue.

As concluding note it is suggested that the state shall raise the level of nutrition, raise the standard of living of its people, improve the public health, and safeguard the environment & eco balance, which all are at present at the receiving end from GM Food Crops, by imposing a ban on the GM Food crop.

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