LEGAL REGIME FOR GENETICALLY MODIFIED FOOD

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Master of Philosophy

Submitted by

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CERTIFICATE

This is to certify that the dissertation entitled LEGAL REGIME FOR GENETICALLY MODIFIED FOOD submitted by SANU M.K. is in partial fulfillment of the requirement for the degree of *Master of Philosophy* (M.Phil.) of this university. It is his original work and may be placed before the examiners for evaluation. This dissertation has not been submitted for the award of any other degree of this university or of any other university.

Prof. Alokesh Barua
(Chairperson)

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(Supervisor)

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ABBREVIATIONS

UN	United Nations
WTO	World Trade Organization
CAC	Codex Alimentarius Commission
CCFL	Codex Committee on Food Labeling
FAO	Food and Agricultural Organisation
GEAC	Genetic Engineering Approval Committee
UNIDO	United Nations Industrial Development Organization
OECD	Organization of Economic Cooperation and Development
WHO	World Health Organization
GATT	General Agreement on Tariffs and Trade
SPS	Agreement on Application of Sanitary and Phytosanitary Measures
TBT	Agreement on Technical Barriers to Trade
EU	European Union
EC	European Community
CBD	Convention of Biological Diversity
IPPC	International Plant Protection Convention
MEAs	Multilateral Environment Agreements
AB	Appellate Body
ICPM	Interim Committee on Phytosanitary Measures
ICJ	International Court of Justice
RCGM	Review Committee on Genetic Manipulation
FDA	Food and Drug Administration
USDA	US Department of Agriculture
EPA	Environmental Protection Agency
DLC	District Level Committee (DLC)
ILC	International Law Commission (ILC)
SBCC	State Biotechnology Co-ordination Committee
IBSS	Institutional Bio-safety Committee
LMO	Living Modified Organism
GMO	Gennetically Modified Organism

CHAPTER I

INTRODUCTION

1.1. Introduction

The Food and Agricultural Organisation (FAO) reaffirms the right of everyone to have access to safe and nutritious food, consistent with the right to adequate food and the fundamental right of everyone to be free from hunger.[1] Going by this standard, during the period 1997-99, food security remained an unfulfilled dream for more than 815 million people in the world.[2] Most of them, living in developing countries are either starved to death or malnourished.[3] In India, even as government granaries have excess food grains, starvation deaths do occur.[4] Various socio-economic and political factors contribute to this menace.[5] Still, because of the ever-growing population, there is a need for increased quality food production to tackle world hunger.

Long strides made in plant biotechnology are often projected as an effective method for increasing food production.[6] Although the term biotechnology is of recent origin, the discipline can be traced back to as early as 5000 BC when human beings began employing microorganisms for making

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[1] Rome Declaration on World Food Security, adopted by The World Food Summit at Rome, November 13 to 17, 1996.

[2] *The State of Food Insecurity in the World* (FAO: Rome 2001).

[3] 777 million of them in developing countries, 27 million in transition countries and some 11 million in developed industrialized nations. *Id.*

[4] Jean Dreze, Starving the Poor", *The Hindu* (New Delhi) February 26, 2001.

[5] Traditionally starvation is seen as a result of entitlement failure. But elimination of hunger not only involves food production and distribution. There need to be income or employment creation on a regular basis, enhancement of economic development in general and growth of incomes of subsistence in particular through expansion of production activities. Political pressure and public opinion play an important role in determining the activities to be taken by the government in this respect. See Jean Dreze and Amartya Sen, *Hunger and Public Action* (Oxford University Press: Delhi 1999).

[6] H.J. Atkinson and Others, "The Case for Genetically Modified Crops with a Poverty Focus", *Trends in Biotechnology*, vol. 19, no.3, 2001, pp. 91-96; James N. Siedown, "Feeding Ten Billion People:

wine, vinegar and curd.[7] Biotechnology in a broad sense means any human directed modification of genetic material of an organism.[8]

In 1860, Gregor Mendel drew upon his simple experiments with cross-pollination of peanuts to elucidate the fundamental principles of modern genetics and heredity.[9] In 1953, James Watson and Francis Creek had discovered the double helix structure and chemical substance of heredity, which triggered a gene revolution.[10]

Modern genetic engineering, i.e., the actual in-vitro modification of DNA at the molecular level, was first reported in 1973.[11] Traditional plant breeding techniques involve the repeated mixing of thousands of genes over several years and generations of plants to achieve a desired trait.[12] The recombinant DNA technology (rDNA) accelerates this process by inserting selected genes (mainly from different species) into plants and brings about the desired traits with much more efficiency.[13]

Three Views", *Plant Physiology*, vol. 126, no.1, 2001, pp. 20-22; L.R. Harrera, Estrella, "Genetically Modified Crops and Developing Countries", *Plant Physiology,* vol. 124 no.3, 2000, pp. 923-25.

[7] B.D. Singh, *Biotechnology* (Kalyani Publishers: New Delhi, 1998), Chapter-1.

[8] Article 2 of the Convention on Biological Diversity, 1992 defines biotechnology as any technological application that uses biological systems,living organisms,or derivatives thereof to make or modify products or processes for specific use.

[9] R. Hubbard, "Genes as Causes", in Vandana Shiva & I Moser (ed.), *Biopolitics* (Zed Books: London, 1995), pp.38-51.

[10] M.S. Swaminathan, "Genetic Engineering and Food Security: Ecological and Livelihood Issues", available at http://www.cgiar.org/biotech xp0100/swaminath.pdf .Gene is a part of a chromosome and is responsible for transmitting the characteristics of a parent to a child, and through each cell throughout life. Chromosome is the body of genetic material (carrying genes) contained in the nucleus of a cell, and it is the basic unit that makes up all living tings. A gene is made up of Deoxyribo Nucleic Acid (DNA) that is usually double- helixed.

[11] J.P. Swazey and Others, "Risks and Benefits, Rights and Responsibilities,; A History of the Recombinant DNA Research Controversy", *Southern California Law Review*, vol. 51, no.6,1978, pp. 1019-23.

[12] The natural processes of gene transfer are rather improvements, which make the recovery of desired gene combination dependent on efficient screening and selection, and the range of the species involved is rather restricted. These put a serious limitation on taxonomic orders. See, n.7.

[13] *Id.*

rDNA technology is the most common method of genetic engineering. Article 3(g) of the Biosafety Protocol, 2001, defines a living modified organism, as any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology. Article 3(i)(a) of the Protocol defines modern biotechnology to include in-vitro nucleic acid techniques including rDNA and direct injection of nucleic acid into cells or organelles or fusion of cells beyond the taxonomic families that overcome natural, physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

rDNA molecule is produced by joining two or more DNA segments usually originating from different organisms. To achieve this, DNA segments are integrated into a self-replicating DNA molecule called vector (most commonly used vectors are either bacterial plasmids or DNA viruses). All these steps, i.e., the piecing together DNA segments of diverse origin and placing them into a suitable vector together, constitute rDNA technology. A vector with newly inserted foreign DNA is considered genetically engineered or rDNA. Then the rDNA has to be inserted into the recipient organism either by chemically treating the rDNA under temperature controlled conditions or painting it in microscopic metal particles that are loaded into a so-called gene-gun in the lab to penetrate the cells of the recipient organism. Then the mixture is returned to normal culture conditions so that the cells can recover and grow.[14] The targeted traits normally include enhanced yield potentials and

[14] L. Thompson, "Are Bioengineerd, Food Safe?: Methods for Genetically Engineering a Plant", *FDA Consumer*, January.-February,2000,p. 18.

tolerance mechanisms to abiotic stresses such as drought, nutrient scarcity, and soil toxicity.[15]

Commercial production of genetically modified (GM) crops began in China in the early 1990 with the release of virus resistant tobacco. In the US, it started with the release of flavor-savor delayed ripening tomato by Calgne.[16] By 1996, transgenic had covered an area of 1.7 million hectare and the coverage increased to 52.6 million hectare in 2000.[17] The principal GM crops were as follows: GE soyabean occupying 65% of global area, GE corn at 19%, transgenic cotton at 13%, and GE canola at 5%.[18]

The leading countries in terms of transgenic crops in 1998 were USA (74%), Argentina (15%), and Canada (10%).[19]Australia, Brazil, and South Africa have expanded their areas under transgenic crops in 1999.[20] The revenues from transgenic crops have increased by approximately thirty fold in the period from 1995 to 1999.[21] The global market for trangenic crops is projected to reach approximately eight billion US dollars in 2005, and ten billion US dollars in 2010.[22]

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[15] K.M. Leisinger, "Biotechnology and Food Security", *Current Science*, vol. 76, no. 4,1999, pp. 488-500; Also see S.K.Renine, "GM Foods can We Afford to Ignore" in B Bhattacharya (edt.) *Biotechnology In Agriculture* (Indian Institute of Foreign Trade: New Delhi, 2000), pp. 21-33.

[16] M.Avarmovic, *An Affordable Development; Biotechnology, Economics and The Implications for The Third World* (Zed Books: London, 1999).

[17] R. Ramachandran, "Green Signal for Bt-Cotton", *Frontline*, vol., 20, no.8, 2002, pp. 77-79.

[18] *Id.*

[19] "Global Review of Transgenic Crops", ISAA Briefs available at http://www.isaaa.org/press%20release/Global%20 Area-Jan2002.htm .

[20] *Id.*

[21] See, Rajesh Kapur, "Genetically Modified Foods: Concern and Their Redressal", in S.K. Bhattacharya (edt.) *Biotechnology in Agriculture*, n.15, pp.34-47.

[22] *Id.*

In India, the Genetic Engineering Approval Committee has cleared the commercialization of the first transgenic (Bt) cotton variety.[23] Laboratory research to test the golden rice and GM mustard technology and adapt to Indian conditions has been recently approved by the Department of Biotechnology.[24] According to the United Nations Industrial Development Organization's (UNIDO) website, till May 2002, 22 varieties of GM plants are at various stages of field trials in India.[25] These include Bt brinjal, Bt tomato (by Indian Council for Agricultural Research) and herbicide tolerant mustard (by ProAgro India Ltd).[26] It is repeatedly alleged by some NGOs such as Research Foundation for Science, Technology and Ecology (RFSTE), Gene Campaign, and Green Peace India that private and public organizations had carried out trangenic field trials without approval or by violating national safety guidelines.[27] They demand public release of data collected from field trials.[28]

1.2. Risks of GM Foods

Various advances made in plant biotechnology are not without opposition. According to some opponents, GM foods will cause environmental and health hazards. There are some empirical studies

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[23] The Bt cotton plant has a foreign gene obtained from a soil bacterium *Bacillus thuringensis* that codes Bt toxin built into the genetic make up of the transgenic crop. The plant produces its own pesticide in the form of Bt toxin all the time in various parts. The Indian cotton variety has been developed by the Maharashtra Hybrid Seeds Company (MAHYCO), using the genetically engineered seed and technology obtained from the American multinational, Monsanto. See, n.17.

[24] Both are supposed to be having enhanced nutritional content, R. Ramachandran, "Now, Golden Rice", *Frontline*, vol. 18, no.1, 2001, pp. 79-81.

[25] UNIDO Biosafety Information Network and Advisory Service (BINAS), http://binas.unido.org/binas/field tran.php3.

[26] *Id.*

[27] See, the Revised Guidelines for Research in Transgenic Plants, 1998, laid down by the Review Committee on Genetic Manipulation (functioning under the Department of Biotechnology, Government of India). The alleged violations in Bt cotton trials include failure to provide for specified isolation distance, absence of precaution containment, failure to adhere to the rDNA Guidelines of the Government of India etc. Vandana Shiva and Others, *Seeds of Suicide* (RFSTE: New Delhi, 2000), Chapter II.

[28] Parvathi Menon, "The Transgenosis Debate", *Frontline*, vol.18, no.14, 2001, p. 107.

substantiating those contentions. For example, Arpad Puztai, a scientist at the Rowett Research Institute in Scotland, reported that the transgenic potatoes damage the health of rats by stunning their growth and injuring immune systems.[29] The main possible risks related to GM foods can be classified into two group: health and environmental. [30]

I.2.1. Health Risks

(a) **Allergens:** The introduction of novel genes with new proteins may cause allergic responses.[31]

(b) **Toxicity:** Possible introduction or increase of toxic compounds as well as novel proteins produced in plants have the potential to cause human toxicity.

(c) **Pleiotropic effects:** Introduction of novel protein combinations may be having unforeseen secondary effects in food plants. No significant secondary effects have been found yet, from commercially available plants or products.

(d) **Antibiotic resistance:** Antibiotic markers like kayamycin are used in plant transformation. They are used for treating infections in humans. Their increased exposure may result in infections in humans to become resistant to antibiotics.

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[29] Devinder Sharma,"Even the Mice won't Eat", *Down to Earth*, vol.10, no.22, 2002, p.51.

[30] See, Human Development Report; Making New Technologies Work for the Human Development, by the United Nations Development Programme (Oxford University Press: New York, 2001); Rajesh Kapur, "Genetically Modified Foods: Concerns and Their Redressal", n. 21,pp.34-47.

[31] A widely known case is that of the allergenicity associated with the original 25 proteins in Brazil nut. The allerginicity found to be retained after it was over expressed in soyabean. Bob B. Buchanan, "Genetic Engineering and the Allergy Issue", *Plant Physiology,* vol. 126, no.1, 2001, pp. 5-7.

1.2.2. Environmental Risks

(a) **Un-intended effects on non-target organisms:** Laboratory studies have shown dangers to the larvae of monarch butterfly feeding on the pollen from Bt plants.

(b) **Effects of gene flow:** Gene flow to close relatives may lead to gene contamination. The transfer of resistance traits to weedy relatives could worsen weed problems.[32]

(c) **Increased weediness:** New traits such as pest or pathogen could cause transgenic crops to become problem weeds, which could result in serious economic harm to farms.

(d) **Pest developing resistance to pest-protected plants:** Insects, weeds, and microbes have the potential to overcome most of the control options available to farmers.[33]

(e) **Concern about virus resistant crops:** GM plants containing virus resistance may facilitate the creation of new viral strains, introduce new transmission characteristics, or cause changes to other, but related, species and viruses.

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[32] There are two reported incidents of crop-to-crop gene flow. One instance is where volunteer canola plants in Canada were found to be resistant to the herbicide round ups. The second incident is a report of the Star Link corn appearing in a variety of supposedly non-engineered corn. N.C. Ellstrand, "When Transgenes Wander, Should We Worry?", *Plant Physiology* vol. 125, no. 4, 2001, pp. 1543-45.

[33] Laboratory studies in India indicate the chances of American and India bollworm population developing resistance to Bt-toxin. It is to be noted that the GEAC, approval for Bt cotton is for a period of three years, after which performance will be evaluated particularly with regard to the evaluation of Bt-resistance in American bollworm. n.18.

(f) **Threat to biodiversity:** Gene flow could spread to wild relatives that are rare and endangered, especially, if the flow happens in the centers of crop diversity.

1.3. International Responses

Concerns regarding GM foods have evoked response from various international bodies. According to the FAO Statement on Biotechnology:

> ... FAO supports a science-based evaluation system that would objectively determine the benefit and risks of each GMO. This calls for a cautious case-by-case approach to address legitimate concerns of the Biosafety of each product or process prior to its release. The possible effects on biodiversity, and the environment and food safety needs to be evaluated, and the extent to which the benefits of the product or process outweigh its risks assessed. The evaluation process should also take into consideration experiences gained by national regulatory authorities in clearing such products. Careful monitoring of the post-release effects of these products and processes is also essential to ensure their continued safety to human beings, animals, and the environment....[34]

In 1995, the Organization of Economic Cooperation and Development (OECD) established a Working Group on Harmonization of Regulatory Over-sight in Biotechnology. The working group develops the 'consensus documents' by setting out the biology of the crop plant, introduced trait of gene products and provides a common base to be used in the regulatory assessment of agricultural product derived through modern biotechnology.[35]

The World Trade Organisation (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures,1994, recognizes the Codex

[34] FAO Statement on Biotechnology, 2000, available at http:www.fao.org/biotech/state.htm .
[35] http://www.oecd.org/ehs/cd.htm .

Alimentarius Commission as the international organisation responsible for setting food safety standards, while the Secretariat of the International Plant Protection Convention is responsible for standards related to plant health.[36]

FAO's and WHO's Codex Alimentarius Commission in 1999 established the Inter-Governmental Task Force on Food Derived from Biotechnology. The Task Force at its third session, in March 2002,came up with the Draft Principles for the Risk Analysis of Food Derived from Modern Biotechnology. The Draft is expected to be approved by the Commission at its 25th Session in July 2003.[37]

A series of Joint FAO/WHO expert consultations were convened in 1990, 1996, 2000 and 2001 regarding foods derived from biotechnology.[38] A fundamental conclusion of the 1990 Consultation was that the use of biotechnology does not result in food inherently less safe than that produced by conventional methods.[39] The consultations focused on the 'substantial equivalence' test, according to which, if a new food or food component is found to be substantially equivalent to an existing food or food component, it can be treated in the same manner with respect to safety. The 2000 consultation agreed that safety assessment of GM food requires an integrated case-by-case approach and was of the opinion that presently there are no alternative strategies that would provide a better assurance of safety than the

[36]Paragraph 4 of Article 3. A Third International standard setting body recognised in the SPS Agreement is the Office of International Epizootics (OIE) for animal health and zoonoses.
[37] Report of the third session of the codex *Adhoc* Intergovernmental Task Force on Foods Derived from Biotechnology, held at Yokohama, Japan, March 2002 available at http://www.codex alimentarius.net . Chapter III of this work analyses the Draft Principles.
[38] See Report of a Joint FAO/ WHO Expert Consultation on Biotechnology and Food Safety, held at Rome, Italy, September 30- October4, 1996, available at http://www.codex alimentarius.net
[39] *Id.*

concept of substantial equivalence.[40] Acknowledging the criticisms of the concept of substantial equivalent test, the 2000 consultation noted that it contributes to a robust safety assessment framework and is not the end point of safety assessment rather, the starting point.[41]

FAO's International Plant Protection Convention (IPPC) offers a common and effective action to prevent the introduction and spread of pests in plants and plant products and the promotion of appropriate control measures. In March 2002, IPPC's Interim Committee on Phytosanitary Measures (ICPM) decided to set up an Expert Working Group to formulate a draft standard providing guidance on the conduct of pest risk analysis for GMOs.[42] The delegates failed to agree whether the standards should constitute a supplement to the existing standard on pest risk analysis (as proposed by the European Commission) or to draw up a stand-alone stand.[43]

1.4. Objective of the Study

The present study aims at examining the issues that are subjects of concern relating to GM foods at both international and domestic levels. An enquiry regarding how the international initiatives have moulded the domestic

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[40] Report of a Joint FAO/ WHO Expert Consultation on Foods from Biotechnology (WHO: Geneva, 2000) available at http://www.codex alimentarius.net This consultation was specific on safety aspect of GM foods of plant origin.

[41] *Id.* It is criticized that while determining equivalence or lack of it, only the bulk, quantitative analysis is carried out. No attempt is made to conduct qualitative biochemical analysis, toxicity or allergenicity tests. In the absence of rigorous testing, it will be impossible to recognize the dangers posed by rDNA technology. Debaghish Banerjee, "Risks of Genetic Engineering," *The Hindu* (New Delhi), May 3, 2001.

[42] The ICPM currently functions as an interim body, until the revised text of the IPPC(1997) comes into force. Documents of the ICPM meeting are available at http:/www.fao.org/ag/a8p/aspp/pq/en/archieve/Kpm4/CPMoze.htm

[43] *Id.*

responses is also intended. For this purpose, the following objectives are set out.

i. To discuss briefly the scientific and economic issues associated with GM foods.

ii. To examine various international and domestic safety regulations and responses in the international trade of GM foods.

iii. To enquire into the nature of a liability regime for international trade in hazardous GM Foods.

1. 5. Scope of the Study

The study is divided into five chapters. The first chapter gives an introduction to the subject of the study, including definitions of key terms used therein. The second chapter identifies major interests associated with GM foods and the applicable law. The third one focuses on the safety regulations in the international trade of GM foods. The fourth chapter examines the redressal mechanisms available against the adverse effects of GM foods. The concluding chapter includes some suggestions. The study does not cover (i) intellectual property protection for GM plants and (ii) safety regulations of laboratory activities that produce GM foods, because the study aims to deal with issue directly related to GM foods and their users.

This chapter attempted an overall view of the status of GM foods and problems associated with it. The playing field consists of various actors having different interests. Some of the interests associated with GM foods are worth mentioning and that is the focus of the next chapter.

CHAPTER II

DIVERSE INTERESTS AND APPLICABLE LAW

2.1. Introduction

The controversies regarding GM foods have different implications for diverse interest groups. Life industries, i.e., the major producers of GM foods, expect maximum profits for their investments and hence desire the unregulated flow of GM foods. The farmers, as the consumers of GM seeds, are in a quandary, whether to go for the much hyped, but still suspect, technology. General consumers of GM goods, fiercely driven by civil society campaigns, do not want to experiment with their health. Concerned government authorities find it hard to handle this perplexing scenario and still are not sure of how to use laws and regulations to satisfy those interests. So any study of GM foods warrants a close examination of various associated interests, followed by a brief sketch of applicable law.

2.2.Diverse Interests

Principal actors in the field of GM foods are farmers, consumers, multinationals and research institutions. All of them have their respective share of interests.

2.2.1.Farmer's Interests

In underdeveloped and developing countries, small-scale farmers are responsible for producing vegetables for their locality. Agriculture is their main source of income. They face the challenge of seed insecurity, which could ultimately affect their self-reliance in food. A frequently cited concern is that as it happened in the case of green revolution varieties, a few superior

trangenic varieties could gain high market shares by replacing more traditional varieties.[1] But the recent happenings in Gujarat (use of unapproved trangenic cotton seeds) reveal that GM seeds are finding favour with small-scale farmers. [2] They prefer such seeds because of its 'bollworm-resistance' capacity and shortened growing season.[3]

Seed companies led by Monsanto had attempted the introduction of 'terminator' seeds in order prevent farmers from saving seeds for successive years.[4] However, the movements against GM crops forced Monsanto to renounce the technology in 1999.[5]

There are also chances of farmers having to spend more time in settling disputes (both as plaintiffs and defendants) than in agriculture. There are reported instances that GM seeds are not performing up to the level as promised by the suppliers.[6] Thus to save the developing country farmers from the situation where they will be further marginalized, the only solution is to take on the 'big companies' by instituting suits.

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[1] Vandana Shiva and Others, "Globalisation and Threat to Seed Security: Case of Transgenic Cotton Trials in India", *Economic and Political Weekly,* vol.34, 1999, pp. 601-612. It is argued that risks of genetic engineering are rooted in the reductionist paradigm of science, which, ignores relationships and inspects and puts value only on one species that is the human being. Vandana Shiva, "Biotechnology; The Failed Miracle", in B Bhattacharya (ed.) *Biotechnology In Agriculture* (Indian Institute of Foreign Trade: New Delhi, 2000),p.54.

[2] C.S. Prakash, 'The Irony of Illegal Bt Cotton,", *The Hindu* (New Delhi) November 7, 2001.

[3] "Walking up to GM cotton", *Frontline,* vol.18, no.21, 2001, pp. 45-46.

[4] The technology may have adverse impact on environment agriculture and health. S.K.Ghosh, "TRAIT-Genetic Use Restriction Tecchnology", *Science and Culture,* vol.67, no.3&4,2001pp.89-92.

[5] Monsanto is currently working on a new technology, which will allow specific traits to be turned on or off. This could be beneficial to farmers, but at the cost of increased dependence on the firm by way of the chemicals necessary to activate the traits. Amitholds Khardori, "Miami Group Vs Rest of the World", 2001, *Down to Earth,* vol.9, February, 15, 2001, pp. 36-45 at p. 37.

[6] Vandana Shiva and Others, *Seeds of Suicide* (RFSTE: New Delhi, 2000), Chapter 1.

Another problem area is the contamination of neighbouring crops by 'gene flow' from GM crops. A perfect example is the 'Star Link' corn incident in the U.S. where the farmers face the continuing possibility of civil litigation by neighbours or grain elevators over contamination issues.[7]

The farmers in GM foods exporting countries are facing a dilemma whether to continue with GM crops or not, because of the altogether rejection of such foods by European consumers.[8] The backlash against GM foods has spread to non-European countries, such as South Korea, Japan, Mexico and even the US.[9] For example, over thirty farm groups across the US have warned their members that planting GM crops would risk their livelihood because of the unpopularity of such crops among the consumers.[10]

2.2.2.Consumer Interests

Currently the international debate over GM foods is mainly going on between a consumer-driven Europe and an aggressive American industry.[11] European consumers are worried about the long-term health and environmental hazards of genetically engineered crops and food products

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[7] Star Link corn was approved by the US Environmental Protection Agency only for animal feed or industrial uses because the corn contains a bio pesticide that may cause allergic reactions in humans. But the corn was found in taco shells and other food products. This was happened due to cross-pollination. Though, Aventis Crop Science, the producer of the corn, had started a buy back programme intended to compensate farmers for their extra costs and lost markets, farmers are facing different kinds of problems. David R. Moles, "GMO Liability Threats for Farmers", November 2001, available at http:/www. Gefood alert.org/ library/ admn/ uploaded files/ GMO-liability- threats- for farmers- ven.doc.

[8] Robert Parlber, " The Global food Fight", *Foreign Affairs* vol.79, no.3, 2000, pp. 24-38.

[9] *Id.*

[10] Some food and beverages companies and several grocery chains have decided not to carry GM foods. See for a narration of such instances, Ved P.Nanda, "Genetically Modified food and International Law- The Biosafety Protocol and Regulation in Europe", *Denver Journal of International Law and Policy*, vol. 28, no.3, 2001, pp. 235-64, at pp. 237-41.

[11] n.8.

though there are no concrete scientific evidence. Consumers demand their right to know what they are buying and eating. [12]

In India, though the consumers are not well versed with the controversy over GM foods, NGOs like RFSTE, Gene Campaign and Green Peace India are generating pressure for transparency in matters related to GM foods. It is recently alleged by Green Peace India that GM foods has entered the Indian market illegally.[13] An independent laboratory test revealed the Proctor and Gamble's Siomil Baby food showing, the presence of Monsanto's GM round up ready crops. [14]

2.2.3.Corporate Interests

The very same companies that produced pesticides and herbicides are now producing genetically engineered crops. This sector is witnessing a number of mergers and takeovers too.[15] Large-scale corporate investments are needed for commercial application of transgenic crops. So it is natural that the corporate seed industry and food producers might be having important commercial interests in maintaining market access for their products.

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[12]K.Dawkins, Battle Royal of the 21st Century", March, 2000 available at http://www.grain.org/publications/mar00/mar001.htm

[13] "Do Imported Foods have GM Ingredients", *Times of India* (New Delhi) June7, 2001.

[14] "Genetic food products have entered India" *The Hindu* (New Delhi) June 7, 2001.

[15] Aventis Crop Science was formed in 1999,with the merger of Hoechst of Germany and Rhone Poulane of France. http://aventis.com. American company Becker Underwood bought Micro-bio Rhizogen Corporation, which is the subsidiary of Micro Bio Group Ltd. based in Britain. http://www.biotech-info.net. World's largest seed companies, Du Pont and Monsanto are agreeing to swap their patent technologies for creating a kind of non-merger monopoly that is overlooked by the government regulations." Dupont and Monsanto: Living in Synergy", 2002, available at http://www.etc.group.org

Both the EU and Japan have steadily cut its purchases of U.S. corn, after the Bt corn was introduced in America.[16] Total American corn exports were down by 12% in the year 2001 in comparison to 2000 and the US believes that the GMO-driven importer alienation has cost the US corn exports.[17] The exporters consider that import restriction on GM foods without sufficient scientific basis hamper free trade.[18]

2.2.4. R & D Interests

R & D in plant genetic engineering is very important for two reasons: to further commercial applications and for assessing the safety concerns. R & D in plant genetic engineering is going to be affected if GM foods suffer a jolt in the market, because research in private domain is always conditional upon returns. Many watch the close association of private sector and public sector in this area cynically.[19]

In India public sector units such as Indian Council for Agricultural Research (ICAR) and the Indian Agricultural Research Institute, are engaged in plant genetic engineering.[20] But there is a considerable increase in the

[16] M.Shah & D. Banerji, "GM Crops and the World Market", *The Hindu* (New Delhi) December 20, 2001.
[17] *Id.*
[18] J.S. Fredland, "Unlabel Their Frankenstein Foods; Exalting a U.S. Challenge to the European Commission's Labeling Requirements for Food Products Containing Genetically Modified Organisms", *Vanderbilt Journal of International Law*, vol. 33, 2000, pp. 183-220.
[19] Alan Ne Huges, "The Regulation of GM foods Who Represents Public Interest?", *International Journal*, vol. LV no. 4,2000, pp. 624-32.
[20] Matin Qaim, "Transgenic Crops and Developing Countries", *Economic and Political Weekly*, vol. 36, n. 32,2001, pp. 3064-70.

number of MNCs involved in plant genetic engineering in the country.[21] Monsanto, Cargil, ProAgro-PGS, Bejo, and Zaden are some of them.[22]

2.3. Legal Response

It is normal of law to respond to changes, which have a social impact. If the existing legal rules are found to be ineffective in handling such impact, there is a need to provide for specific legal provisions. Whatever be the case law performs an onerous function of balancing various conflicting interests. A brief examination of how law deals with the different interests discussed above will be worthwhile.

2.3.1.Applicable Law

There are two sets of applicable law: one emerging from the World Trade Organisation and the other a directly related treaty.

2.3.2. Relevant WTO agreements

Mainly three WTO agreements, namely the General Agreement on Tariffs and Trade (GATT), the Agreement on Application of Sanitary and Phytosanitary Measures (SPS) and the Agreement on Technical Barriers to Trade (TBT), impinge on the international trade in quality GM foods.

GATT provides for certain basic obligations of member countries, such as most favored nation clause (Article I), national treatment clause (Article III), and prohibition of quantitative restrictions (Article XI). But restrictions

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[21] n. 27.
[22] Vandana Shiva and Others, *Seeds of Suicide* (RFSTE: New Delhi, 2000), Chapter 2.

can be imposed on the import of products into a member country in order to protect human, animal or plant health or to conserve exhaustible natural resources (Article XX (b) and (g)).

The SPS agreement essentially provides a framework within which measures intended for human, animal or plant life or health can be imposed.

The TBT agreement sets the parameters for technical regulations and allows such regulations for legitimate objectives such as the protection of health or safety of human, animal or plant life, or the environment.

But how adequately these deal with transgenic foods is not very clear. There may be further clarifications and elaboration of existing provisions in order that they may apply in a predictable, effective and transparent manner.

2.3.3. The Cartgena Protocol on Biosafety, 2001

This Protocol under the framework of the Convention on Biological Diversity (CBD),1992 imposes a general obligation to ensure the development, handling, transport, use, transfer and release of living modified organisms (LMOs include GM foods and seeds, but do not include food products containing GMOs), in such a manner that it prevents risks to biological diversity and human health.

But the Protocol does not impose any obligation on Parties to comply with the Advance Informed Procedure (which is the center piece of the transparency procedure) for LMOs intended for direct use as food or processing.

A peculiar feature of the Protocol is the incorporation of the precautionary approach in risk assessment (Article 10.6 and 11.8). Precautionary approach is given a provisional nature in the SPS agreement, limited by express provisions of the agreement, particularly the need to take into account risk assessment and available scientific evidence. The WTO Appellate Body in the *EC- Beef Hormones* case reiterated this.

2.4. Redressal Mechanisms

Regarding the liability and redress for damage resulting from trans-boundary movement of LMOs, the Inter-governmental Committee on the Cartgena Protocol is in the process of elaborating appropriate rules and procedures. In India, a person can initiate proceedings under Article 32 or 226 of the Constitution of India over the introduction of GM foods. RFSTE has a suit pending in the Supreme Court challenging Monsanto's Bt cotton field trials, alleging a violation of conditions of trial permits. With respect to injuries caused by GM foods, a person can avail the remedy under the Consumer Protection Act, 1986, or can sue for damages under the law of tort.

The EU has come up with a number of regulations regarding the regulation of GM foods. India also has the Manufacture, Use, Import and Storage of Hazardous Genetically Engineered Organisms or Cells Rules, 1989 (promulgated under the Environment Protection Act, 1986) that are applicable against GMS foods (Rules 2 (2) and 17).

CHAPTER III

SAFETY REGULATORY REGIME

3.1.Introducion

The international trade arena is witnessing a fight over the safety regulations of GM foods. So the WTO, which is the most important forum regulating multilateral trade relations, must be having concerns over these issues. This chapter tries to find out the WTO-covered agreements, which attract the safety regulations of GM foods. The legitimacy of the regulatory measures (like import ban or labeling) in the light of these agreements is also examined. The chapter also analyses the Biosafety Protocol, which is predominantly an environmental agreement concerning the trans-boundary movement of GM foods. The Protocol's relation and possible conflicts with the relevant WTO agreements are also analysed. In the final part of this chapter the domestic regulations of GM foods in the US, the EU, and India are also investigated.

As seen in the first chapter, GM foods pose risks to human and plant health and environment. The General Agreement on Tariffs and Trade, 1994 (GATT), the Agreement on Application of Sanitary and Phytosanitary Measures, 1994 (SPS), and Agreement on Technical Barriers to Trade, 1994 (TBT) agreements have provisions regarding these ends.[1]

[1] For the texts see, *The Results of the Uruguay Round of Multilateral Trade Negotiations* (GATT Secretariat: Geneva, 1994).

3.2. GATT, 1994

The GATT contains some basic obligations like most-favoured-nation treatment,[2] national treatment[3], and general elimination of quantitative restriction against imports.[4]

But members are allowed to deviate from these obligations to serve the legitimate objectives such as to protect human, animal or plant health and to protect exhaustible natural resources. Article XX of GATT, 1994 states:

> Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between the countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:
>
> ...
>
> (b) necessary to protect human, animal or plant life or health;
>
> ...
>
> (g) relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with domestic production or restrictions on consumption.

Article XX (b) and (g) of GATT are commonly considered the 'green' exception of the GATT because they offer space for the environmental policies of developed states.[5]

[2] Any concession granted by a contracting party to a product of another country, 'shall be accorded immediately and unconditionally to the like product originating in or destined for the territories of all other contracting parties. Article 1.1.

[3] A member must apply the same standards to domestic and imported products alike without discrimination. Article III.

[4] Article XI.

[5] M.E Foster, "Trade and Environment: Making Room for Environmental Trade Measures with in the GATT", *Southern California Law Review,* vol.91, 1998, pp. 389-430

3.2.1. Protection of Human, Animal or Plant Life or Health under Article XX (b) of GATT, 1994

In the *Thailand-Restriction on Importation of and Internal Taxes on Cigarettes* case, the US challenged before the GATT panel, a ban on imports of cigarettes into Thailand on the ground that it a violated Article XI of GATT, 1947.[6] Thailand defended the ban under Article XX (b) as necessary for the protection of public health: The panel noted:

> ...the import restrictions imposed by Thailand will be considered to be necessary in terms of Article XX(b) only if there were no alternative measures consistent with the General Agreement or less inconsistent with it; which Thailand could reasonably be expected to employ to achieve it health policy....[7]

The panel further noted:

> ....Other countries had introduced strict, non-discriminatory labelling and ingredients disclosure regulations which allow governments to control, and the public to be informed of the content of the cigarettes. A non-discriminatory regulation implemented on a national treatment basis in accordance with Article III:4 requiring complete disclosure of ingredients coupled with a ban on unhealthy substance, would be an alternative consistent with the General Agreement....[8]

Thus the panel found that the importation ban was not necessary within the meaning of article XX (b) because it considered that there were various measures consistent with the General Agreement, which were reasonably available to Thailand to achieve its health policy goals.

In the *Asbestos* case, the WTO Appellate Body (AB) upheld a French ban on Canadian asbestos by holding that it was up to each member of GATT

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[6] GATT,BISD 34S/28(1991).
[7] *Id.*Para.75.
[8] *Id.*Para.77.

to decide on the level of protection that should be made available to its people.[9] The AB noted:

> In our view, France could not reasonably be expected to employ any alternative measure if that measure would involve a continuation of the very risk that the decree seeks to 'halt'. Such an alternative measure would in effect prevent France from achieving its chosen level of health protection.... Given these factual findings by the Panel we believe that 'controlled use' would not allow France to achieve its chosen level of health protection by halting the level of asbestos-related health risks. 'Controlled use' would thus, not an alternative measure that would achieve the end sought by France.[10]

Member States are not obliged to follow majority scientific opinion when it comes to health policy. The AB stated that in assessing the likeness of products, factors like composition, structure, tariff classifications and consumer preferences should also be looked into.

After its entry into force in January 1995, the SPS agreement takes care of all SPS measures affecting international trade and this, independently, from the GATT.[11] The final preambular paragraph of the SPS agreement reads as:

> *Desiring* therefore to elaborate rules for the application of the provisions of GATT 1994, which relate to the use of sanitary and phytosanitary measures, in particular, the provision of article XX (b).

A footnote to this paragraph clarifies that reference to Article XX (b) includes also the chapeau of that article. Thus it is clear that SPS agreement has a standing of its own.

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[9] 2001, *EC- Measures Affecting Asbestos or Products Containing Asbestos*, WT/DS/135/AB/R (March 12, 2001).
[10] *Id.*Para.174.
[11] F. Pauwelyn, "The WTO Agreement on Sanitary Phytosanitary Measures (SPS) as Applied in First Three SPS disputes", *Journal of International Economic Law*, vol.2, 1999, pp.640-664.

Further it is stated that SPS measures which conform to the relevant provisions of the agreement shall presumed to be in accordance with obligations of the members under the provision of GATT 1994 which relate to the use of SPS measures, in particular provision of a Article XX (b).[12]

The panel in the *Beef Hormones* case remarked:

> ...if we were to examine GATT first, we would in any event need to revert to the *SPS Agreement*... (i.e., if a violation of GATT were found we would need to consider whether article XX (b) could be invoked and then would necessarily need to examine the SPS)....[13]

3.3. SPS Agreement

The SPS agreement aims to balance the need to regulate movement of products across the borders in order to protect public health and the need to disallow their use for protectionist purposes.[14] Sanitary or phytosanitary measure is defined in the agreement as any measure applied:

> (a) To protect animal or plant life or health with in the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease–causing organisms;
>
> (b) To protect human or animal life or health with in the territory of the Member from risks arising from additives, contaminants, toxins or disease causing organisms, foods, beverages or feed stuffs;

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[12] Article 2.4. Further Article 3.2 states that SPS measures, which conform to international standards, shall deemed to be consistent with relevant provisions of the SPS agreement and of GATT 1994. The SPS agreement is given effect by Article 14 of the Agreement on Agriculture too.N.1, pp. 39-68.

[13] Report of the panel, *EC- Measures Concerning Meat and Meat Products (Hormones)* – Complaint by Canada, WT/DS48/R/CAN (August 15, 1997) para. 8.45.

[14] For a discussion of the origins and principal provision of the agreement, see, Donne Roberts, "Preliminary Assessment of the Effects of the WTO Agreement on Sanitary and Phytosanitary Trade Regulations", *Journal of International Economic Law,* vol.1, 1998, pp. 377-405 at pp. 377-85; J.J. Barcelo, "Product Standards to Protect the Local Environment the GATT and the Uruguay Round Sanitary and Phytosanitary Agreement", *Cornell International Law Journal,* vol. 27, 1994, pp. 795-776; Julie Corner, "Sanitary and Phytosanitary Measures: What They could Mean for Health and Safety Regulation under GATT", *Harvard International Law Journal,* vol. 36, 1995 , pp. 557-69.

(c) To protect human life or health with in the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or

(d) To prevent or limit other damage with in the territory of the Member from the entry, establishment or spread of pests.[15]

This definition seems to be enough to cover many risks posed by GM foods. But it is observed that potential risks caused by GM foods to the environment or ecosystems are not covered [16]. Moreover, only risks connected with pests or diseases are contemplated; risks that are not strictly consequential upon a 'disease' or pests are also not covered.[17]

The SPS agreement applies to all sanitary and phytosanitary measures that may directly or indirectly affect international trade.[18] But the right of members to undertake any SPS measure is not unlimited. The measure must be applied only to the extent necessary to protect human, animal or plant life or health and is to be based on scientific principles and sufficient scientific evidence.[19] Also the measure shall not be applied in a manner, which would constitute a disguised restriction on international trade.[20]

Members shall base their SPS measures on international standards, guidelines or recommendations wherever they exist.[21]

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[15] "SPS measures include all relevant laws, decrees regulates, requirements and procedures including, *inter alia* and product criteria; process and production methods, testing, inspection, certification and approval procedures... methods of risk assessment, and packaging and labeling requirements directly related to food safety". Annex A, para.5 to the SPS agreement.

[16] A.H. Qureshi, "The Cartgena Protocol on Biosafety and the WTO –Co-existence or Incoherence?", *International and Comparative Law Quarterly*, vol. 49, 2000, pp. 843-55 at p. 849.

[17] *Id.*

[18] Article 1.

[19] Article 2.2.

[20] *Id.* Para. 3.

[21] The agreement specifically refers to three organizations, (1) Codex Alimentarius Commission of FAO/WHO, for food safety: (2) Secretariat of the International Plant Protection Convention (IPPC)

Article 3 paragraph 2, of the SPS agreement sets forth the presumption that SPS measures, which conform to international standards, are consistent with the SPS agreement and GATT 1994. Referring to Article 3, paragraph 2 the Appellate Body (AB) in *Beef Hormones* case noted:

> ... such a measure would embody the international standards completely and, for practical purposes converts into a municipal standard. Such a measure enjoys the benefit of presumption (albeit a rebuttable one) that is consistent with the relevant provisions of *SPS Agreement* and of the GATT 1994.[22]

Thus it is necessary to enquire whether there is any international standard on GM food safety.

3.3.1. The Codex Alimentarius Commission and GM Foods

The Codex Alimentarius has relevance in international food trade because of the need for universally uniform food standards for the protection of consumers.[23] Codex standards have become benchmarks against which national food measures are regulated within the legal parameters of the agreement. The Codex standards are non-mandatory.[24]

The Codex Intergovernmental Task Force on Foods Derived from Biotechnology has agreed to advance the Draft Principles for the Risk

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(3) International Office of Epizootics for Animal Health and Zoonoses. *Id.* Article 3 para. 4, preambular para. 6 and para.3 of Annex A.

[22] *European Communities- Measures Concerning Meat and Meat Products*, WT/DS48/AB/R (January 16, 1997) para. 170. The AB explained that the object and purpose of article 3 is to harmonies SPS measures on a wide basis as possible. *Id.* Para. 165. There are two other cases under the SPS agreement (I) The *Japan-Measures Affecting Agricultural Products* case, WT/DS 76/AB/R (February 22,1999) (II) *Australia – Measures Affecting Importation of Salmon*, WT/DS/18/AB/R (October 20, 1998).In all the three cases the respective SPS measures were found to be violative of the agreement.

[23] *Understanding the Codex* (FAO/WHO:Rome,1999), available at http://www.fao.org/docrep/wg114e/w 9114eoo. htm

[24] In practice Codex is strongly influenced by industry and biotech representatives, which often results in decisions that benefit profit and production at the expense of health and nutrition. John Fagan, "A Report on the Codex Committee on Food Labeling", available at http://www.geocities.com/athens/1527/fcodex.htm

Analysis of Foods Derived from Modern Biotechnology for the consideration of the 25th session of the Codex Alimentarius Commission (CAC)[25]. This could be the first international standard on GM foods if adopted by the CAC in July 2003.[26]

The purpose of the draft Codex principles is to provide a framework for undertaking risk analysis on the safety and nutritional aspects of foods derived from modern biotechnology and the document does not address environmental, ethical, moral or socio-economic aspects of the research, development and production and marketing of these foods.[27] The principles state that risk assessment includes a safety assessment, which is characterized by an assessment of a whole food or a component thereof relative to the appropriate conventional counterpart:

(a) taking into account both intended and unintended effects;

(b) identifying new or altered hazards;

(c) identifying changes, relevant to human health in key nutrients.[28]

A pre-market safety assessment should be undertaken following a structured and integrated approach, which is to be performed on a case-by-case basis.[29] The risk assessment approach is to be based on a consideration of

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[25] Report of the Third session of the Codex *Ad hoc* Intergovernmental Task Force on Foods Derived from Modern Biotechnology (Japan, 4-8, March ,2002) Appendix II.

[26] There are 8 steps taken in the setting of codex standards. The draft principles are at the final step where the draft is returned to the commission for adoption as a Codex standard to be sent to governments for final acceptance. A.A Mackenzie, "The Process of Developing Labeling Standards for G.M foods in the Codex Alimentarius", *Agribiofourm*, vol. 3, no. 4, 2000 pp. 203-208, available at http://www.agbioforum.org

[27] n .25,para. 7.

[28] *Id.* Para. 11.

[29] *Id.* Para. 12.

science-based multi-disciplinary guidelines.[30] Scientific data are generally obtained from a variety of sources such as the developer of the product, scientific literature, general technical information, independent scientists, regulatory agencies, international bodies and other interested parties.[31]

The Draft principles also set out risk management measures which are to be based on the outcome of risk assessment and should be proportional to the risk.[32] Risk management measures may include food-labeling conditions for market approvals and post market monitoring.[33] Post-market monitoring may be undertaken on a case-by-case basis during risk assessment and its practicability should be considered during risk management.[34]

The specific tools for enforcement of risk management measures include the tracing of products for the purpose of facilitating withdrawal from the market, when a risk to human health has been identified or to support post-market monitoring.[35]

The Draft principles further calls for effective interactive risk communication, which should include transparent safety assessment and risk

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[30] The accompanying guidelines include:
(i)Draft Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant – DNA Plants, n. 25, Appendix III.
(ii)Proposed Draft Annex on the Assessment of Possible Allergenicity, n. 25, Appendix IV.
(iii)Proposed Draft Guidelines for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant – DNA Micro Organisms, n. 25, Appendix V.
[31] n.25, Appendix II, paras. 13-14.
[32] *Id.* Para. 16.
[33] *Id.* Para. 19.
[34] *Id.* Para. 20.
[35] *Id.* Para. 21. Footnote to this paragraph makes it clear that application of this should be consistent with the provisions of SPS and TBT agreements. The delegation of the US stated that the issue of tracebility was not unique to food derived from modern biotechnology, while NGOs representing consumer and environmental interests stressed that tracebility was a key risk management measure and could effectively be used in post-market monitoring of un intended effects and control of labeling. The discussions regarding tracebility will be continued with in Codex under the Committee of Food Import and Export Inspection and Certification System. N. 21, paras.22-27 and 89.

management processes.[36] There is a need for consistent, transparent, and well-defined regulatory framework in characterizing and managing the risks.[37] Approach to safety assessment should be reviewed when necessary, to ensure that emerging scientific information is incorporated into the risk analysis.[38]

3.3.2. Codex and GM Foods Labeling

The Codex Committee on Food Labeling (CCFL) examines international food-labeling standards and it is considering the major issues around the labeling of biotechnology-derived products.[39] The committee held nine sessions in a seven-year effort to develop a standard for labeling of such foods.[40]

The 27th session of the CCFL in 1999 set up a Working Group to consider (i) the establishment of a threshold level in food or food ingredients obtained through modern biotechnology, below which labeling would not be allowed, and (ii) the establishment of a minimum level for adventitious or accidental inclusion in food or food ingredients obtained through biotechnology.[41]

It is evident that the Codex is trying to evolve international standards for GM foods, which could be of great importance to the SPS agreement.

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[36] n. 25, Paras. 22-24.
[37] *Id.* Para. 25-26.
[38] *Id.* Para. 30.
[39] D.Buckingham, "The Labeling of GM Foods: The Link between Codex and the WTO", *AgriBioforum* vol. 3, no. 4, 2000, pp. 109-212, available at http://www.agbioforum.org
[40] *Id.*
[41] n.39.Canada and the U.S argued that labels are necessary only if the foods pose a proven risk while developing countries particularly India demanded mandatory labeling of all GM foods. Mark M., "US and Canada Again Derail Global Rules for GM Food Labeling", available at http://www.purefood.org/gefood/dercilabeling.cfm.

3.3.3. Measures Based on International Standards under the SPS Agreement

Under Article 3 paragraph 2 of the SPS agreement, SPS measures can also be 'based on' international standards meaning that such measures may adopt some, not necessarily all, elements of the international standard under Article 3, paragraph.1.[42] Such measures do not benefit from the consistency presumption 'conforming' SPS measures under Article 3, paragraph 2. But the normal burden of proof rules requiring a *prima facie* case of consistency with Article paragraph 1 or other provisions of the SPS agreement or GATT 1994 apply.[43]

3.3.4. Level of Protection

Members have a sovereign right to set a level of protection different from that implicit in international standards and to implement that level of protection in a measure not based on international standard.[44] However this is not an absolute right. Members can adopt higher level of protection:

> ... if there is scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a member determines to be appropriate in accordance with the relevant provision of paragraphs 1 through 8 of Article 5....[45]

A footnote to Article 3.3 of the SPS agreement says that there is scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of

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[42] In *EC- Hormones* case the AB overruled the panel's interpretation of a 'general rule- exception' relationship between article 3.1 and 3.3 of the SPS agreement and the panel equating SPS measures 'based on' and 'conform to' to international standards. n.22, para.171.
[43] *Id.* Para.172.
[44] Article 3.3. It is also laid down that all measures, which are different from that, which would be achieved by measures based on international standards shall not be inconsistent with any other provisions of this agreement.
[45] *Id.*

the agreement, a member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of SPS protection.[46] This examination and evaluation would appear to per take risk assessment required in Article 5.1 and defined in paragraph 4 of Annex A to the SPS agreement.[47]

3.3.5. Risk Assessment and Sufficient Scientific Evidence

The AB in the *Beef Hormones* case remarked that the requirement of a risk assessment as well as of sufficient scientific evidence under Article 2.2 of the SPS agreement is essential for the maintenance of the delicate and carefully negotiated balance in the SPS agreement between the shared but sometimes competing interests of promoting international trade and protecting the life and health of human beings.[48]

Risk assessment is defined in paragraph 4of Annex A of the SPS the agreement as:

> *the evaluation of likelihood of entry, establishment or spread of a pest* or disease within the territory of an importing member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economical consequences; or *the evaluation of the potential adverse effects on human or animal health* arising from the presence of additives, contaminants, toxins or disease-causing organisms in food beverages of feed stuffs.[49] {emphasis supplied}

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[46] The AB in *Japan- Agricultural Product* case noted that there is a scientific justification for on SPS measure, if there is a rational relationship between SPS measure at issue and the available scientific information. The rational relationship is to be determined on a case-by-case basis and will depend on particular circumstances of the case including the characteristics of the measure at issue and the quality and quantity of scientific evidence. n.22, paras. 73-74.

[47] The AB in *EC- Beef Hormones* interpreted any other provisions of the agreement in the last sentence of Article 3.3 to include Article 5. n.22, para. 175.

[48] Regarding the relation between two provisions, both the panel and AB considered that article 5.1 may be viewed as a specific obligation contained a Article 2.2. n.22, para. 172.

[49] Case laws lay down three cumulative requirements for risk assessment:
(i) identify the diseases whose entry, establishment or spread a member wants to prevent within its territory,ssociated with the entry, establishment of spread of the diseases;

In the *Beef Hormones* case, the second part of the risk assessment definition was at issue, i.e. 'potential adverse effects on human health, and the AB noted that the ordinary meaning of 'potential' relates to possibility and is different from the ordinary meaning of probability.[50] In the *Salmon* case, the first part of the definition was at issue, i.e. likelihood of entry, establishment or spread of a pest or disease within the territory of an importing member. The AB here considered the ordinary meaning of 'likelihood' as the same as 'probability'.[51] It is doubtful whether this would mean the introduction of a higher burden and evaluation in a risk assessment of pest-related risks compared to food-related risks.

3.3.6. Factors to be Considered

In assessing risks, members shall take into account available scientific evidence of risks, risk-assessment techniques developed by relevant international organizations, relevant process and production methods, relevant inspection and sampling methods, prevalence of specific diseases or pests, relevant ecological and environmental conditions and quarantine other treatment.[52]

Thus it seems that while assessing the risks of food products, importing country can consider the fact that they are produced by the genetic

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(ii) identify the entry ,establishment or spread of these diseases as well as the associated potential biological and economic consequences; and

(iii) evaluate the likelihood of both according to the SPS measure which might be applied .*Salmon,* para.121, *Japan-Agricultural Product* case, para.112.n.22.

[50] The AB expressed significant concern over the panel's use of the word 'probability' which according to the AB implies a higher degree of potentiality or possibility. *EC- Hormones.* N.22, para. 184.

[51] According to it a risk must be ascertained and defined, rather than being stated in vague terms as a simple possibility that is something that all events in an under-determined universe could occur.N.22, *Salmon*, para.123.

[52] Articles 5.1and 5.2.

engineering techniques. Environmental conditions also could be taken into account.

There is nothing to indicate that the list of factors provided in Article 5.2 is a close list and it is to be borne in mind that risk is to be evaluated under Article 5.1of SPS agreement is not merely only the risk ascertainable in a science laboratory operating under strictly controlled conditions but risks in human societies. In other words, actual potential for adverse effects on human health in the real world where people live and work and die. [53]

Thus there is no need to make a quantitative evaluation of risks, but the risks must be ascertainable. The existence of unknown and uncertain elements does not justify a departure from the risk assessment requirement. [54]

A member need not have to conduct a risk assessment by itself. Assessments may be carried out by other members and international organizations. The only thing necessary is that there must be a rational relationship between the measure and the risk assessment. [55]

Article 5.5 of the SPS agreement demands that while adopting a SPS measure against risks each member shall avoid arbitrary or unjustifiable

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[53] *EC- Beef Hormones ,n.*22, para.187.

[54] *Id.* The AB found that a quantitative requirement finds no basis in the SPS agreement. *Id.* Para.186. But the AB has not given its reasoning to show how scientific uncertainty itself can reflect risk. Risk also involves uncertainty of lack of knowledge of a possible hazard. So the risk of harm is real as long as safety is unproven. V.R. Walker, "Keeping the WTO from Becoming the World Tran-science Organization: Scientific Uncertainty, Science Policy and Fact Finding of Growth Hormone Dispute", *Cornell International Law Journal,* vol. 31, 1998, pp.251-345 at p. 305.In the *Salmon* case the AB held that some evaluation of the likelihood or probability is not sufficient, but the definition in para. 4 to Annex A refers to the evaluation of likelihood and not to some evaluation of likelihood. n.22, para.124. The AB added that the object and purpose of the SPS agreement justify the examination and evaluation of all such risks for human health whatever their precise and immediate origin may be. *Id.* Para. 206.

[55]There is only this substantive requirement under Article 5.1 and no procedural requirement i.e., to submit evidence that it actually to de in to account risk assessment when it enacted the SPS measure. Thus in this count the AB overruled the Panel's findings. n.22, para. 193

distinction it considers appropriate in different situations if such distinction results in discrimination or a disguised restriction on international trade. Thus the article requires the presence of three elements:

(i) the member adopts different appropriate level of protection in different situations;

(ii) those level of protection exhibit differences which are 'arbitrary' or unjustifiable; and

(iii) the measure embodying those differences result in discrimination or a disguised restriction on international trade.

In the *EC-Hormones* case the AB acknowledged the depth and extent of societies experienced within the European Community over the results of the general scientific studies (showing carcinogenicity of hormones), the dangers of abuse and the intrinsic concern of consumers over the quality and drug-free character of the meat available in the internal market. [56]The EC was bound to react to the concerns shown by European consumers, both towards domestically hormone-treated beef and those coming from other countries and hence, the ban was not really designed to protect EC domestic beef producers. [57]

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[56] n.22, para. 245.

[57] But still the EC measure was condemned on the basis of lack of scientific basis. *Id.* para. 245. Thus the AB was creating a legal link between the level of public anxiety and the question whether trade measures conform to the WTO regime. B. S. Chimini, "WTO and Environment: Shrimp Turtle and EC-Hormones Case", *Economic and Political Weekly*, vol. 35, 2000, pp. 1759-61 at p 1756 –59. In the *Salmon* case the dispute involved the complaint by Canada regarding Australia's 1975 ban on importation of eviscerated salmon from Northern Hemisphere. The cited aim was to protect recreational and commercial fish stocks from exposure to exotic pathogens. However stricter sanitary measures applied to two different but comparable situations. This resulted in distinction in level of sanitary protection, which was found to be arbitrary or unjustifiable. n.22, para.158. There were also doubts over the intended domestic protection of Australian salmon industry and the lack of seriously strict sanitary standards on the internal market of salmon products. *Id.* Para.159. If the measure is not based on risk assessment, or insufficient risk assessment, or no risk assessment at all,

3.3.7. Selection of Appropriate Level of Protection

If an ascertainable risk is detected, a member has to make a choice whether it can accept the risk or not. If it can accept it, there is no need for a SPS measure. By adopting a measure it will try to reduce level of risk it can accept.

The determination of appropriate level of protection, a notion defined in paragraph 5 of Annex A, is a prerogative of the concerned member and not of the panel or the AB. [58]

Article 5.6 of the SPS agreement demands that while determining an appropriate level of protection, a member shall ensure that the measure to be adopted is not more trade restrictive than required to achieve their appropriate level of protection taking into account technical and economic feasibility. The AB in the *Salmon* case had determined that this provision requires a three-pronged test. If there is a measure which:

(a) is reasonably available taking into account technical and economic feasibility;

(b) achieve member's appropriate level of protection;

(c) is significantly less trade restrictive than the SPS measure contested, there is a violation of Article 5.6. [59]

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it indicates that the trade restriction measures taken in the guise of SPS measure is a disguised restriction on international trade. *Id.* Para.166.

[58] *Salmons* case, n.22, para.199. The panel in *Hormones* case held that this is achieved by risk management based on non-scientific factors and involves a social value judgment. But the AB overruled this distinction made by the panel between risk assessment and risk management and noted that SPS agreement only speaks of risk assessment and thereby no textual basis of such distinction. n.19, para.181.The AB opined that a member could take into account management of risks when they conduct a risk assessment. *Id.* Para.205-206.

A relevant question in this respect could be whether labeling of GM foods is (i) significantly less trade restrictive to trade than ban; (ii) whether it is technically and economically feasible; and (iii) whether it meets importing countries' appropriate level of protection. Labeling could be a compromise solution than a ban on GM foods (if no specific risk is ascertainable at that time). But exporting countries like the US and Canada have doubts over the economic and technical feasibility of labeling, because they find it very difficult to segregate transgenic and conventional grains. Labeling could also inform the consumers whether the food is genetically modified or contain GMOs, the inclination shown by the AB in the *Beef Hormones* case towards consumer anxiety should also be taken into account.

3.3.8.Provisional Measures

Article 5.7 of the SPS agreement allows members to take provisional measures if the following conditions are satisfied:

(i) when the scientific evidence is insufficient;

(ii) adopt SPS measures on the basis of available pertinent information;

(iii) after adopting the measures, additional information necessary shall be sought for a more objective assessment of risk; and

(iv) a review of the measure accordingly with in a reasonable period of time.

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[59] n.22, para.144. Also see *Japan--Agricultural Product* case, n.22, para.123. In the *Hormones* case the panel seems to suggest voluntary labeling scheme to take care of consumer concerns. N.13, para. 8.278.

The AB defined possibility of provisional measure as a 'qualified exemption' from the obligation to maintain sufficient scientific evidence.[60] Neither Article 5.5 nor any other provision of the agreement sets out explicit prerequisites regarding the additional information or a specific collection procedure or what actual result must be achieved with the additional information.[61]

What constitutes a reasonable period of time for review has to be established on a case-by-case basis and depends on the specific circumstances of each case including the difficulty of obtaining additional information necessary for review and the characteristics of the SPS measure. [62]

In the *EC-Hormones* case, the EC did not invoke Article 5.7 of the SPS agreement, but argued that the precautionary principle was a customary rule of international law or at least a general principle of law and Articles 5.1 and 5.2 of the agreement could not prevent members from being cautious when setting health standards in the face of conflicting scientific information and uncertainty.[63] The AB noted:

> ...the precautionary principle is regarded by some one as a general principle of international environmental law. Whether it has been widely accepted by members as a principle of general international law is less than clear. We consider however that, it is unnecessary and probably imprudent for the Appellate Body in this appeal to take a position on this important, but abstract question....[64][foot note omitted]

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[60] *Japan-Agriculture Product* case, n.19, para.80. This is the only case in which Article 5.7 was directly in question.

[61] Since Article 5.7 demands that a member has to conduct a more objective assessment of risk, the information sought must be germane to conducting such risk assessment. *Id.*Para.92.

[62] Since Japan did not seek to obtain additional information and did not review the varietal test with in reasonable period of time, the AB held that Japan's measure violated Article 5.7, even if it was adopted in accordance with the first two elements. *Id.* Paras.92-94.

[63] n.22, para.16

[64] *Id.* Para.123.

The AB then commented on some aspects of the relationship of the precautionary principle to the SPS agreement:

(i) the principle has not been written into the agreement as a ground for justifying SPS measures that are otherwise inconsistent with the obligations of Members set out in the particular provisions of the agreement;

(ii) the principle finds reflection in Article 5.7, but it does not exhaust the relevance of precautionary principle. The principle is reflected also in the sixth paragraph of the preamble and in Article 3.3;

(iii) a panel while determining the issue of sufficient scientific evidence has to bear in mind that responsible representative governments commonly act from the perspective of prudence and precaution where risks are irreversible,i.e., life-terminating damage to human health, are concerned.

(iv) though the principle does not, by itself and without a clear textual directive to that effect, relieve a panel from the duty of applying the normal (i.e. customary international law) principle of treaty interpretation in reading the provisions of the agreement[65].

Thus the AB, particularly in the *EC-Hormones* case favoured a flexible approach to risk assessment and scientific knowledge, by rejecting the minimum quantifiable magnitude of risk, by ruling that validity of scientific evidence should not be determined by a general acceptance criteria by

[65] *Id.* Para.162.

acknowledging the legitimate role of public concerns, and by acknowledging the role of precaution in the action of responsible governments. [66]

However it seems that a measure under the SPS agreement whether import prohibition or mandatory labeling has to pass the scientific tests established therein. The same conclusion on the lack of scientific basis, which apply to a ban would also apply to a labeling requirement. [67] So a ban or mandatory labeling requirement of GM foods is to be based on risk assessments, which show specific ascertainable risks on a case-by-case basis.[68]

3.4. Conservation of exhaustible natural resources under Article XX (g) of GATT, 1994

Risks related to GM crops include a long-term threat to biological diversity. As mentioned in the first chapter of this study, a monoculture trend may displace the otherwise rich biodiversity of the developing world. So the argument that the diverse biodiversity comes within the ambit of exhaustible natural resources, especially in the context of GM crops threats, is forceful.

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[66] Oren Perez, "Reconstructing Science; the Hormone Conflict between the EU and the United States," *European Foreign Affairs*, vol.3, 1998, pp.562-582; S.P.Quintillion,"Free Trade, Public Heath Protection and Consumer Information, in the European and WTO context", *Journal of World Trade*, vol.33, no.6, 1999, pp.147-197 at p.164. But there is a criticism that the *Hormones* decision will be harmful to the necessary goal of harmonizing the needs of international trade and public health by undermining the role of science. R.D. Thomas, "Where's the Beef? Mad Cows and the Blight of the SPS Agreement", *Vanderbilt Journal of Transnational Law*, vol.32, 1999, pp. 487-517.

[67]. There are two possible labels (i) voluntary labels which would read as "this product (or seed) contain no GMOs (ii) mandatory labels which would involve statements like "this product may contain GMOs". C.F. Range and L.A. Jackson,. "Labeling Trade and Genetically Modified Organisms", *Journal of World Trade*, vol.34, no.1, 2000, pp.111-122.

[68] The AB in the *EC- Beef Hormones* case determined that the scientific information that the EC submitted in support of the measure did not provide sufficient support for the ban undertaken. The evidence showed a general risk of cancer but was not specific enough, as required by the definition of risk assessment under the SPS agreement. n.22, paras.198-200.

In case of measures to protect exhaustible natural resources, the measures must be made effective in conjunction with restrictions on domestic production and consumption. Thus the 'necessary' requirement under Article XX (b) is not applicable to achieve the objective of protecting exhaustible natural resources and hence any measures that limits depletion of natural resources is justified *perse*[69].

There are four important cases under Article XX (g): (i) the GATT panel decision in the *Tuna-Dolphin* case; (ii) *Canada – Measures Affecting Salmon case*;(iii) the AB decision in the *Reformulated Gasoline* case; and (iv) the AB decision in the *Shrimp- Turtle* case. [70]

In the *Tuna-Dolphin* case Mexico challenged the U.S. embargo on all tuna caught using purse-seine nets (which are known ensnare dolphins that swim above the tuna) on two grounds: (i) the U.S. ban violated requirements of Article XI of GATT, 1948 and (ii) the ban was an attempt to protect the domestic US industry. [71] The GATT panel ruled in favour of Mexico on the grounds that the use of trade to protect the environment outside a nation's sovereign territory was not permitted under the agreement and that the ban was not necessary to save dolphins. [72] In the *Canada – Measures Affecting Salmon* case the US challenged the Canadian requirement that harrying and

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[69] P. Bentley Q.C, A Re-assessment of Article XX paragraphs (b) and (g) of GATT 1994in the Light of Growing Consumer and Environmental Concern about Biotechnology", *Fordham International Law Journal*, vol.24, 2000,p.107atp.112.

[70] Panel Report: *United States- Restriction on Imports of Tuna* (16 August, 1991) *International Legal Materials*, vol.1992, p.1598; *Canada-Measures Affecting Exports of Unprocessed Herring and Salmon*,GATT,BISD,355,1988,p.98;United States *Standards for Reformulated and Conventional Gasoline*, WT/ DS2/ AB/R (29 April,1996); *United States-Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R (12 October, 1998).

[71] n.70,para.3.58.

[72] *Id.* Para.5.38.

Salmon caught in Canadian waters be processed in Canada before export, violated article 11 of GATT. The GATT panel interpreted Article XX (g) requirement that measures to be related to conservation of exactable of natural resources as meaning primarily aimed at such conservation. The panel viewed this as a weaker requirement than the requirement of necessity imposed by Article XX (b). The panel found that the Canadian export ban was not primarily aimed at conservation, because accurate statistical data could be collected without such a ban.

The *Gasoline* case was related to the regulation of pollution standards from Gasoline, which allowed domestic refiners to use three different standards whereas the foreign refiners have only one. The AB agreed with the panel's conclusion that clean air was an exhaustible natural resource. The AB stated that the panel should have looked at whether the rules were primarily aimed at the conservation of exhaustible natural resources, not whether the less favourable treatment of imported gasoline was aimed at conservation. The chapeau of Article XX (g) makes it clear that it is the measures, which are to be examined under Article XX (g) and not the legal finding of less favourable treatment and held that the measure met the general requirements of Article XX (g). However, it was found that regulations failed to meet the requirements of the chapeau of Article XX and this constituted 'arbitrary or unjustifiable discrimination' creating a disguised restriction on international trade, because there were other options available to the US.[73]

[73] For a brief discussion of the case see, Craig A.A. Dixon, "Environmental Survey of WTO Dispute Panel Resolution and Panel Decisions, Since 1995; Trade at all costs?", *William and Mary Environmental Law and Policy Review*, vol. 89, 2000, pp. 1-26, at p.4-5

In the *Shrimp-Turtle* case, the US had banned import of shrimps that were caught by Asian fishers through methods not corresponding to the US environmental standards. The US argued that too many sea turtles were killed due to their fishing practice. The AB approved the two-tier test it had laid down in the *Gasoline* case in order to prevent an impugned measure from being pronounced GATT illegal without considering the legitimacy of the measure involved.

The AB observed that the words of Article XX (g) must be read by a treaty interpreter in the light of contemporary concerns of the nations about the protection and conservation of environment and therefore it proceeded to refer to several environmental treaties including the Convention on Biological Diversity, 1992, in order to justify its interpretation of exhaustible natural resources. [74]

The AB found that measures concerning foreign process and production methods could fall under the provisions of the exception clause of Article XX (g). However, the AB stressed the need to strike a balance between the right of a member to invoke an exception under Article XX and the duty of the same member to respect the treaty rights of other members and hence the measure was struck down for the U.S. not pursuing an alternative course of action available rather than relying on unilateral actions. [75]

The AB in *United States –Import Prohibition of Certain Shrimp and Shrimp Turtle Products: Recourse to Article 21.5 of the DSU* by Malaysia case legitimised the use of unilateral measures to realize environmental

[74] n.70,para. 120.
[75] n.70, para. 171.

protection goals, subject to the conduct of good faith negotiations to arrive at a bilateral and multilateral agreement. [76]

So if a dispute comes before a WTO panel import regulations of GM foods, under Article XX (b) or XX (g), recognition of the relevance of process production methods as laid down in the *Shrimp-Turtle* case cannot be overlooked. Indeed, consideration of GM foods as different from ordinary food, on the basis of 'the genetic modification techniques' is a distant possibility.

3.5. Agreement on Technical Barriers to Trade (TBT)

This agreement aims to ensure that regulations and standards, including packaging, marketing and labeling requirements and procedures for assessment of conformity with technical regulations and standards, do not create unnecessary obstacles to international trade.[77] The provisions of this agreement dc not apply to SPS measures as defined in Annex A to the SPS agreement.[78] According to Article 1.1, the agreement covers all products, including agricultural products.

According to Article 2.1 of the TBT agreement, in respect of all technical regulations members shall ensure that products imported from the territory of any member shall be accorded treatment no less favorable than that accorded to like products of national origin and to like products

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[76] WT/DS58/AB/RW (October22,2001). This is seen as a clear move away from the understanding that GATT/ WTO rules shall not regulate process and production methods, i.e., as opposed to product characteristics and move to legitimize green protectionism. B.S. Chimni, "WTO and Environment: Legitimization of Unilateral Trade Sanctions", *Economic and Political Weekly*, vol. 37, no.2, 2002, pp. 133-139

[77]. For the text of the agreement see, n. 1,pp.138-162.

[78] *Id.* Article 1.5.

originating in any other country. Technical regulation is defined by paragraph1 of Annex 1 as:

> Document which lays down product characteristics or related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labeling requirements as they apply to a product, process or production methods.

A standard is defined in paragraph 2 of Annex I as:

> Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labeling requirements as they apply to a product, process or production method.

Thus a technical regulation is a mandatory requirement, while standard is non-mandatory.

Technical regulations aimed to fulfil legitimate objectives such as protection of human health or safety, animal or plant life, or the environment, and prevention of deceptive practices, shall not create unnecessary obstacles to international trade and shall not be more trade restrictive than necessary.[79] In assessing the risks, which the technical regulations target, the relevant elements of considerations include available scientific and technical information, related processing technology or intended end-uses of products.[80]

It is to be noted that the SPS agreement requires a measure to be scientifically justified under the TBT agreement. Scientific and technical information are only relevant elements to be considered. The agreement

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[79] Article 2.2.
[80] *Id.*

encourages the use of internationally agreed standards as a basis for their technical regulation i.e. when such standards exist or their completion is imminent except when such standards or regulation would be an ineffective or inappropriate means for fulfilling the legitimate objectives pursued. [81] Such instances may be fundamental climatic or geographical factor or fundamental technological problems. [82] Thus labeling of GM foods either to take care of the rich biodiversity or to overcome the lack of technology to detect GM ingredients might be a good justification for deviating from international standards.

If a member adopts a technical regulation in accordance with international standards, a presumption is that unless there is a proof to the contrary it does not create any unnecessary obstacles to trade. Article 2 paragraph 9 of the TBT agreement casts an obligation on members to notify other members, products to be covered by the regulation with a brief indication of its objective and rationale if the relevant international standards do not exist or is not in accordance with the technical content of relevant international standards and if the regulation may have significant effect on trade of other members. Article 2 paragraph 10 of same instrument allows the members to bypass this procedural requirements in case of emergencies, but have to go through the same process, once the regulation are adopted.

Developing countries enjoy a special and differential treatment under this agreement. It is recognized that they may face institutional and infrastructure problems in the application of technical standards, regulation

[81] *Id.* Article 2.4.
[82] *Id.*

and conformity assessment procedures. They may *inter alia* adopt technical regulation or standards aimed at preserving indigenous technology and production methods and are not expected to use those international standards that are not appropriate to their development, financial or trade needs.[83] However the scope of this paragraph is not clear regarding whether a member can require labeling of GM seeds (if international standards do not require labeling) for protecting indigenous agricultural production methods. The likes of terminator seeds have strong potential to upset the existing agricultural production methods in developing countries.

In the final analysis, mandatory labeling of GM foods is possible under the TBT agreement. While adopting a labeling measure for GM foods, the notion of like products, as used in Article 2.1 of the agreement, may create some difficulties. The exporters claim that GM and conventional foods are substantially equivalent. Because of this they might be classified as like products, labeling requirement would be violative of Article 2.1. Additionally, Article 2.8 of the agreement requires the members to base technical regulations on product performance requirements. [84] Unless the production or process characteristics are detectable in the final product, these products cannot be discriminated. So it will be interesting to see how process and production methods play their roles in the regulation of GM foods under the TBT agreement.

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[83] Article 12.4.

[84] J.S. Fredland, "Unlabel Their Frankenstein Foods: Evaluating a U.S. Challenge to the European Commission's Labeling Requirements for Food Product Containing Genetically Modified Organisms", *Vanderbilt Journal of International Law*, vol. 33, 2000, pp. 183-220.

Another critical area is the non-exclusive list of legitimate objectives. The list does not explicitly provide for a consumer's right to know, cited in support of GM foods labeling. Questions might also rise when the goal of labeling is not protection against known health risks but protection against unknown risks, including environmental risks. [85]

Apart from the above-discussed WTO agreements, there is one major international environmental instrument, i.e., the Biosafety Protocol, 2001, that seeks to control GM foods. The term used in the Protocol is 'Living Modified Organisms' or LMOs, which is used inter-changeably for GMOs. An appraisal of the Protocol is necessary to understand the impact it could create in the international trade of GM foods.

3.6. Biosafety Protocol, 2001

This Protocol was negotiated under the umbrella of the Convention of Biological Diversity, 1992. [86] Article 8(g) of the Convention mandates each contracting party to establish or maintain means to regulate, or manage risks associated with the use and release of living modified organisms resulting from biotechnology, which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.

The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advanced informed agreement procedure, in the safe transfer, handling and use of any

[85] "GMOs in Multilateral Trade" available at http://www.foodmarketexchnage.com/data_center low/detail/ dc.ir-reference-GMO wto.htm

[86] The Convention was adopted in the UN Conference on Environment and Development (UNCED), Rio de Janeiro, Brazil, *International Legal Materials*, vol. 31, 1992, p. 818.

living modified organism resulting from modern biotechnology as that may have adverse effects on the conservation and sustainable use of biodiversity. [87] Accordingly, the issue was taken up by constituting an Open Ended *ad hoc* Group of Experts on Biosafety at the insistence of G-77 countries and China at the first conference of parties (COPI) in 1994, against the opposition of the US biotech industries.[88] Because of the domestic pressure, the EU joined with the G-77 to have a legally binding Biosafety Protocol. From 1996, onwards the Working Group had several meetings to arrive at a general consensus. But it took four years to arrive at a formal agreement. After fifty ratifications the Protocol will come into force. As of July,8,2002,22 Countries have ratified the Protocol.

Before analyzing the provisions of the Protocol it is necessary to know about who were the key players in the negotiations. [89]

The *Miami Group:* This consisted of the US, Argentina, Canada, Chile and Uruguay. It was interested in protecting free trade in biotech products. Because of the US non-ratification of the CBD, it had only an observer status. But the US had a say in the negotiations through the Miami group. Group members wanted (1) to ensure the Protocol to be consistent with WTO rules, based on sound science, i.e., exclusion of precautionary principle, (2) limited only to certain categories of GMOs, (3) no mandatory labeling rules and (4) not to include socio-economic considerations and liability issues.

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[87] Articles 19(3) and 19(4) require parties to provide any available information about the use and safety regulations required by the Contracting Party in the handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party in to which those organisms are to be introduced.

[88] Special Report, "Modified Treaty", *Down to Earth*", vol.8, 2000, February 29, pp. 24-25

[89] Amitaph Khardosi, "Miami Group Vs Rest of the World", *Down to Earth, vol.* 9, no.9, 2001, pp. 36-45

The *European Union* was firm on its stand on the inclusion of the precautionary approach in the Protocol.

Like -Minded Group: Most of the developing countries and China formed this group. They wanted to protect countries without adequate regulatory or institutional capacity to handle GMO imports. Among their demands were the inclusion of the precautionary principle, the right to take into account potential socio-economic impacts of GMOs, and effective labeling and redressal mechanisms.

The Protocol covers the transboundary movement, transit, handling and use of all LMOs that may have adverse effects on the conservation and sustainable use of biological diversity taking also into account risks to human health. [90]

The objective of the Protocol is stated thus in Article 1:

> In accordance with the precautionary approach contained in principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute ensuring adequate level of protection in the field of safe transfer, handling and use of living modified organisms, resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also in to account risks to human health, and specifically focusing on transboundary movements.

[90] *Id.* Article 4. For a discussion of the Protocol, see, Ved. P. Nanada "Genetically Modified Food and International Law", *Denver Journal of International Law and Policy*, vol. 28, n.3, 2001, pp. 235-64; Sean. D. Murphy. "Biotechnology and International Law", *Harvard International Law Journal*, vol. 42, no.1, 2001, pp. 47-139 at pp. 76-79; K.P.S. Chauhan and R.K. Tyagi, "Application of the Biosafety Protocol: An Indian Perspective", *Ris- Biotechnology Development Review*, vol. 3, no.2, 2000, pp. 10-38; Thomas J. Schoenbaum, "International Trade in Living Modified Organisms: The New Regimes", *International and Comparative Law Quarterly*, vol. 49,2000, pp. 856-866.

The Protocol covers only LMOs, i.e., any biological entity capable of transferring and replicating genetic material and thus inanimate food stuffs like cookies made from GM grains will not come under its purview.

The Protocol's core regulatory mechanisms can be discussed under two heads: (i) advanced informed agreement procedure and (ii) procedure for LMOs intended for direct use as food or for processing.

3.6.1. Advance Informed Agreement (AIA) Procedure

The advance informed agreement procedure, which is set out in Articles 8, 10, and 12 of the Biosafety Protocol shall apply prior to the first intentional transboundary movement of LMOs for intentional introduction into the environment of the Party of import. [91]This procedure is not applicable to LMOs transit through the territory of party, LMOs intended for contained use and LMOs identified in a decision of the COP, as not likely to have adverse effects. [92] Thus, as far as GM foods are concerned, the AIA procedure is applicable only to the transboundary movement of GM seeds for planting.

The Party of export shall notify, or require the exporters to ensure notification, in writing to the competent national authority of Party of import prior to the international transboundary movement of a LMO and the notification shall contain at a minimum, the information specified in Annex

[91] Intentional introduction into the environment does not refer to LMOS intended for direct us as food or feeder processing. *Id. A*rticle 7.2.
[92] *Id.* Articles 6 and 7.1

I.[93] The Party of export shall ensure that there is a legal requirement for the accuracy of information provided by the exporter. [94]

The Party of import shall acknowledge the receipt of notification in writing to the notifier within 90 days of its receipt. [95] The acknowledgment shall state whether the notification, prima-facie, contains the information refereed to in article 8 and whether to proceed according to the domestic regulatory framework of the Party of import or according to the procedure in Article 10. [96]A failure of the Party of import to acknowledge a receipt of a notification shall not imply its consent to an international transboundary movement. [97]

The Party of import shall with in 90 days of the receipt of notification, inform the notifier, whether the international transboundary movement may proceed only after it has given its written consent or after, no less than 90 days without a subsequent written consent. [98]

Within 270 days of the date of receipt of notification, the importing Parties shall inform Biosafety Clearing House the decision taken pursuant a risk assessment. [99] The importing Party can: (i) approve the import with or without conditions including how the decision will apply to subsequent imports of the same LMO; or (ii) prohibit the import; (iii) request for additional relevant information in accordance with its domestic regulatory

[93] Annex 1 demands the details of the exporter, importer, details of the LMO, suggested methods for safety assessment, and regulatory status of the LMO with in the state of export.
[94] *Id.*Article 8.2.
[95] *Id.* Article 9.
[96] *Id* Article 2.
[97] *Id.* Article 9.4.
[98] *Id.* Article 10.2.
[99] *Id.*Article 10.3. The Biosafety Clearing House is established under the Protocol to facilitate the exchange of scientific technical environment and legal information on and experience with LMOs and it will assist parties to implement the Protocol. *Id. A*rticle 20.

framework; or (iv) inform the notifier, the extension of 270 days limit by a definite period of time. [100] Again a failure to communicate a decision shall not imply the importing Party's consent to the transboundary movement of a LMO. [101]

Paragraph 6 of Article 10 of the Protocol sets out the precautionary principle by stating that lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of potential adverse effects of a LMO shall not prevent a party of import from taking a decision as appropriate in order to avoid or minimize such potential adverse effects (on conservation and sustainable use of biological diversity, taking also into account risks to human health).

3.6.2. Procedure for LMOs Intended for Direct Use as Food or for Processing

This procedure covers GM grains, fruits etc. and LMOs (like genetically engineered micro-organisms) for food processing. A Party making a final decision regarding the domestic use, including the placing on the market these types of LMOs, within 15 days of making that decision, shall inform the other parties through the Biosafety Clearing House. [102] This information shall contain at a minimum, details of the applicant, authority name and identity of the LMO, description of the gene modification, the techniques used and the resulting characteristics of the LMO approved uses, risk assessment reports, suggested safety methods, etc. [103] A Party may take a

[100] *Id.* Article 10.3 (a) – (d).
[101] *Id.* Article 10.5.
[102] *Id.* Article 11.1.
[103] *Id.* Annex. II

decision on the import, under its domestic regulatory framework that is consistent with the objective of the Protocol. [104]

LMOs intended for direct use as food may be used for or are capable of replication and thus can escape into the environment. In simple words, GM food grains intended for direct use as food may be used for planting purposes also. However, paragraph 8 of Article 11 allows a party to take a decision in accordance with the precautionary principle, the language of which is couched in the same way as in Article 10.6.

3.6.3. Review of Decisions

A Party of import may at any time, in light of new scientific evidence on potential adverse effects, review and change a decision regarding the intentional transboundary movement and that decision with reasons shall be communicated to the notifier and also to the Biosafety Clearing House within 30 days. [105]

A Party of export or notifier may request the Party of import to review a decision made under Article 10 if it considers that (i) a change in circumstances has occurred which may influence the outcome of the risk assessment upon which the decision was made; or (ii) additional scientific or technical information has become available. [106] A Party of import shall respond in writing within 90 days, or at its discretion can require a risk assessment for subsequent imports.

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[104] *Id.*Article 11.4.
[105] *Id.* Article12.1.
[106] *Id.* Article 12.2

3.6.4. Risk Assessment

The Party of import shall ensure that risk assessments are carried out for decision taken under the AIA procedure. It may require the exporters to carry out the risk assessment and the costs of risk assessment shall be borne by the notifier if the Party of import so requires. [107] Article 15.1 requires that risks assessment undertaken pursuant to the Protocol shall be carried out in a scientifically sound manner in accordance with Annex III.

According to Annex III to the Protocol, risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice and guidelines developed by relevant international organizations. Risk assessment should be carried out on a case-by-case basis. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk. Risks associated with LMOs or products thereof, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of risks posed by the non-modified recipient or parental organisms in the likely potential receiving environment.

Annex III lays down the methodology for risk assessment. This includes the following steps;

(a) an identification of a novel genotypic and phenotypic characteristic associated with the LMOs that may have adverse effects;

[107] *Id.* Article 15.2.

(b) an evaluation of the likelihood of these adverse effects being realized taking into account the level and kind of exposure of the likely potential receiving environment to the LMO;

(c) an evaluation of the consequence these adverse effects should create, be realized;

(d) an estimation of the overall risk posed by the LMO based on the evaluation of the likelihood and consequence of the adverse effects being realized;

(e) a recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and

(f) whether there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the LMO in the receiving environment.

Article 16.2 of the Protocol deals with risk management, by stating that measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects. [108] Without prejudice to this, each party shall endeavor to ensure that any LMO, whether imported or locally developed, has undergone an appropriate period of observation that is proportionate with its

[108] *Id.* Article 16.1.

life cycle or generation time, before it is put to its intended use. [109] Parties shall cooperate to identify and to take appropriate measures regarding the treatment of LMOs or specific traits of LMOs that may have adverse effects.[110]

3.6.5.Labeling Requirements under the Protocol

Each Party shall take appropriate measures taking into account relevant international rules and standards, in order to avoid adverse effects of LMOs that are subject to transboundary movement within the scope of the Protocol are handled, packaged and transported under the conditions of safety. [111]

For LMOs that are intended for direct use as food or for processing, it has to be clearly identified that they 'may contain LMOs and are not intended for intentional introduction into the environment'. The COP shall take a decision on the detailed requirements for this purpose, including specification of their identity and unique identification no later than two years after the entry into force of the Protocol. [112]

LMOs that are destined for contained use have to be clearly identified as living modified organisms. [113]

LMOs that are intended for intentional introduction into the environment of the importing party have to be clearly identified as living modified organisms, specifying their identify and relevant traits, safety

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[109] *Id. A*rticle 16.4.
[110] *Id. A*rticle 16.5.
[111] *Id.* Article 18 (2) (a).
[112] *Id.A*rticle 18 (2) (b).
[113] *Id.*Article 18 (2) (c).

requirements and have to contain a declaration that the movement is in conformity with the requirement of this protocol applicable to the exporter.

The ongoing discussions in the Codex Committee on Food Labeling over the labeling of GM foods will have to take into account this development, especially the "may contain LMOs" requirement for LMOs intended for direct use as food or for processing, though the Codex is not concerned with environmental impact of GM foods. But the Protocol covers both adverse effects to biodiversity and human health.

The Protocol requires parties to cooperate in the development and/or strengthening of human resource and institutional capacities, including biotechnology to the extent that it is required for biosafety, for the purpose of the effective implementation of the Protocol.[114] In reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, a Member may take into account socio-economic consideration arising from the impact of LMOs on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities. Cooperation in research and information exchange in this area is called for.[115]

A descriptive discussion of the Protocol reveals that it effectively creeps into the ground already covered by the WTO agreements earlier examined, especially the SPS agreement. So an enquiry is to be made to identify the converging or conflicting areas and find out whether reconciliation is possible.

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[114] *Id.*Article 22.
[115] *Id.* Article 26.

3.7. WTO Agreements and the Biosafety Protocol

The WTO's Committee on Trade and Environment has been engaged in a debate over the years on the relation between Multilateral Environment Agreements (MEAs) and WTO rules. [116] Many industrialized countries want to place the environment and trade measures on the agenda of trade negotiations. Environmental organizations and their industrialized governments think that increasing discipline in trade policy brought about by the WTO will undermine the effectiveness of MEAs. [117]

To developing countries, the multilateral WTO dispute settlement procedure is an important safeguard to protect their economic and development interests and their options for choosing environmental standards adequate to their economic status. [118] They feel that current rules and dispute settlement system provide enough scope for the protection of the environment. Developing countries fear that accommodating MEAs under WTO rules provides no guarantee that unilateral measures will cease to be used. [119]

World trade policies and environmental policies do provide a certain amount of conflict. But are they reconcilable? If trade rules are pushed to their limit, clearly, that will cause damage to environmental objectives. Likewise, if environmental policies are pushed to the maximum at the expense

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[116] D.B. Mottal, "Multilateral Environmental Agreements (MEA's) and WTO Rules: Why the Burden of Accommodation should Shift to MEAs", *Journal of World Trade,* vol.35, no.6, 2001, pp.1215-1233.

[117] F. Bierman, "The Rising Tide of Green Unilateralism in World Trade Law; Options for Reconciling the Emerging North-South Conflict", *Journal of World Trade*, vol. 35, no.4, 2001, pp. 421-448.

[118] *Id.*

[119] For the different positions taken on the reconciliation of trade and environmental rules, see, n.112.

of trading rules, world trade will suffer. [120] So where and how to strike a balance when two different bodies of international law would react when measures falling under both jurisdictions become a matter of dispute? Any discussion on the relation of the Biosafety Protocol with the WTO agreements has to be pursued, taking into account these opposing stands.

3.7.1. Relationship Between the Biosafety Protocol and the WTO Agreements

The Preamble to the Protocol states:

> *Emphasizing* that this Protocol shall not be interpreted as implying a change in the rights and obligations of a party under any existing international agreements;
>
> *Understanding* that the above recital is not intended to subordinate this Protocol to other international agreements.
>
> *Recognizing* that trade and environment agreements should be mutually supportive with a view to achieving sustainable development.

Nothing in concrete can be traced out from these statements. The relevant rules of interpretations applicable here could be Article 31 of the Vienna Convention on the Law of Treaties, 1969. It reads as:

> 1. A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.
>
> 2. ...
>
> 3. There shall be taken in to account, together with the context;
>
> (a) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions;
>
> (b) any subsequent practice in the application which establishes the agreement of the parties regarding its interpretation;

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[120] John. H. Jackson, *The Jurisprudence of GATT and the WTO* (Cambridge University Press: London, 2000) Chapter 21

(c) any relevant rule of international law applicable in the relations between the parties.

The application of this would appear to mean that the content of the Protocol is intended to supplement the WTO agreements.[121] This situation arises only when a dispute arises as to the application of a treaty either in the WTO or before the dispute settlement mechanisms under the Protocol.

The WTO seems to have stronger dispute settlement mechanism as Article 3 of the Understanding on the Rules and Procedures Governing the Settlement of Disputes (DSU) mandates the members to adhere to the rules and procedures therein.[122] It is recognized that the dispute settlement system of the WTO is a central element in providing security and predictability to the multilateral trading system. Article 23 (1) of the DSU states:

> When members seek the reddress of a violation of obligations or other nullification or impairment of benefits under the covered agreements or an impediment to the attainment of any objective of the covered agreements, they shall have recourse to, and abide by, the rules and procedures of this understanding.

The Biosafety Protocol is yet to evolve a specific dispute settlement mechanism and the Conference of Parties is to exercise functions as may be required for the implementation of the Protocol. [123]

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[121] T.J. Schoenbaum, "International Trade in Living Modified Organisms: The New Paradigms", *International and Comparative Law Quarterly*, vol.49,2000, pp. 856-866.
[122] n.1 , pp.404-433
[123] Article 29 (4) (f).

3.7.2. Conflicting Substantive Provisions

3.7.2.a. Precautionary Approach

The precautionary approach as applied in the environmental context means that it is better to err on the side of regulating or controlling new technologies than to risk new or unforeseen problems. [124]

The precautionary approach has become an important component of international environmental law, right from its incorporation into the Rio Declaration on Environment and Development, 1992. Principle 15 of the Declaration declares:

> 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 Biosafety Protocol, as seen earlier in this chapter, has also embraced the precautionary approach in decision-making. [125]

It is argued that the precautionary principle is not an algorithm for making decisions, for it does not make decisions but is a principle on which

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[124] Precautionary approach has been incorporated in a number of international environmental agreements like Vienna Convention for the Protection of Ozone Layer 1985; Article 3.3 of UN Framework Convention on Climate Change; 9th preambular paragraph of the Convention on Biological Diversity, 1992.

[125] In applying the precautionary approach to LMOs, the following points are to be considered (I) definitions of adverse effects i.e., (a) what is the nature and extent of potential harm (b) what standards are used to measure them;(2) recognition of uncertainty i.e., (a) error bias (b) weight of evidence (c) participation and transparency and; (3) the precautionary action,i.e.,either ban new LMOs or phasing out of existing LMOs;(b) moratoria on further development and commercialization; and (c) conditional approval with monitoring, K. Barret, "The Cartgena Protocol on Biosafety: Applying the Precautionary Principles", 2001 available at http://www.biotech-info.net

one can base decisions. [126] But there are others who feel that the precautionary approach will undermine the benefits of biotechnology, which could be fatal especially to the developing countries. [127]

However, the status of precautionary approach in international environmental law is in any way going to affect the non-parties to the Protocol, especially the US, which is the major exporter of GM foods. According to article 34 of the Vienna Convention on Law of Treaties, 1969, a treaty does not create either obligations or rights for a third state without its consent. Article 38 of the Vienna Convention on Law of Treaties states thus:

> Nothing in Articles 34 to 37 precludes a rule sat forth in a treaty from becoming binding upon a third state as a customary rule of international law.

Further, Article 3 paragraph 2 of the WTO Dispute Settlement Understanding recognizes:

> ... it (i.e., the dispute settlement system of WTO) serves to preserve the right and obligations of Members under the covered agreements, and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law... [Clarification added].

Here comes the importance of the EC argument in the *Beef-Hormones* case that the precautionary principle has become customary rule of intentional law or at least a general principle of law. [128]

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[126] It is a principle for assessing the burden of proof. The principle requires those who want to introduce a new technology to assign the burden of proof, particularly in cases where there is little or no established need or benefit or where the hazards are serious and irreversible. Moe-Wan Ho. "The precautionary principle is coherent", 2000 available at http://biotech-info.net

[127] H.H. Adler, "More Sorry than Safe: Assessing the Precautionary Principle and the Proposed International Biosafety Protocol", *Texas International Law Journal,* vol.35, no. 2,2000, pp. 173-205.

[128] n.22,para. 121

The International Court of Justice in 1998 recognized that the precautionary approach in environment protection couldn't override the obligation of the treaty between Czechoslovakia and Hungary. [129] Referring to this case and several academic writings, the AB in the *Beef- Hormones* case held that whether the precautionary principle is a part of customary international law is far from clear. [130]

Larger trading nations would exploit the lack of scientific evidence for protectionism or for internationalising their value systems. This would lead to a North-South conflict in the field of international trade law as well as global environmental policy. Developing countries therefore have generally objected to any further strengthening of the precautionary principle in WTO law. [131]

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[129] *Case Concerning the Gabcikovo-Nagymero Project (Hungary/Slovakia),* ICJ Judgement, *International Legal Materials*, vol. 37,1998, pp. 162-246 paras.111,114 and 140.

[130] The fact that operationalizing procedure are being established to and in precautionary implementation, itself lends credence to the view that the principle is accepted as a viable and legitimate principle of international law, James Canneroon and J. Aboncher, "The Status of Precautionary Principle in International Law", in P. Freestone and E. Hey (edt.) *The Precautionary Principle and International Law* (Kluwer International: London, 1995) Chapter III. Also see Peter H. Sands, "The Precautionary Principle; Coping with Risk", *Indian Journal of International law,* vol. 40, no. 1,2000,pp. 1-13. But it is argued that great varieties of interpretations given to the precautionary principle and novel and far reaching effects of some applications suggest that it is not yet a principle of international law. The question whether the point at which it become applicable to any given activity remain unanswered, seriously undermines the normative character and the practical utility, although support for it does indicate a policy of greater prudence on the part of those states willing to accept it. P.W Birnie and Boyle, *International Law and Environment* (Oxford University Pres: London, 1992) p. 98.

[131] M. Shahin,"Trade and Environment in the WTO", 1997 available at http://www.twinside.org.sg/title/ach-en.htm .In case of scientific uncertainty, it is argued that the precautionary principle is a necessity. In such instances, the WTO dispute settlement panels should be highly deferential to scientific determinations of national authorities that underlie regulatory measures to protect the environment and public health. David Wirth, "The Role of Science in the Uruguay Round and NAFTA Trade Disciplines", *Cornell International Law Journal*,vol. 27, 1994, pp. 815-859.

3.7.2.b. Production and Process Methods

The Biosafety Protocol brings in the production-process criteria in controlling the transboundary movement of LMOs, by discriminating ordinary organisms and organisms produced out of modern biotechnology.

The WTO does not allow trade barriers to be put in place on the basis of production and processing methods, because it would provide a wide-open door for protectionist interests.[132] But the SPS and TBT agreements consider production and process as relevant while assessing risk.[133] It may seem that insertion of genetic material through biotechnology represent a product characteristic as well as production and processing method, and hence could be handled by the existing WTO rules.[134] This along with the decision of the AB in *Shrimp-Turtle* case seems to legitimise the consideration of production and process a relevant criterion in risk assessment.

In which direction these conflicting provisions lead one is still not clear. The fact that a measure is applied in accordance with the framework set out in that multilateral environmental agreement can also be of some relevance in assessing whether the measure was applied in compliance with the provision of chapeau of Article XX, since the function of the panel is to assess whether the measure is applied in good faith without being a disguised restriction on international trade.

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[132] P.W.B. Philips and W.A. Kerr, "Alternative Paradigms: The WTO versus the Biosafety Protocol for Trade in Genetically Modified Organisms", *Journal of World Trade,* vol. 34, no. 4,2000, pp. 63-75.

[133] See relevant parts of this study

[134] Genetic engineering is a process falling under definition of the Protocol but it is difficult to argue that non-transgenic use of the process adds characteristic to the product (non-transgenic means transfer of genes between the same species). In case of processed foods it is hard to find the GMOs from the products.n.132.

An evaluation to the domestic regulation of GM foods in the US, (the largest exporter of GM foods), the EU (one of the largest importers of US agricultural products) and India will be fruitful in this context.

3.8. US Regulations

In the US there is no special law dealing with the safety of GM foods. The biotech approval process involves three departments: (i) US Food and Drug Administration (USFDA); (ii) Department of Agriculture (USDA); and (iii) Environmental Protection Agency (EPA). [135]

In 1986, the Co-ordinated Framework for Regulation of Biotechnology was issued by the Office of the Science and Technology Policy, prescribing jurisdictions over biotech regulation among several federal agencies. The framework laid down some general principles like, existing laws are to regulate biotechnology, the products of biotechnology and not the process are to be regulated, safety of a product is to be determined on a case-by-case basis, and a coordinated effort is needed among all regulating agencies. [136]

3.8.1. Food and Drug Administration

Biotech food products are regulated under the FDA's Federal Food, Drug and Cosmetic Act (FFDCA). FDA can take regulatory action against foods that are adultered or improperly labeled. A food is considered to be adultered and unlawful if it bears or contains an added poisonous or deleterious substance that may render the food injurious to health, or a naturally occurring

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[135] J.M. Caroll, "US Biotech Regulatory System", in B Bhattacharya (edt.) *Biotechnology In Agriculture* (Indian Institute of Foreign Trade: New Delhi, 2000), p.48.

[136]. For a detailed discussion on US safety regulation of GM foods see, J.C. Kunich, "Mother Frankenstein Doctor Nature, and the Environmental Law of Genetic Engineering", *Southern California Law Review*, vol. 74,2001, pp. 807-911, at pp. 823-846.

substance at a level that is ordinary injurious. Labeling is required for foods containing known allergens or in cases where the nutritional or chemical composition has been significantly altered as compared to conventional counterpart.

In 1992, FDA published a statement that explains how foods derived from new plant varieties (including those developed through biotechnology) are regulated under the Act. [137] Under this policy there is no mandatory pre-market approval, but rather voluntary consultation process to ensure that the industry has addressed all the pertinent issues and concerns. The policy laid down the concept of "substantial equivalence" in the safety assessment of biotech foods. Under the Proposed Rules (2000), the FDA will take steps to ensure that it is informed at least 120 days before the marketing of genetically engineered foods. The information and agency's conclusions will be made available to the public. The new rules would replace the current voluntary practice of consultations with the agency. After reviewing a company's submission, the FDA will issue a letter to the firm describing its conclusion about the safety and regulatory status of the food. [138]

The FDA will also develop guidelines for voluntary labeling of biotech food products to help ensure product label claims on the status of such foods are truthful and not misleading. The draft labeling guidelines will be developed with the help of focus groups for ensuring transparency and to receive maximum consumer output.

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[137] n.135 at pp. 50-51

[138] R.Formonek, "Proposed Rules Issued for Bio-engineered Foods", *US Food and Drug Administrator Consumers Magazine*,2001 available at http://www.fda.gov./fda/feature/2001/2001-food.html

But consumer organizations have criticized that the U.S. system for regulating GM foods has huge loopholes that allow manufactures to market these products with little government control and it frees the FDA from blame if these foods are later found to be unsafe. [139]

Two bills to amend the FFDCA to address the safety and labeling of bio-engineered foods have been introduced in both houses of the U.S. Congress. [140] The Genetically Engineered Food Safety Act would make all transgenic components of bio-engineered foods subject to pre-market review as food additives.

The Genetically Engineered Food Right to Know Act would require labeling of food that contains a genetically engineered material or is produced with a genetically engineered material. [141]

3.8.2. US Department of Agriculture

USDA's Animal and Plant Health Inspection Service (APHIS) ensures that new biotech plant varieties are safe to be used in agriculture as conventional varieties. USDA/APHIS has authority to prevent the introduction and dissemination of plant pests under the Federal Plant Pest Act

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[139] This hands off regulatory approach to GM food regulation was devised by openly pro-business U.S. Administrations in past to benefit the fledging agricultural industry. T. Foreman, "Report Says U.S. Regulation of Genetically Modified Foods, Includes Huge Loopholes" available at http://consumerfed.org/gmfoods.htm.

[140] K.A. Goldman, "Bio-engineered Food-Safety and Labeling", 2000 *Science*, vol. 290, pp. 457-459

[141] In *Stauber* v. *Shalala*, 1995 a district court turned down a demand to require labeling of milk produced with in recombinant bovine somastrophine, because the milk was compositionally indistinguishable from milk produced without the hormone; In *International Diary Foods Association* v. *Amestoy*, 1996 the Court of Appeals for the 2nd circuit held that a Vermont low requiring labeling rbST enhanced milk violated commercial speech rights of the diary manufacturers, because it imposed the equivalent of a warning about method of manufacture, even though the composition of the milk war unaffected, consumer right to know' was insufficient to compel labeling in the absence of a substantial government interest, such as health and safety concerns. *Id.* at p. 459.

and the Plant Quarantine Act. [142] Field-testing of biotech plants in open environment is subject to the authorization under these statutes unless the plant is exempted from APHIS regulation.

In deregulating a biotech plant, APHIS bases its decision on findings that a new plant variety (i) exhibits no pathogenic properties; (2) is no more likely to become a weed than the non-engineered plant; (3) is no more likely to increase the weediness of any other plant which is sexually compatible; (4) will not cause damage to processed agricultural commodities; and (5) is not likely to harm endangered, threatened or non-target species, or other organisms that are beneficial to agriculture. Once reaching such a determination, the new variety is allowed to be treated like any other variety of the same crop. [143]

But it is doubted that previously unregulated plants may become pests upon cross-pollination and in the absence of explicit and reliable regulatory guidelines, the regulators are inadequately prepared to conduct a realistic risk assessments. [144] The regulators rely on the assurances offered by the proponents of a new crop. [145]

3.8.3 Environmental Protection Agency

The EPA conducts extensive scientific reviews to ensure public health and environmental protection by regulating introduction into the environment of new plant pesticide substances (for example, Bt corn), plants or new uses of herbicides in conjunction with transgenic plants (for example, round up

[142] n.135 at p.50.
[143] n.136 at p 840
[144] *Id.* at p. 840-41
[145] *Id.*

ready soybeans).[146] The Toxic Substances Control Act, 1967, is used by the EPA as a statutory mechanism to extent control over certain aspects of genetically engineered plants. For example, the TSCA Biotechnology Programme Office defined microorganism as a chemical substance.[147] When EPA finds that a chemical substance presents an unreasonable risk, the agency may promulgate TSCA regulations to require to stop or to limit the production of that substance. The microbial commercial activity notice is required when person intended to use intergenerics, for commercial purposes in the US.[148]

The EPA regulates pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 1994.[149] This Act mandates the registration of pesticides before distribution and use. It has been used by the EPA to regulate genetically engineered organisms.

Applicants usually conduct field studies to gather information concerning product performance, use and other types of data necessary to support the registration of the product. Registration will be granted if the EPA determines that the pesticide will not cause "unreasonable adverse effect" on the environment when used properly, taking into account economic, social and environmental benefits of the pesticides.

But if the pesticides are produced solely for export to a foreign nation, they need only satisfy certain labeling requirements and be produced by a

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[146] n.135 at pp. 51 .
[147] n.136 at pp .824-30.
[148] *Id.* at p.828.
[149] *Id.* at pp.831-37.

registered applicant subject to the FIFRA record- keeping mandates. There is no need to undertake a detailed risk assessment. [150]

The FIFRA only applies to such life forms that are intended for use as commercial pesticides and there is no mechanism under the Act to control GM life forms other than those designed for marketing as pesticides. [151]

3.9. European Regulations

Consumer anxieties in Europe over GM foods forced different states to adopt different regulatory standards for such foods. The European Community has evolved certain specific regulations regarding GM foods.

3.9.1. Council Directive 90/220/EEC

The Preamble of the Directive puts forward three reasons for the regulation of deliberate release of GMOs: (i) the need to take preventive action; (ii) the need to prevent the potential effects of GMO releases on the environment, which may be irreversible; and (iii) the need to approximate laws of the member states to ensure that the likely unequal conditions for competition or barriers to trade because of disparity between member state's regulation of products containing GMOs do not adversely affect the functioning of the common market. [152]

The manufacturers or importers of a GMO have to notify the competent authorities of the member state in whose market the GMO is to be placed for

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[150] *Id.* at p. 833.

[151] It is also criticized that, the Act is inadequate for providing useful guidelines for the industry, lacks overall guidance, does not cover the issue of cross pollination which will make the living pesticides something new (from the organisms that were subject to FIFRA pre-registration testing) and data collection. *Id.* at p. 833-36.

[152] Official Journal of European Communities, 23.8.1990-No. L.7.

the first time. [153] A risk assessment must be conducted concerning the possible effects on human health and the environment. [154] The notifying party must also provide its proposal for labeling and packaging. [155]

The competent authority of the member state, after receiving a notification, is required to examine it for compliance with the Directive giving particular attention to the environmental risk assessment and the recommended precaution related to the safe use of the product. [156] The authority is required to forward the dossier to the Commission with a favourable opinion or reject the proposed release within 90 days of receiving the notification.[157]

The Commission then has to inform other member states, forwarding the dossier. In case of no objection from other states, the competent authority that received the original notification is to give its consent for the release, informing the Commission and other member states. [158] But if there is any objection from the competent authority of another state, the commission is to submit the proposed measure to a committee composed of the member states and chaired by the representative of the Commission.[159] The Commission is to adopt the measures if they are in accordance with the opinion of the committee. [160] If they are not in accordance with the opinion of the committee or if no opinion is delivered, the Commission is to forward the proposal to the

[153] *Id.* Article 11 (1).
[154] *Id.*
[155] *Id.*
[156] *Id.* Article 12 (1).
[157] *Id.* Article 12 (2).
[158] *Id.* Article 13 (1).
[159] *Id.* Article 13 (3), 21.
[160] *Id.* Article 21.

Council, which will decide the issue by a majority. [161] If the Council does not act within a period of three months, the Commission is to adopt the measures.[162]

If a favourable decision is taken, the competent authority that had received the notifications is to give its written consent for the placing of the GMO product and is to inform other members and the Commission its decision.[163] After such written consent, the product may be used without further notification, throughout the EU.

The Directive authorizes provisional restriction by a member on the use and sale of GMOs in its territory if there are justifiable reasons to consider that such product constitutes a risk to human health or environment.[164]

3.9.2. Commission Directive 2001/I8/EC

This Directive on deliberate release of GMOs amends the Directive 90/220/EC on several counts. [165]

Labeling and tracebility - All food derived from biotechnology, including highly processed corn and soyabean oils, are now exempted, because they cannot be tested for novel DNA or proteins. [166] The tracebility provisions would require records to be kept from farm level on, through the production process. The rule includes a 1% threshold for 'adventitious'

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[161] *Id.*
[162] *Id.*
[163] *Id.* Article 13 (5).
[164] *Id* Article 16 (1).
[165] Available at http://www.biosafety.ihe.be/GB/Dir.Eur GD/DE/1201/2001-18/2001-18-T.html
[166] *Id.* Article 26 and Annex-IV.

presence of GM materials in non-GM commodities. [167] Producers must be able to show that the traces were "technically unavoidable" and the EU or an outside country, for use in food, must have approved that GM material.

The Directive acknowledges that the effects of GMOs may be irreversible and thus precautionary measures should be taken in line with the Cartgena Biosafety Protocol. [168]

Comprehensive environmental risk assessment - This includes compulsory monitoring plans for cumulative long-term effects on human health and biodiversity after release. Any adverse effects to human health and environment that may occur through gene transfer from GMOs shall be accurately assessed on a case-by-case basis. Ethical considerations are also included in the biosafety assessment. To this end, the Commission will set up a centralized authorization procedure that includes the lodging of GMO samples for inspection purposes.[169] The genetic stability of the inserted gene and the phenotypic stability of the GMO must be demonstrated, including any changes to the ability of the GMO to transfer genetic material to other organisms and its potential interactions with the environment. The new directive stipulates phasing out of antibiotic resistance marker gene by 2004. [170]

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[167] *Id* Annex-IV; Environment Committee of the EU recently voted to require the mandatory labeling for meat, diary products and highly refined goods as sunflower oil produced from biotech ingredients, even if no remnants of genetic modifications are available. It also voted to lower, threshold level to0.5% instead of 1%and forbid the sale of any products containing traces of bio-tech ingredients not authorized in the 15 nation EU, even if they are widely authorized grown outside EU. http://www.bio-tech info.net/more-labeling.html

[168] *Id.* Preambular para. 13, Article 32.

[169] *Id.* Annex IV.

[170] *Id.*Article 4.

Public Consultation - Member states have to consult the public and appropriate groups on the proposed release, and make arrangements for this consultation, including reasonable time period for consultation. [171]

3.9. 3. Regulation number 258/97

This European Union adopted regulation applies to "foods which have not hitherto been used for human consumption to a significant degree with in the Community, including food products containing GMOs within the meaning of Directive 90/220/EC, food produced by, but not containing GMOs, food with a new or intentionally modified primary molecular structure. [172] The procedure for approval is similar to that in Directive 90/220/EC.

The purpose of the Regulation is to inform the final consumer through labeling that GMOs are present in the food or that they 'may contain' GMOs, which is to be labeled as such. [173]

3.9.4. Commission Directive 97/35/EC

The Commission considered it necessary to amend Annex-III to the 90/20/EC Directive containing the additional information required in the case of notification for placing of GMOs is to the market. This must include.

(i) A label or accompanying document indicating that the product contains, or consists of genetically modified organisms;

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[171] *Id.*Article 11.
[172] Commission Regulation No. 258/97, Official Journal of European Union Communication, 27.1.1997, no. 43, Article1 (2).
[173] *Id.* Article 8 (1) (d).

(ii) if products are to be placed in mixtures with non-GMOs, information on the possibility that GMOs may be present, is sufficient. [174]

3.9.5.Council Regulation 1139/1998

The novel food regulation (EU Regulation no. 258/97) did not apply retroactively. This regulation applies to "foods and food ingredients which are to be delivered as such to the final consumer, produced whole or in part from GM soya and maize, which had been earlier authorized under Directive 90/220/EC. [175]

The regulation is not to apply to food additives, flavourings for use in foodstuffs or extraction solvents used in the production of foodstuffs. [176]

No new authorization has been granted since the October 1998 *de facto* moratorium on authorizing GM food products irrespective of the fact that several applications are pending. The EU is likely to lift the moratorium on GMO approval that had been in place for nearly four years. But the shipment of bio-engineered corn and other products will not be cleared for sale until 2003 because of the administrative procedure connected with the approval process and continuing resistance among some EU member states.[177]

The next part will assess on the Indian regulatory system, especially in a situation where GM varieties are ready to hit the Indian market.

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[174] Commission Directive 97/35/EC, Official Journal of European Union Communication, 18.6.1997- no. L. 169.
[175] Council Regulation No. 1139/1998, Official Journal of European Union Communication, 26.5.1998-no.L.159.
[176] The Commission Decision 98/613/EC announced in 1998 that it intended to remove this exemption.
[177] *Food an Drink Weekly*, June3, 2002 available at http//: www.special northern light.com/ gmfoods/gmo-imports.htm3#doc

3.10. Indian Regulatory System

In India, in 1989, the Central Government formulated, the Rules for Manufacture, Use, Import, Export, and Storage of Hazardous Micro-organisms, Genetically Engineered Organisms or Cells, which have been in force since 13 September 1993. [178] These rules shall apply to genetically engineered organisms, microorganisms and cells and correspondingly to any substance, and products and foodstuffs etc. of which such cells, organisms or tissues here of form part.[179] Paragraph 2(4) of the Rules lays down the application of it in the following specific cases:

(a) sale, offer for sale, storage for the purpose of sale, offers and any kind of handling over with or with out a consideration;

(b) exportation and importation of genetically engineered cells or organisms:

(c) production, manufacturing, processing, storage, import, drawing off, packaging and replacing of the genetically engineered products;

(d) production, manufacture etc. of drugs and pharmaceuticals and food stuffs, distilleries and tanneries etc. which make use of genetically engineered macro-organisms in one way or other.

3.10.1. Implementation Structure

The Rules set out competent authorities and composition of such authorities for handling of all aspects of GMOs and production thereof.

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[178] These rules are notified by the Ministry of Environment and Forests under the Environment (Protection) Act, 1986.
[179] *Id.* Para 2(2).

3.10.1.a. Recombinant DNA Advisory Committee

The committee functioning under the Department of Biotechnology is to monitor the developments in biotechnology at national and international level. It shall recommend suitable and appropriate safety regulations for India in recombinant research, use and applications from time to time. [180] The committee prepared the first Indian Recombinant DNA Biosafety Guidelines in 1990 for conducting research and handling of GMOs in India. [181]

3.10.1.b. The Review Committee on Genetic Manipulation (RCGM)

The RCGM is constituted by the Department of Biotechnology to monitor safety related aspects in the ongoing research projects and activities involving genetically engineered organisms or microorganisms. The committee also has to bring out manuals of guidelines specifying procedures for regulatory process with respect to activities involving genetically engineered organisms in research, use and applications. [182]

All ongoing projects involving high-risk category and controlled field experiments shall be reviewed by the RCGM to ensure that adequate precaution and containment conditions are followed. The RCGM can lay down procedures restricting or prohibiting, production, sale, importation and use of GMOs. [183]

The RCGM can also approve applications for small experimental field trials that are limited to a total area of 20 acres in multi-locations in one crop

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[180] *Id.* Para. 4(1).
[181] The Indian Recombinant DNA Safety Guidelines and Regulations are available at *http://www.binas.uniodo.org/binas_show_php32=27rty=html_&_table_=_regulation-source-dr_=_regulation.*
[182] *Id.* Para.2(2).
[183] *Id.* Para. 2(3)(e).

season. [184] For monitoring contained field experiments with GM plants, the RCGM had set up a Monitoring-cum-Evaluation Committee, which makes spot visits of the experimental sites and advises the RCGM about the steps to be followed in the conduct of experiments for assessing agronomic benefits, besides conducting environmental risk assessments. [185]

In 1994 and subsequently in 1998, the RCGM has revised the 1990 guidelines for conducting research, using GMOs. [186] The 1998 guidelines emphasize on GM microorganisms and plants. They prescribe detailed procedures for conducting contained field experiments using GM plants and also provide guidance for generating food safety data for transgenic plants.

3.10.1.c. Institutional Bio-safety Committee (IBSC)

This committee is to be constituted by an occupier or any person conducting research activities handling GMOs. Such institutions shall prepare with the assistance of the IBSC an up-date on-site emergency plan according to the manual/guidelines of the RCGM.[187]

3.10.1.d. Genetic Engineering Approval Committee (GEAC)

This committee functions under the Ministry of Environment and Forests and is responsible for approval of activities involving large-scale use of GMOs in research, industrial production and application. The clearance of the GEAC is only from the environmental angle. The committee is responsible for

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[184] N. 181, Chapter 7

[185] P.K. Ghosh, "Evaluation of Transgenic Organisms: An Overview of Rules and Procedures in India", *RIS Biotechnology and Development Review*, vol.3, no.2, 2000, pp. 39-60, pp. 41-42

[186] See n.27,to Chapter 1 of this study.

[187] *Id.* Para. 2(3).

the approval relating to release of GMOs and products into the environment, including field trials. That means large-scale experiments beyond the limits specified within the authority of the RCGM have to be authorized by the GEAC only. [188]

No person shall import, export, manufacture, process or sell any hazardous GMOs except with the approval of the GEAC. Deliberate release of GMOs to the environment or nature for experimental purposes shall not be allowed. However, it can be done in special cases with the permission of the GEAC. [189]

Any food stuffs, ingredients in foodstuffs and additives including processing and containing or consisting of GMOs shall not be produced, sold, imported or used, except with the approval of the GEAC. [190]

All approvals by the GEAC shall be for a specific period not exceeding four years at the first instance, which is renewable for a period of 2 years at a time. The GEAC shall have power to revoke such approvals in following situations:

(a) if there is any new information as to the harmful effects of GMOs;

(b) if the GMOs cause such damage to the environment, nature or health as could not be envisaged, when the approval was given; or

(c) if there is non-compliance with any conditions stipulated by the GEAC.[191]

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[188] *Id.* Para. 7(1).
[189] *n* .178, para 4(6)
[190] *Id.* Para. 7(1)
[191] *Id.* Para.13.

The GEAC may supervise the implementation of the terms and conditions of the approvals either by itself or through the State Biotechnology Coordination Committee or State Pollution Control Board/District Level Committee or any person authorized on its behalf. [192]

3.10.1.e. State Biotechnology Co-ordination Committee (SBCC)

This committee has powers to inspect, investigate and take punitive actions in case of violations of any statutory provisions through the Nodal Department and the State Pollution Control Board/Directorate of Health/Medical Services. [193]

3.10.1.f. District Level Committee (DLC)

This committee to be constituted at the district level is to monitor the safety regulations in installations engaged in the use of GMOs in research and applications. The DLC or representatives of it shall make on-site visits and find out hazards and risks associated, with a view to meeting any emergency. They shall prepare off-site emergency plans and shall regularly submit its report to the SBCC or the GEAC. [194]

Any persons aggrieved by any GEAC or SBCC decision, in pursuance of the 1989 Rules, within 30 days of such decision, may file an appeal to such authority appointed by the Ministry of Environment and Forests. [195]

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[192] *Id.* Para.14.
[193] *Id.* Para. 4(5).
[194] *Id.* Para 4 (6).
[195] *Id.* Para. 19.

3.10.2. Functioning of the Mechanism

The many tired, inter-ministerial set up to monitor the illegal entry of GM germplasm, GM foods and field trials had often been caught off guard. Chapter II of this study pointed out the presence of foods with GM ingredients in India and cultivation of transgenic cotton in India without any prior approval of the GEAC. Although in the second instance, the GEAC was quick to react by directing the Gujarat SBCC to uproot the standing cotton crops and destroy it by burning. It also ordered the destruction of all breeding lines, seed production plots, harvested seeds, plucked cotton bolls and breeding material with the company. [196]

Another instance of lack of compliance with the applicable rules is the manner in which MAHYCO's Bt cotton field trials were conducted. The clearance for all the trials of Bt cotton came through the advisor of the RCGM, where rules clearly stipulates that any such permission can be granted only by the GEAC. The date of sowing obtained from the individual farmers by the RFSTE team shows that the crop had been sown before the trial permissions were obtained in July 1998. [197]

On this basis, the RFSTE filed a suit before the Supreme Court in 1999. The petition *inter alia* sought to check the violation of biosafety regulations in the country. The petition claims that the respondents went against the environmental regulations right from the import of 100gm of seeds

[196] Licenses of the dealers who sold the seeds have been cancelled and the company has been blacklisted. The state government suggested the GEAC to spare the plants and seeds from being destroyed in order save the already troubled farmers. But it was too late because retrieving the germplasm was realistically impossible. "Walking up to GM Cotton", *Frontline*, vol. 18, no. 23,2001, pp 45-46; B.Venkateswaralu , "The Indian Biosafety Regulations on GMOs under Test", *Biotechnology and Development Monitor*, no. 47,2001.

[197] Vandana Shiva and Others, *Seeds of Suicide* (RFSTE; New Delhi, 2000) Chapter 2.

of GM cotton carrying Bt genes in 1995, to multiplying and bulking up of these seeds throughout the country to conduct multi-centric trials of these seeds in the open environment. It is also argued that the trial design lacked steps to preclude the possibility of pollen flow and isolation distance observance. [198]

A few experimental designs have been evolved by the RCGM for conducting trials using GM plants in the open environment. [199] Some Indian studies show that pollen escape is a phenomenon and the implication of this issue has yet not satisfactorily resolved. [200]

The lack of containment of field trials implies that the GMO and the transgenic contained in it can escape into the larger environment through pollination, food chains, and marketing chains. The inherent tendency of biological organisms to multiply and reproduce and interact with other species implies that it can have irrepressibly damaging impact on the environment. [201]

RFSTE has been arguing that the so-called buffer zone of 5 meters isolation distance under the trial designs is not a containment measure in any ecological sense because:

(i) it does not ensure containment by prevention of non-target species feeding on the plants, plant parts having an impact on

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[198] Sachin Saxena, "India and GM crops: Transition with Caution", *AgricultureToday,2001* pp.12-22 .
[199] n.175, 8, p. 57.
[200] *Id.*
[201] n.197.

soil ecology and soil organism, and plant products sold in the market;

(ii) there is arbitrariness throughout the process of designing the scientific basis of the trials on the actual isolation distance required;

(iii) since hybridization and cross-pollination increase from natural to hybrid any hybrid to GMOs, the buffer zones for GMO trails need to be higher than insulation distances used for higher seed breeding;

(iv) even 5 meters is not an adequate safeguard as pollen can travel much further than 5 meters. [202]

Lack of transparency in decision making is another area where criticisms have arisen. The industry considers that the absence of a transparent system has led to unnecessary doubts in the public mind about the implication of GMOs.[203] But on the other hand NGOs are accusing that there is absence of democratic elements in decision making regarding field trails and analysis of the data from field trials. [204]

Status of GMOs intended for direct use as food or for processing is ambiguous, though the GEAC is the relevant authority to give consent. But it cannot expect to screen each and every shipment to the country. The ports and

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[202] *Id.*

[203] . It is argued that the case-by-case approaches is causing unnecessary delays and deny industries the opportunity to present their case. On the other hand, lack of clear guidelines enables the industries to have more influence on formulation and implementation of guidelines. K.P.S. Chauhan and R.K. Tyagi, "Implications of the Protocol on Biosafety-an Indian Perspective", *RIS-Biotechnology Development Review*, vol.5, n.2, 2000, pp. 10-38.

[204] *Id.*

other points of entry are managed by personnel from quarantine agencies working under the Ministry of Agriculture and Ministry of Health and Family Welfare. [205] Then there is the Central Committee for Food Standards under the Prevention of Food Adulteration Act, 1956, which regulates food articles intended for domestic consumption within India. These authorities do not have any facility to detect GMOs or GMO content in any food product. [206] This chapter has attempted an overall view of regulatory regimes for GM foods, both international as well as domestic. Now it is to be seen what are the remedies available to persons adversely affected by GM foods.

[205] Sachin Chaturvedi, "Continued Ambiguity on GMOs", *Economic and Political Weekly*, vol.36, 2001, p.3981
[206] *Id.*s

CHAPTER IV

REDRESSAL MECHANISMS

This chapter presents a brief appraisal of a liability regime suitable for international trade in GM foods. Options available to an Indian adversely affected by such foods are also enquired.

4.1. Basic Law

According to Salmond, "liability is the bond of necessity that exists between the wrongdoer and the remedy of the wrong. Where the remedy is a civil one the party wronged has a right to demand the redress allowed by law and the wrongdoer has a duty to comply with this demand."[1] Thus an effective and efficient redressal mechanism is a necessity for the realization of the rights and obligations of parties.

Article 27 of the Biosafety Protocol mandates the Conference of Parties to:

> ...adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analyzing and taking due account of the ongoing processes in international law on these matters, and shall endeavor to complete this process with in four years.

The Intergovernmental Committee on the Cartgena Protocol 2 (ICCP2) had discussions on this subject in 2001.[2]

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[1] P.J. Fitzgerald, *Salmond on Jurisprudence* (Tripathi: Bombay, 1997 edn.), p. 349.

[2] The ICCP2 recommended the COP to establish an open –ended *ad hoc* group of legal and technical experts to carry out the process pursuant to Article 27 of the Protocol. See, the Report of the Inter-governmental Committee for the Cartgena Protocol on Biosafety, on the Work of its Second Meeting at Nairobi, October 1-5,2001available at http://www.biodiv.org.

4.1.a. State Responsibility

Liability for international environmental harm is embedded in the concept of state responsibility, which predates the international environmental liability regime. In the *Trial Smelter Arbitration* case (1938-41), the Arbitration Tribunal affirmed that "under the principle of international law, as well as of the law of the United States, no state has the right to use or permit the use of its territory in such a manner to cause injury by fumes in or to the territory of another or of property or persons therein, which the case is of serious consequence and the injury is established by clear and convincing evidence."[3]

In the *Cofu Channel* case (1949), the ICJ observed that there were general and well recognised principle of international law concerning every state's obligation not to allow knowingly its territory to be used for acts contrary to the rights of other states.[4] In 1996 the ICJ in its advisory opinion on *The Legality of Threat or Use of Nuclear Weapons* case, declared that "the existence of the general obligations of states to ensure that activities within their jurisdiction and control respect the environment of other states or of areas beyond national control is now part of the corpus of international law relating to the environment."[5] Principle 2 of the Rio Declaration on Environment and Development states:

> States have, ... the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other states or of areas beyond the limits of national jurisdiction.

According to Ian Brownlie, "today one can regard responsibility as a general rule of international law, a concomitant of substantive rules and of the supposition that acts and omissions may be categorized as illegal by reference

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[3] *American Journal of International Law*, vol.35, 1941, p.684, at p.716.
[4] 1949 *ICJ Reports*, p.4.
[5] 1996 *ICJ Reports*, p.15.

to the rules establishing rights and duties."[6] Rules of international law as to state responsibility concerns the circumstances whereby the injured state becomes entitled to redress the damage suffered.[7] In the *Chorozow Factory* case the Permanent Court of International Justice (PCIJ) in 1928 held that it is a principle which seemed to be established by international practice and in particular by the decisions of arbitral tribunals that reparation must, as far as possible, wipe out all the consequences of the illegal act and re-establish the situation which would in all probability have existed if the act had not been committed.[8] In the *Gabghikovo-Nagimaros Project* case the ICJ noted the limitations inherent in the very mechanism of reparation of environmental damage.[9] Thus state responsibility has two parts: to prevent the occurrence of transboundary and to redress the damage if the transboundary harm occurs.

4.1.b. International Law Commission (ILC) and State Responsibility

Since 1949 the ILC has been working on the topic of state responsibility. The latest version being the Draft Articles on Responsibility of States, May, 2001.[10] Every breach by a state of an obligation under international law constitutes an international wrongful act and entails international responsibility of that state.[11] Specific legal consequences arise from such an international wrongful act. The responsible state must cease its wrongful act if it is of a continuing character and must offer appropriate

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[6] Ian Brownlie, *Principles of Public International Law* (Oxford University Press: London, 1998, 5th edn.) p.436.
[7] J.G. Starke, *Introduction to International Law* (Aditya Books; Delhi, 1995) p. 293.
[8] n.6, at p.461.
[9] Because of this and due to the fact that such damage is often irreversible, the Court emphasized the need for vigilance and prevention. *Case Concerning the Gabcikovo-Nagymero Project* (Hungary/Slovakia) ICJ Judgment, International *Legal Materials*, vol. 37,1998, pp. 162-246.
[10] Report of the 53rd Session of the ILC, Chapter 4, available at www.un.org/ilc session/53/53sess.htm
[11] *Id.* Article 1.

assurances and guarantees of non-repetition if circumstances so require.[12] The responsible state is under an obligation to make full reparation for the injury caused by the internationally wrongful act; injury includes any damage, whether material or moral, caused by the international wrongful act of a state.[13] Full reparation can take three forms: restitution, compensation and satisfaction, or these in combination.[14]A responsible state is under an obligation to make restitution that is to re-establish the situation, which existed before the wrongful act was committed. Responsibility is to the extent that reinstatement is not materially possible and does not involve a burden out of all proportion to the benefit deriving from reinstatement instead of compensation.[15] In so far as the damage is not made good by restitution, the responsible state is under an obligation to compensate for the damage caused by the wrongful act. Compensation shall cover any financially assessable damage including the loss of profits so far it is established.[16] Where the restitution or compensation cannot make good the damage, the responsible state is under an obligation to give satisfaction (which may be an expression of a formal apology, regret or another appropriate modality) for the injury caused.[17]

The ILC has been working on the topic of International Liability for Injurious Consequences of Acts not Prohibited by International Law since 1978. Reparation itself is a primary obligation consequential on the causation of harm and not based on any theory of breach of obligation and this will cover transboundary environmental

[12] *Id.* Article 30.
[13] *Id.* Article 31.
[14] *Id.*Article34.
[15] *Id.* Article 36.
[16] *Id.* Aticle36.
[17] *Id.* Article 37.

damages.[18] The ILC has narrowed the scope of its work to "prevention of trans-boundary harm and minimizing the risks" thereof.[19]

But dependence on state responsibility for resolving environmental disputes is considered to be deficient. Jurisdictions of international tribunals are rarely compulsory; remedies available may be limited or inadequate. Thus although compensation for transboundary movement of environmental damage may in appropriate cases, be recovered through international claims, state responsibility is an insufficient means for allocating these costs.[20] This obviously signifies the need for Multilateral Environmental Agreements (MEAs) to deal with liability issues as principle 13 of the Rio Declaration states:

> States shall develop national law regarding liability and compensation for the victims of pollution and other environmental damage. States shall also co-operate in an expeditious and more determined manner to develop further international law regarding liability and compensation for adverse effects of environmental damage caused by activities with in their jurisdiction or control to areas beyond their jurisdiction.

International liability and redress regime for the establishment of environmental policies and standards established through multilateral treaties is a necessity for three reasons. Firstly, threat of incurring liability and potential burden of redress measures act as an incentive towards more precautionary approach to economic activities resulting in the avoidance of environmental risk and damage.

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[18] A.E Boyle, "State Responsibility and International Liability for Injurious Consequences of Acts not Probated by International Law: A Necessary Distinction", *International and Comparative Law Quarterly*, vol. 39, no.1, 1990, p. 1.

[19] See, Draft Articles on Prevention of Transboundary Harm from Hazardous Activities, in n.10,Chapter 5.

[20] P. W. Birnie and A.E. Boyle, *International Law and the Environment* (Oxford University Press: London, 1992), pp. 150-160.

Secondly, a reparative function is served by shifting the cost of environmental damage from society at large to the person or persons responsible for the activity causing damage. Thus a liability and redress regime functions as an instrument for the implementation of the polluter pay principle. Thirdly, holding the author of the environmental harm (either state or non-state actor) responsible for redressing it may act as a deterrent regarding environmentally harmful activities or at least lead to investment in preventive measures.[21]

4.2. Prospective Liability Regimes

A variety of approaches have been used in international law to foster liability and compensation.[22]

4.2.1. Status quo Regime

This is to rely on the existing remedies, both domestic (transnational/litigation) and intergovernmental (negotiation/litigation). Under transnational litigation, injured parties may pursue compensation in domestic or foreign courts based on civil remedies available. Injured parties can approach courts for enforcement of foreign civil judgments. But pursuit of local remedies by claimanents, particularly in foreign courts will be difficult, because of the lack of knowledge and financial resources. In intergovernmental negotiation or litigation, states are the primary actors for resolving claims that arise from private activities.

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[21] See, the CBD Secretariat Document, UNEP/ICCP/2/3, July 31, 2001, available at http;//www.biodiv.org.

[22] For a discussion see Sean. D. Murphy, "Prospective Liability Regime for the Transboundary Movement of Hazardous Wastes", American *Journal of International Law*, vol. 88, no. 1,1994, p. 24. at pp. 37-61.

4.2.2. Soft law Regime

This is quickly negotiated and non-binding in nature. The rationale is to identify the problems in securing and enforcing local judgments and then to persuade governments to agree to correct these problems and commit themselves to intergovernmental dispute resolution. But lack of formality allows governments to take them less seriously. Under the *transitional process regime* there is no establishment of substantive standards to be applied by courts, but would seek to minimize or eliminate difficulties relating to subject matter, choice of law and enforcement of judgments.

4.2.3. Negotiated Civil Law Regime

Most environmental liability agreements contain wholly or primarily private law regime committing states to apply uniform liability rules to private parties under national law. Liability regime set forth in MEAs is defined on the basis of the risk bearing activities and the perception of damage resulting from the activity. The party in this regime might be either a private party or a state or both of them. These agreements would be a civil liability regime, making the operator or exporter liable for injury resulting from the activity addressed in the agreement.[23] This regime would cover the issues related to burden of proof, available damages, and limits of recovery requirements for compulsory insurance or other financial guarantees and channeling of liability.

But for the Biosafety Protocol, most of the developing countries support a state liability regime, because of the cost of litigation, lack of legal

[23] M. Gandhi, " Toward a Liability Regime under Biosafety Protocol", in the *Souvenir and Conference Papers of the International Conference on International Law in the New Millennium: Problems and Challenges Ahead* (organized by Indian Society of International Law, New Delhi, 4-7 October 2001), vol. 1, p. 108.

resources to handle a case before a foreign court and difficulties in executing a decree of national courts in a foreign country. So a combination of state liability and civil liability is also desirable where the state liability will be limited to the extent the state has failed to discharge its regulatory duties.[24] Under the Biosafety Protocol, NGOs are campaigning for a liability regime somewhat similar to the Basal Liability Protocol under which the liability lies with carrier, shipper or other parties found to be at fault.[25]

4.3. Main Issues

The Executive Secretary's Note identifies a number of issues concerning the nature and content of a liability and redress regime that would have to be addressed within in the framework of the Biosafety Protocol.[26] A discussion of those issues will shed some light on a prospective liability regime under the Protocol.

4.3.1. Activities and Damage

The scope of the Biosafety Protocol extends to transboundary movement, transit, handling, and use of LMOs that may have adverse effects

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[24] *Id.*, p. 118

[25] K. Dawkins, "Who should Pay for the Cost of the Star Link Scandal", available at http://wwwmerid.org.

[26] N.21.The CBD Executive Secretaries' Note on the Review of the Existing Relevant international Instruments includes the Vienna Convention on Civil Liability for Nuclear Damage (Vienna Convention) 1963, Convention relating to Civil Liability in the Field of Maritime Carriage of Nuclear Materials (Brussels Convention) 1971, Protocol to Amend the 1963 Convention on Civil Liability for Nuclear Damage (the Vienna Amending Protocol), 1997, the Convention on Supplementary Compensation for Nuclear Damage (the Convention on Supplementary Compensation), 1997, the International Convention on Civil Liability for Oil Pollution Damage (the Oil Pollution Convention), 1967, the International Convention on the Establishment of an International Fund for Compensation for Oil Pollution (the Oil Pollution Fund Convention) 1971, the Convention on Civil Liability for Oil Pollution Damage Resulting from Exploitation and Exploration of Seabed Mineral Resources, 1977, the Convention on Civil Liability for Damage caused During Carriage of Dangerous Goods by Road, Rail and Land Navigation Vessels, 1989, the International Convention on Liability and Compensation for Damage in Connection with the Carriage of Hazardous and Noxious Substances by Sea (the HNS Convention), 1996, the Basel Protocol on Liability and Compensation for Damage Resulting from Transboundary Movement of Hazardous Wastes and Their Disposal (Basel Protocol), 1999, the Convention on Liability for Damage Caused by Space Objects, 1972 and the Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment (the Lugano Convention) 1993, adopted under the auspices of the Council of Europe.

on the conservation and sustainable use of biological diversity, taking also into account risks to human health.[27] So a liability regime would cover these adverse effects.[28] Thus a liability regime under the Protocol will cover pest-resistance problems, pollen movement, genetic contamination, and loss of biodiversity and antibiotic and allergen risks. A general perception is that effects of LMOs may only be observed over a potentially long period of time. So damage may be manifested well after the completion of a specific shipment or well after the introduction of the LMO into the environment of the importing country. Whether scope of Article 27 of the Protocol includes unintended movement of LMOs without any deliberate act to transport them is to be discussed.[29]

4.3.2. Concept and Threshold of Damage

Normally environmental damage is limited to (1) the costs of measure of reinstatement of impaired environment; (2) loss of income deriving from an economic interest in any use or enjoyment of the environment, incurred as a result of the impairment of the environment and; (3) the cost of measures undertaken or to be undertaken to prevent the environmental damage.[30]

For example under the HNS Convention of 1996, liability is with respect to loss of life or personal injury, loss or damage to property; loss or damage by contamination of environment and the cost of preventive measures. Compensation for

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[27] Article 4.

[28] Sean D. Murphy, "Sean. D. Murphy. "Biotechnology and International Law", *Harvard International Law Journal*, vol. 42, no.1, 2001, pp. 47-139 at pp. 76-79 p. 92. But there is one argument that the liability regime under the Protocol should concern only those Transboundary movements, which would result in the damage to biological diversity. See the Meridian Institute Report on the Dialogue Meeting on Liability and Redress Issues under the Cartgena Protocol on Biosafety held in Rome from 11-13 September, 2001 available at http:www.merid.org

[29] n.21, para.75.

[30] n.21,para.78.

impairment of environment other than profit from such impairment is limited to costs of reasonable measures of reinstatement actually undertaken or to be undertaken.[31]

Article 27 of the Protocol speaks about the 'damage resulting from the transboundary movements of LMOs, thereby indicating the source rather than the nature of damage. Other provisions of the Protocol (Articles 4, 7.4 and 10.6) refer to LMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account human health. Article 8(g) of the CBD mentions about LMOs, which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account human health.[32] So the question could be whether 'adverse environmental impacts' add anything extra to the scope of the Protocol. According to Article 2 of the CBD, biological diversity means:

> The variability among living organisms from all sources including, *inter alia,* terrestrial, marine and other aquatic systems and the ecological complexes of which they are part; this includes diversity with in species, between species and of ecosystems.

It will be easy to assess the damage to different species and ecosystem. But the idea of variability among living organisms makes it difficult to assess the quantity of damage.[33] Again there could be differences between 'damage to the conservation and sustainable use of biodiversity' and 'damage to biological diversity'.[34]

Liability under the Basel Protocol of 1999, is with regard to loss of life or personal injury, loss or damage to the property, loss of income directly deriving from an economic interest in any use of the environment incurred as a result of the

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[31] Article 1.6. Preventive measures is defined by Article 1 para 7 as any reasonable measures taken by any person after an incident has occurred to prevent or minimize damage,

[32] Article 14(2) of the CBD refers to issue of liability and redress, including reparation and compensation for damage to biological diversity.

[33] n.21,para.77.

[34] *Id.*

impairment of the environment, the cost of measures actually undertaken or to be undertaken and the cost of preventive measures.[35]Article 2 (2) (d) defines measures of reinstatement as any reasonable measure aiming to assess, reinstate, or restore damage or destroyed components of the environment.

Personal injuries resulting from exposure to LMOs would need to be considered in any definition of damage under the Protocol. Further, there is article 26, which allows members to consider socio-economic impact of LMOs on the conservation and sustainable use of biodiversity.

The problem of 'threshold' of damage also deserves attention. The UN Convention on the Law of Non-Navigational Use of International Watercourses, 1997, provides that watercourse states shall take all appropriate measures to prevent 'significant harm' to other watercourse states.[36] The 1997 Protocol to amend the Vienna Convention on Civil Liability and Damage, 1963 provides for liability for impaired environment unless such impairment is insignificant. [37]

The Biosafety Protocol only speaks about the adverse effects on the conservation and sustainable use of biodiversity, taking also into account human health and there is no indication of the threshold of such effects. But the CBD mentions about the significant adverse impacts on the conservation and sustainable use of biodiversity.[38] Whether liability under the Protocol needs to exceed a minimum threshold of damage, depends on the future negotiations.

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[35] Article2. (c).
[36] Article 7.
[37] Article 7.1.
[38] Articles 7 (c) and 8 (i)

4.3.3. Jurisdictional Application and Geographical Scope

The Oil Pollution Liability Convention, 1969, applies only to pollution damage suffered in the territory of a contracting state, including its territorial sea.[39]

The Basel Protocol is applicable to damage suffered in the national jurisdiction of a Contracting State. But there are two exceptions (1) as regards damage to person or property or cost of preventive measures and (2) as regards damage suffered in an area of a transit non-contracting state as long as such state appears in Annex A of the Protocol.[40]

The HNS Convention applies to any damage caused in the territory including territorial sea and exclusive economic zone of a state party. Nevertheless it is applicable to preventive measures wherever taken and damage (other than by contamination of environment) caused in the territorial sea.[41]

> Article 4 of the CBD defines the jurisdictional scope of the Convention thus:
>
> Subject to the right of other states, and except as otherwise expressly provided in this Convention, the provisions of this Convention apply, in relation to each Contracting Party:
>
> (a) In the case of components of biological diversity, in areas within the limits of its national jurisdiction; and
>
> (b) In the case of process and activities, regardless of where their effects occur, carried out under its jurisdiction or control, within the area of its national jurisdiction or beyond the limits of national jurisdiction.

Further, Article 3 of the CBD sets out the principle that states have the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other states or areas beyond the limits of national jurisdiction. According to the CBD Executive Secretary's Note, "transboundary

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[39] Article 2.
[40] Article 3.
[41] Article 3.

movement of LMOS is in fact, the only specific and practical case clearly identified so far as a process or activity which has likely adverse effects that might occur anywhere, including areas beyond the limits of national jurisdiction".[42] Thus, liability could not only be with respect to biological diversity of other parties but also with respect to damage to the biological diversity of non-party and areas outside national jurisdiction.

Since the Biosafety Protocol does not lay down specific jurisdictional limits the CBD's jurisdictional scope might be extended to a liability regime under the Protocol.

4.3.4. Nature of Liability

There are mainly three kinds of liability: fault liability, absolute liability and strict liability. Fault liability requires the victim to prove the fault on the part of who cause harm intentionally or negligently. Normally the standard of transnational pollution damage in international law is based on fault.[43]

In case there is no admissible evidence, absolute liability has been imposed in international conventions in the field of nuclear accidents and dangers covered by space objects.[44]

Strict liability is based on the English decision of Rylands v. *Fletcher* (1865) where it was held that a person who, for his own purposes brings on his lands and collects and keeps there anything likely to do mischief if it

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[42] n.21,para.83.

[43] L.F.E. Giddie, "Liability for Damage and the Progressive Development of International Law", *International and Comparative Law Quarterly,* vol. 14,1965, p. 1189.

[44] The Convention on International Liability for Damage Caused by Space Objects, 1972 states that, the state that launches a space object, procures the launch, or from whose territory the object is launched is absolutely liable to pay compensation for damage cased by the space object on the surface of the earth or to aircraft in flight.

escapes, must keep it in at his peril and if he does not do so, he is prima-facie answerable for all the damage which is the natural consequences of its escape.[45] Certain defenses like consent of the plaintiff, the common benefit for the plaintiff and defendant, act of strangers, act of god, and statutory authority are available.[46]

International law has already accepted the strict liability standards in specific contexts. It plays an important role in providing compensation for specific environmental damages from activities with low probability harm but severe consequences of the harm should occur.[47]

In many modern activities it would be very difficult for a victim to prove fault on the part of another. Strict liability alleviates this burden that would otherwise weigh upon a victim who suffered damage by requiring a connection between the act and the resultant damage.

The Vienna Convention, 1963, establishes a strict liability for nuclear damage. Though the Convention characterizes liability as 'absolute', specific exceptions are there like occurrence of an incident due to armed conflict, hostilities, civil war, or insurrection or a grave disaster of an exceptional character.[48] Under the Oil Pollution Convention, 1971, the owner is not liable if it can be proved *inter alia* that the damage was as a result of an act of war, hostilities, civil war, insurrection or a natural phenomenon of an exceptional, inevitable, and irresistible character.[49]

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[45] W.V.H. Rogers, *Winfield and Folowicz on Tort* (Sweet and Maxwell; London, 1979) pp. 398-399.
[46] *Id.*
[47] G.E. Gains, "International Principles for Transnational Environmental Liability: Can Developments in Municipal Law Help Break the Impasse?", *Harvard International Law Journal* vol. 30, no. 2,1989, p. 311 at pp. 329-333.
[48] Article IV.
[49] Article3; Also see, Article 7.2 of the HNS Convention.

Articles 4 and 5 of the Basel Protocol, 1999, impose both strict and fault liability respectively. Liability is imposed on any person of damage caused or contributed by his lack of compliance with the provisions of the convention or by his wrongful international, recklessness, or negligent acts or omissions. However, the fault-based liability imposed under Article 5 is expressed to be without prejudice to the regime of strict liability.

Thus a strict liability regime is imposed for environmental damage caused by inherently dangerous activities. Strict liability may be attributed even though the activity does not involve a high degree of risk, if the risk carries with it the possibility of such widespread harm that it becomes abnormally dangerous.[50] It is to be noted that the term 'dangerous activities or substances' also incorporates those activities and substances, that have a low probability of the dangerous incident occurring but with high magnitude of damage once the incident occurs. This is precisely why the precautionary approach has become the central theme of Biosafety Protocol. Hence, there is no reason why there should not be a 'strict liability regime' for adverse effects caused by the transboundary movements of LMOs.

4.3.5. Nature and Scope of Redress Including Valuation of Damage

Under public international law, the defendant is required to make full reparation for the damage caused and reparation can be either in the form of restitution or compensation. Under environmental regimes also, the situation is same. For example, the Vienna Amending Protocol, 1997, defines damage as including the cost of measures of reinstatement of impaired environment. The measures of reinstatement are any reasonable measures which aim to reinstate or restore damaged

[50] n.47.

or destroyed components of the environment or to introduce, where reasonable, the equivalent of these components into the environment.[51]

The HNS Convention, 1996, has the object of ensuring adequate, prompt and effective compensation to persons who suffer damage caused by incidents in connection with the carriage by sea if hazardous and noxious substances are involved. The objective of the Basel Protocol is to provide a comprehensive liability regime as well as a mechanism to ensure adequate and prompt compensation for damage resulting from the transboundary incidents occurring because of illegal traffic of such wastes.

Valuation of damage to biological diversity assumes importance, because restoration or reinstatement may not be feasible. So it is absolutely necessary to apply monetary compensation for loss suffered, because dependence on biological diversity is so important in the socio-economic life of the inhabitants of the affected state in general and of the indigenous and local communities in particular.[52]

4.3.6. Channeling the Liability

The only agreement that establishes full state liability is the Space Objects Liability Convention, 1972. Under the Convention, a state which launches or procures the launching or from whose territory an object is launched is liable.[53]

The Vienna Convention, 1963, channels liability exclusively to the operators of the nuclear installation.[54] The HNS Convention, 1996, imposes liability on the

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[51] Article 9.
[52] n.21,para. 94.
[53] Article
[54] Article 2.

owner of the ship at the time of accident for carrying hazardous and noxious substances by sea or boards a ship.[55]

The Basel Protocol imposes liability on a series of persons like the notifier, disposer, exporter, importer, or re-importer.[56] Under the Biosafety Protocol, there are various parties associated like Party of import, Party of export, exporter, and importer.[57] Exporter is defined by Article 3 (a) as any legal or natural person under the jurisdiction of the Party of export, who arranges for a LMO to be exported.[58]

Exporting and importing states, exporter, importer or notifier might be jointly or separately liable for the adverse effects caused by LMOs or activities involving LMOs.[59] This depends on each one's control over the LMOs or activities involving LMOs.

4.3.7. Limitation of Liability

There has to be a balance between allocating prompt and adequate compensation for victims of damage and the legitimate financial interests of those who carry out the particular economic activity.

The Vienna Convention 1963 provides that the liability of the operator may be limited by the installation State to not less 5 million US dollars for any one nuclear accident.[60] The Vienna Amending Protocol, 1997, sets a new minimum level of operator's liability of 300 million SDRs or 5 million SDRs together with a 'topping-

[55] Article 7.
[56] Article 4.
[57] Article 9.1;Article 10.3.
[58] Article 3(f) in similar way defines an importer.
[59] n.21,para.88.
[60] Article 5.

up sum' from public funds to be made by the Contracting State of the operator in the event of a nuclear accident up to a total of 300 million SDRs.[61]

Under the HNS Convention, 1996, liability of the owner of a ship is limited on the basis of the tonnage of the ship.[62] The owner shall not be entitled to limit the liability if it is proved that damage resulted from the fault of the owner.[63] In case of strict liability for any one incident, the Basel Protocol 1999 limits the liability in accordance with the tonnage of the ships.[64] In case of fault- based liability there is no financial limitations.

For generating adequate and prompt payment of compensation international liability agreements demand the person responsible to maintain insurance or other financial security to cover his maximum liability. [65]

For example, under the HNS Convention 1996, the owner of a ship carrying hazardous and noxious substances shall be required to maintain insurance or financial security, such as the guarantee of a bank or similar financial institution to cover his liability for damage under the convention.[66]

The Basel Protocol requires the persons liable under the strict liability regime to establish and maintain during the time limit of the period of liability insurance, bonds, or other financial guarantee covering such liability.[67]

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[61] Article 7.
[62] Article9.
[63] *Id.* Para. 2
[64] Article 2.
[65] Insurance cover was denied for LMOs on the basis that the technology is new and risks are unknown. "Environment: Insures Wary on Gene-Engineered Products", available at http://www.data.free.de/gen.free.de/genetech/1998/Nov.-Dec/insg 00169.html
[66] Article 4.
[67] Article 14.

The Oil Fund Convention 1971 and HNS Convention 1996 create international funds to provide compensation when the protection afforded by the owner's or operator's liability regime is either inadequate or unavailable.

The Oil Fund Convention established the International Oil Pollution Fund.[68] The Fund is under an obligation to pay compensation in case where a victim is unable to obtain full and adequate compensation under the 1969 Convention because (1) no liability arises under the 1969 Convention or (2) the owner liable under the 1969 Convention is financially incapable of meeting his obligations in full; or (3) the damage exceeds the owners liability under the 1969 Convention.[69] The Fund is to indemnify the ship owner or his insurer for a portion of the ship owner's liability under the 1969 Convention.[70] The Fund may also provide assistance to contracting party to take measures to prevent or mitigate pollution damage for which the Fund may be called upon to pay compensation.[71] The Fund's obligation to pay compensation is limited.[72]

The HNS Convention establishes the International Hazardous and Noxious Substance Fund.[73] The situations when the Fund will pay compensation are the same as in the Oil Fund Convention.[74] The Fund has to give assistance to State Parties upon request to undertake measures to prevent or mitigate damage arising from an incident in respect of which the Fund may be called upon to pay compensation.[75] Contributions to the Fund are to be made by consignees of specified cargo in each

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[68] Article 2.
[69] Article 4.
[70] Article 5.
[71] Article 4.
[72] Article 5.
[73] Article 13.
[74] Article 14.
[75] Article 15 (c).

State Party.[76] The State Party may at the time of becoming a party declare that it agrees responsibility imposed by the Convention on any person liable to pay compensation to the fund.[77]

Under various liability instruments, there are time limitations within which claims for compensations can be instituted. The HNS Convention provides that right shall be extinguished unless an action is brought there under within three years from the date when the person suffering the damage knew or ought reasonably to have known of the damage and of the identity of the owner. In no case, an action shall be brought latter than ten years from the date of the incident, which caused the damage.[78]

There has to be a cautious approach in carving out a time limit for instituting claims under the Biosafety protocol, because environmental, health and socio-economic impact of LMOs may not be apparent in a short-term period.

4.3.8. Jurisdiction, Mutual Recognition and Enforcement of Judgments

Victims of damage must be sure of the court or/and courts before which actions for claims can be initiated. Uncertainty over jurisdiction creates hardships for the victims. It is also necessary that once the judgment is delivered, it should be recognized as final and binding in the respective territories of enacting states and a victim should be able to enforce it in any of those territories.[79]

Under the HNS Convention, if in the territories of one or more State Parties, preventive measures have been taken to prevent or minimize damage in such territory,

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[76] Articles16-22.

[77] Article 23.The Fund shall have an Assembly consisting of all State Parties and a Secretariat. The Director shall be Chief Administrative Officer of the Fund and he shall function subject to the instruction given by the Assembly. Articles 26-30.

[78] Article 37. Under the Basel Protocol, it is 5 and 10 years respectively (Article 13). The Vienna Amending Protocol 1997, fixes the time limit as 30 years in case of loss of life or property or personal injury or 10 years with regard to any other injury (Article 8).

[79] n.21,para. 99.

action for compensation may be brought only in country of any such Sate Parties.[80] Jurisdictions regarding action for incidents outside the territory of any state lie with the courts of the country where the ship is registered (in case if the ship is unregistered, the state party whose flag the ship is entitled to fly) or the state party where the owner has his habitual residence or principal place of business or a State Party where a fund for compensation has been constituted by the owner.[81] Under the Basel Protocol, actions for compensation can be brought before the courts of the Contracting Party where the damage was suffered, incident occurred, or the defendant has his habitual residence or principal place of business.[82]

In most of the liability instruments, it is provided that any judgment given by a court with jurisdiction which is enforceable in the state of origin where it is no longer subject to ordinary forms of review, shall be recognized in any state party except when the judgment is obtained by fraud or where the defendant was not given reasonable notice and a fair opportunity to present the case.[83]

A combination of civil liability regime and international fund regime seems to be ideal for the Biosafety Protocol. The civil liability regime provides a direct and efficient remedy devoid of the complexities of law of state responsibility and it takes on the persons who actually cause the injuries.[84] Also it acts as a deterrent for the MNCs who will be forced to evolve adequate safety assessment techniques. The international fund regime will be helpful for the hapless farmers and consumers who may be adversely affected by GM foods.

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[80] Article 38 (1).
[81] Article 38(2).
[82] Article 17.
[83] See, Articles 40 of the HNS Convention; Articles XI and XII of the Vienna Convention 1963 and Article 21 of the Basel Protocol.
[84] n.20, p.201

4.4. Redressal Mechanisms in India

In India, the law directly applicable to GM foods is the 1989 Rules.[85] Any violation of those rules attracts the application section 15 of the Environment (Protection) Act, 1986. Whoever fails to comply with those rules shall be in respect of such failure or contravention be punishable for a term which may extend up to 5 years or fine which may extend up to 1 lakh rupees or with both. If it is a continuing failure or contravention, additional fine shall be imposed which may extend up to Rs.5000 for every day which such failure or contravention continues. After the conviction, if such failure or contravention continues beyond one year from the date of conviction, the offender shall be punishable with imprisonment for a term, which may extend up to 7 years.

According to section 19 of the Act, a court can take cognizance under the Act only on a complaint made by (i) the central government or any officer authorized in this behalf by the central government; or (ii) any person who has given notice not less than 60 days in the manner prescribed, of the alleged offence and of his intention to make complaint to the central government or officers authorized.

4.4.1. Remedies Available under Articles 32 and 226 of the Constitution

Articles 32 and 226 of the Indian Constitution guarantee the right to move the Supreme Court and High Court respectively to enforce the

[85] See Chapter 3 of the study.

fundamental rights guaranteed by part III of the Constitution and both can issue appropriate writs or directions for the enforcement of those rights.[86]

The Supreme Court of the India through its judicial pronouncements has relaxed the rule of *locus standi* in proceedings under the writ jurisdiction. Thus public interest litigations can be filed at the instance of public spirited citizens for the enforcement of those people's rights who because of their poverty or socially or economically disadvantaged position are unable to approach the Court for relief.[87]

The Supreme Court, through its creative interpretations of Article 21 of the Constitution, has elevated certain rights like the right to health, the right to clean environment, and the right to livelihood to the status of fundamental rights, so that persons can directly approach the Supreme Court or High Court for the violation of those rights.[88]

Some decisions of the Supreme Court in the environmental field will have some bearing on GM foods. In *Rural Litigation and Entitlement Kendra* v. *State of U.P,* the Court ordered the closure of certain limestone quarries on the ground that there were serious deficiencies regarding safety measures. The Court had appointed a committee for the purpose of inspecting certain lime stone quarries.[89]

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[86] The jurisdiction of High Court is not limited to the protection of fundamental rights but also for other legal rights. See J.N. Pandey, *Constitutional Law of India* (Central Law Agency: Allahabad, 1994).
[87] *S.P. Gupta and Others* v. *President of India and Others,* A.I.R. 1982 SC 149. For a discussion of other cases see, n. 86, pp. 244-248.
[88] n. 22, pp. 165-191.
[89] (1985) 2 SCC 431.

In *Shriram Food and Fertilizers* case the Court directed the company, manufacturing hazardous and lethal chemicals and gases posing danger to health and life workmen and people living in its neighborhood, to take all necessary safety measures before reopening the plant. The management was directed to deposit a sum of Rs.20 lakhs by way of security for payment of compensation claims of the victims. The Court enunciated the principle of strict and absolute liability for harms caused by enterprises engaged in hazardous and inherently dangerous activities. This liability, according to the Court is not subject to any of the exceptions, which operate vis-à-vis the tortious principle of strict liability under the rule in *Rylands* v. *Fletcher.*

The Court also held that the measure of compensation payable should be correlated to the magnitude of the injury caused and the capacity of the enterprise so that the same can have a deterrent effect. However compensation under writ jurisdiction would be given only in appropriate cases. The Court clarified that ordinarily a petition under Article 32 should not be used as a substitute for enforcement of right through the ordinary process of civil courts. This mechanism will be used only when it would be gravely unjust to ask the victim to go to the civil court for claiming compensation.[90]

In *Vellore Citizen Welfare Forum* v. *Union of India,* the Court stated that the polluter pay principle, precautionary principle, and the special concept of onus of proof are part of the environmental law of the country.[91]

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[90] *M.C. Mehta* v. *Union of India,* A.I.R. 1987 SC 1086.
[91] (1996) 5 SCC 647.

In *A.P. Pollution Control Board* v. *M.V. Nayadu* the Court held that precautionary duties must not only be triggered by the suspicion of concrete danger but also be justified by concern or risk potential.[92]

4.4.2. Liability under Law of Tort

Tortious liability arises from the breach of duty primarily fixed by law. This duty is towards persons generally and its breach is redressible by an action for unliquidated damages.[93] Thus tortious duties are not dependent upon the agreement or consent of persons subjected to them.

Genetic contamination caused by GM crops might hold farmers and seed companies liable for claims under trespass to land, nuisance, negligence, or strict liability.[94]

Trespass to land means interference with the possession of land without lawful justification. It could be committed by a person himself or through some material object.[95]

Nuisance occurs when someone unlawfully interferes with a person's use or enjoyment of land or some right over or in connection with it. This interference need not cause property damages. It is enough that person's ability to use and enjoy his or her property is affected.[96] The tort of negligence arises when a person fails to act reasonably under the circumstances and this failure cause harm to another. The necessary elements of negligence are (1) the existence of a duty on the part of defendants to

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[92] A.I.R. 1999 SC 812.
[93] n.45, p.5.
[94] *Id.*, Chapter 11.
[95] *Id.* p. 335.
[96] *Id.* p. 352.

protect plaintiff from injury; (2) failure of the defendant to perform that duty; and (3) injury to the plaintiff resulting from that failure.[97]

A duty of care is expected from persons dealing with GM foods. A breach of that duty (like adopting safety measures) will make them tortiously liable.

4.4.3. Liability for Defective GM foods

According to the decision in *Donoughe* v. *Stevenson* (1932) a manufacturer of products owes a reasonable duty of care to the consumer, i.e. to intend the products to reach the ultimate consumer, in the form of which left him with no reasonable possibility of intermediate examination with the knowledge that absence of such reasonable care in the preparation or putting up of products will result in an injury to the consumer's life or property. This principle has been extended to cover persons who have done something active to create the danger.[98]

In India, this aspect is taken care of by the Consumer Protection Act, 1986. According to its statement of object and reasons, the Act has provisions for better protection of the interest of the consumers. It also seeks *inter alia* to promote and protect the right of consumers, such as the right to be protected against the marketing of goods which are hazardous to life and property; informed about the quality, quantity, purity, standard and price of goods and the right to consumer education.

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[97] *Id.* p. 66.
[98] *Id.*, pp. 231-244.

Defect is defined in section 2(f) of the Act as any fault, imperfection or shortcoming in quality, quantity, potency, purity or standard which is required to be maintained by or under any law for the time being in force under any contract, express or implied or as is claimed by the trader in any manner whatever in relation to any goods.

So a consumer (defined in section 2(d) as anyone who buys any goods for a consideration) of defective GM foods can approach the Consumer Disputes Redressal Forums established under the Act.

Section 39(2) of the Protection of Plant Varieties and Farmers' Rights Act, 2001 deals specifically with liability regarding non-performing propagating material of variety registered under the Act. The breeder of such variety has to disclose to the farmers, the expected performance under the given conditions and if such propagating material fails to provide such performance under given circumstances, farmers may claim compensation before the Authority under the Act, which may direct the breeder to pay such compensation as it deems fit.

According to section 29(3) of the Act, no variety of any genera or species, which involves any technology, that is injurious to the life or health of human beings, animals or plants, shall be registered under the Act. An explanation to the sub-section clarifies that the expression "any technology" includes genetic use restriction technology and terminator technology.

This chapter attempted an evaluation of the redressal mechanisms (both international and national) available against the risks of GM foods. The need for a strict liability regime in this area is evident from the ongoing

debates over the Biosafety Protocol. The Indian law, in a general way offers well-placed mechanisms to deal with the dangers of GM foods. But this general nature of liability and redressal mechanisms could be ineffective. Common men like farmers and consumers are not expected to fight the MNCs in the Supreme Court and High Courts, which lie beyond their reach. Not to mention the snail paced civil justice administration system in the country. So the provisions in the Protection of Plant Varieties and Farmers' Rights Act, 2001 can be considered as a positive step. Special laws and redressal mechanisms are sometimes more effective than the general mechanisms. It is the duty of the civil society to make sure that a new statutory mechanism will not become 'just another' mechanism.

CHAPTER V

CONCLUSION

If the approval for commercial cultivation of Bt cotton is an indication of things to follow, India could well be an exporter of GM foods in the near future. So safety regulations of GM foods in India are important for two reasons: to protect domestic consumers and farmers from hazardous GM foods and to maintain export markets for such foods.

Any complaint regarding import regulatory measures, whether it is in the name of safety or not, will attract the jurisdiction of the prime organization governing international trade relations, i.e. the WTO. So safety regulations of GM foods have to pass the tests laid down by relevant WTO agreements. At the same time there is the Biosafety Protocol, an environmental agreement that prescribes certain conditions and procedures for the transboundary movement of GM foods. Thus there are two different regimes trying to govern the same subject matter. This situation is nothing new, but just an addition of a new chapter to the seemingly never-ending trade-environment conflict.

Articles XX (b) and XX (g) of GATT, 1994 allow members to deviate from their basic obligations such as national treatment, MFN treatment and general elimination of quantitative restrictions in order to protect human, animal or plant health and conservation of exhaustible natural resources. If the deviation is for a sanitary or phytosanitary purpose, the SPS agreement will come into play because the agreement elaborates up on Article XX (b) of GATT. The definition of sanitary and phytosanitary measures, as contained in

Annex A to the agreement, covers risks associated with pests, disease-carrying and disease-causing organisms and food additives. Thus GM crops causing contamination could come under the definition only if genetically altered pollen is to be considered a pest, disease-causing organism or disease-carrying organism. The definition does not seem to cover threat to biodiversity.

However, threat to biodiversity could come under the purview of Article XX (g) of the GATT, 1994, considering the interpretation given to exhaustible natural resources by the WTO Appellate Body (AB) in the *Gasoline* case (where 'clean air' was interpreted as an exhaustible natural resource) and in the *Shrimp Turtle* case (where it was held that the term exhaustible natural resources is a generic term and not static). Then there is no reason to doubt the status of biological diversity. Any measure to achieve the ends set out in Articles XX (b) or (g) has to satisfy the conditions contained in the chapeau of Article XX, i.e., the measure shall not be applied in an arbitrary, or unjustifiable discriminatory manner where the same conditions prevail and shall not cause disguised restriction on international trade.

A measure under the SPS agreement shall not be more trade restrictive than necessary and shall not be applied in a manner that would constitute a disguised restriction on international trade. There is a presumption that any measure, which conforms to international standards, will be consistent with the SPS agreement. Thus the agreement encourages harmonization of standards. Presently,the Codex Alimentarius Commission's Intergovernmental

Task Force is working on the international standards for GM foods and the Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology are expected to be adopted in July 2003. The Secretariat of the International Plant Protection Convention, another international body mentioned in the agreement, has started discussions on the pests and quarantine standards related to GM plants.

Under the agreement, Members can adopt their appropriate level of protection, which may be higher than international standards. This leeway has the potential to undermine the importance of standard harmonization principles, which the SPS agreement aims to facilitate. The adoption of higher standards could be misleading, as the SPS agreement seems to have become instrumental in selectively warding off imports from developing countries by the advanced countries prescribing higher standards than international ones.[1] So it is better for the developing countries not to take refuge in the 'higher standard' argument in regulating GM food imports.

Measures under the agreement have to be 'based on' risk assessment (it is not necessary that a member has to conduct the risk assessment itself) and sufficient scientific evidence. There has to be a rational relationship between the measure and the available scientific evidence. The notion 'sufficient scientific evidence' appears to be vague. In the *Beef Hormones* case the AB held that there was no need to quantify evidence. Also, sufficiency was not equated with majority scientific opinion. But the AB in the *Japan-*

[1] R. T. Tamarajakshi, "Doha Declaration and Agriculture in Developing Counties", *Economic and Political Weekly*, vol. 37, no.11, 2002, p. 23.

Agricultural Product case noted that the rational relationship between a measure and available scientific information depends on particular circumstances of the case including the characteristics of the measure at issue and the quality and quantity of the scientific evidence.

Same is the case with the assessment of risks. The AB in the *Beef Hormones* case spoke about the evaluation of possible risks to human health (which according to the AB denotes a lesser requirement than probability). The AB in the *Salmon* case demanded probability of risks while evaluating pest-related risks. Whether a higher standard is needed for pest-related risks is quite unclear.

WTO members can take provisional measures under the agreement when scientific evidence is insufficient and the measure is taken on the basis of available pertinent information. There must be a review of the measure within a reasonable period of time. The AB in the *Beef-Hormones* case held that though the precautionary principle is reflected in article 5.7 (which allows members to take provisional measures), it could not override the express provisions of the agreement, since it is less than clear whether the precautionary principle is a customary rule of international law.

So if risk assessment of GM foods reveals any specific ascertainable risk within the parameters of the SPS agreement, a country can ban its importation. If the scientific evidence is insufficient it can adopt provisional measures, but subject to the conditions set out in Article5.7.

The TBT agreement allows members to adopt technical regulations to protect human, animal or plant health and environment. Here also the regulations shall be not more trade restrictive than necessary and shall not create unnecessary obstacles to international trade. The agreement encourages the use of internationally agreed standards, but does not explicitly mention any international bodies. It could be the same bodies mentioned in the SPS agreement. Members must review the regulations if the circumstances change.

Labeling of GM foods could be a compromise solution because it is a less trade restrictive measure. But exporters of GM foods are campaigning for a voluntary labeling regime than a mandatory one. But voluntary labeling requirements are not suited to protect the consumers' interests. Voluntary labeling reverses the burden to the producers and manufactures who are not dealing with GM foods, to take the cost of labeling and testing to prove that their foods are GM-free.[2] Mandatory labeling will help the consumers to avoid allergic and hazardous foods. It is also necessary for post-market monitoring measures including tracebility. It will be easier for an injured consumer to prove causation of injury if GM foods are labeled as such.

Labeling of GM foods can be mandated either under the SPS agreement or the TBT agreement. However the TBT seems to be a more viable option because the rigors of risk assessment and scientific evidence are less while

[2] Voluntary labeling requirements are causing considerable hardships for conventional milk producers in the US. Monsanto, the major producer of rBGH (hormone treated) milk had instituted suits against small non-rBGH milk producing companies for not following the Food and Drug Administration's requirement for a voluntary label stating 'no significant difference between milk derived from rBGH treated cows and non-rBGH cows'. However the cases were settled out of the courts. "Why Voluntary Labeling of Genetically Engineered Food won't Help Consumers", available at http://www.centerfoodsafety.org/

adopting a regulation. Scientific and technical information are only relevant elements of consideration in assessing the risk. The non-exclusive list of legitimate objects does not explicitly set out the consumer's right to know, which is often raised in support of GM food labeling. Questions might also arise when the goal of labeling is not protection against known health risks, but protection against unknown risks.

The Biosafety Protocol covers transboundary movements of LMOs that may have an adverse effect on the conservation and sustainable use of biodiversity, taking also into account human health. The Protocol only covers LMOs, i.e. organisms that are capable of replicating genetic material, and thus will not cover food products made out of GMOs.

The Advanced Informed Agreement procedure, which is the centerpiece in providing transparency to the transboundary movement of LMOs, is applicable only to LMOs to be imported for intentional introduction into the environment. Thus LMOs intended for direct use as food or for processing and contained use have to be dealt under respective national regulatory regimes. It is to be emphasized that LMOs intended for these purposes are capable of replication by escaping into the environment.

The Biosafety Protocol runs counter to the relevant WTO agreements in several respects. The major one being the precautionary principle, which is a main component of decision-making process regarding importation of LMOs under the Protocol. Though the principle is reflected in article 5.7 of the SPS agreement, it cannot override the express provisions of the agreement. The argument that the precautionary principle is a customary rule of international

law might look attractive. It is suitable for a highly advanced industrialized unit like the EU. But developing countries have been opposing the precautionary principle in the WTO and any support of this will surely open the floodgates for developed countries to impose unilateral import regulations of developing country products.

Another problem area is that of mandatory labeling. The Biosafety Protocol requires LMOs intended for direct use as food or processing to bear a 'may contain LMO' label. LMOs intended for introduction into the environment or contained use have to be labeled specifically. Generally the GATT/WTO system is concerned with the product characteristics. Both the SPS and TBT agreements allow relevant process and production methods to be considered while assessing the risks. Thus product-related processes could come within the ambit of WTO agreements.[3] The AB in the *Shrimp-Turtle* and *Beef-Hormone* cases reiterates this. Under the SPS agreement, the product-related process has to show specific ascertainable risks to justify ban or labeling. The TBT agreement requires the Members to base technical regulations on product performance requirements. Thus it seems that under the TBT agreement, mandatory labeling requirements could be illegal if production or product characteristics are not detectable in the final product.

The legitimization of process and production methods will be problematic for developing countries in the larger framework. This most

[3] A.C. Appleton, *Environmental Labeling Programmes: International law Implications*: (Kluwer; London, 1997) p. 85.

probably will encourage the adoption of unilateral measures against developing country products.

Article 26(1) of the Biosafety Protocol allows the Parties to take into account socio-economic considerations arising from the impact of LMOs, especially with regard to the value of biological diversity to indigenous and local communities while taking decisions on the importation of LMOs. This has to be consistent with other international obligations. The Miami Group was successful in denying any role to socio-economic impact in the risk assessment process.

Under the TBT agreement, developing countries can adopt technical regulations or standards aimed at preserving indigenous technology and production methods and are not expected to use international standards, which are not appropriate to their financial or trade needs. Thus if a country can demonstrate higher order links between socio-economic impacts (unwanted effects including changes in the structure of agriculture) and the conservation of biological diversity, actions taken could be WTO legal.

If a dispute arises as to the import ban or regulations of GM foods before the Dispute Settlement Body of the WTO, the above-mentioned problems will surface. In that parlance, consistency with the MEA concerned (Biosafety Protocol) could be one of the relevant considerations to determine whether the measure is legitimate under the WTO rules.

An important question in this regard is whether the WTO is capable of dealing the complex scientific issues associated with risk assessments. WTO

panels have been using the service of experts and *amicus curiae* briefs to decide on scientific issues.[4] But if there is a conflict among these expert opinions, panels will be in trouble. A possible way out could be the use of MEA mechanisms for reaching at right conclusions on scientific issues or let the issue be settled by the mechanisms under the respective MEAs.

This does not solve the issue at the policy level. It is an irony that developing countries, which were against the trade-environment interface, are now finding themselves in the opposite side, bringing in the environmental connection into the international trade of GM foods. The SPS Committee had already discussed the issues related to ban and labeling of GM foods, at the instance of the US and Canada.[5]

But it is better for developing countries like India to continue their stand on the trade environment-interface. Because of the largely unprepared government departments, lack of homework in identifying priority areas and expertise on the subject, India must oppose Biotechnology being dealt within the WTO.[6] As an alternative, India must take a lead role in the deliberations of international standard setting bodies like the Codex and Committee on Phytosanitary Measures under the International Plant Protection Convention.

Regarding the safety regulation of GM foods, the US has opted for a general safety assessment system under the Environmental Protection Agency, Department of Agriculture, and Food and Drug Administration, based on the

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[4] Joost Pauwelyn, " The Use of Experts in WTO Dispute Settlement", *International and Comparative Law Quarterly,* vol. 51, 2002, p. 325.

[5] See WTO News items November 2001 available at http://www.org/engligh/news-e/new-e/news01-e/SPS-nov2001-e.htm.

'substantial equivalence' approach. But even in a technologically advanced country like the US, there is a hue and cry over the loopholes in the safety assessment of GM foods.

The EU has adopted a specific regulatory regime in this regard, whether for intentional introduction of GMOs into the environment or for placing of novel foods or additives in the market. The latest European Commission Directive 2001/I8/EC has incorporated the precautionary approach consistent with the Biosafety Protocol. This coupled with the producers' duty to demonstrate the genetic stability of a new GM variety would, to a large extent, prevent the introduction of GM crops in Europe.

India seems to have adopted the US method i.e., the inter-ministerial multi-tired structure. But controversies regarding the Bt cotton trials have put doubts over the efficiency and democratic nature of the system. The committees (state level and district level), which have to be constituted under the Manufacture, Use, Import and Storage of Hazardous Genetically Engineered Organisms or Cells Rules, 1989, are not in place in many states. It is only the GEAC, which can give consent for field trials or for placing of GM foods in the market. It has to consult other committees under the Rules and must arrive at consensus with the state governments, because agriculture is a state subject under the Indian Constitution. There has to be transparency in the decision making process, which is mandatory under the WTO agreements and the Biosafety Protocol. Not to mention the need for public consultation, because all these efforts are supposed to be meant for the people

[6] Suman Sahni, " India Should Oppose Biotechnology in WTO", in B Bhattacharya (ed.)

of this country. Prospects of mandatory labeling of GM foods is still not seriously discussed in the country, though India has been vociferously arguing for it in the Codex Committee on Food Labeling.[7] There has to be a proper co-ordination between the various food-standardizing agencies in India, under the umbrella of GEAC, to monitor and detect the entry and the placing of GM foods in the market.

India should voice for a regime based on strict liability principles under the Biosafety Protocol. State Parties should be made liable to the extent of their failure to implement proper regulatory measures. An international fund should be constituted under the Biosafety protocol so that any liabilities above the insurance limits have to be borne by the fund. State contributions to the fund have to be based on each state's share in the international trade of LMOs. Under Indian law, the existing redressal mechanisms seem to be sufficient for dealing with the risks of GM foods. However a specific statute providing for the regulation of and liability for GM foods will not be a bad idea. This is desirable because of the 'biotechnology boom', which is all set to swallow the agriculture and food sector.

Finally it is to be admitted that the study regarding legal regime for GM foods is incomplete if it does not address the intellectual property issues associated with GM foods, because the control of seed production is a necessity in achieving food self sufficiency. One cannot speak about food

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Biotechnology In Agriculture (Indian Institute of Foreign Trade: New Delhi, 2000), p.77.

[7] Para.6.10 of the National Seed Policy, 2002, formulated by the Ministry of Agriculture, Government of India, states, "Packages containing transgenic seeds/planting materials, if and when placed on sale, will carry a label indicating their transgenic nature. The specific characteristics including the agronomic/yield benefits, names of the transgenes and any relevant information shall also be indicated in the label",http://agrico/nic.in/seedpolicy.htm .

security through biotechnology if such technologies are controlled by a few multinationals. Further, an examination of related intellectual property rights (IPRs) would have been helpful in exposing the 'substantial equivalence' approach cited in favor of the safety of GM foods, because producers are claiming GM plant varieties and seeds as substantially new for claiming IPRs.

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