# BIOSAFETY, CONSUMER PROTECTION AND INTERNATIONAL TRADE

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**INTRODUCTION**

Biotechnology provides a powerful means to modify existing agricultural plants and animals. Proponents of agricultural biotechnology insist that it will bring a broad range of benefits to society. Scientists and advocates of this technology foresee the following contributions:

- Reduce of the crop lands, decreasing the pressure to expand the agricultural frontier to areas such as fragile ecosystems.
- Less crop loss
- Better nutritional value
- Reduced use of energy, transport and pesticides.

However, modern agricultural biotechnology also presents unprecedented risks to human health and the environment, raises serious ethical questions, and may have significant international implications. Creating laws and policies that adequately address these issues is, therefore, one of the most challenging regulatory tasks facing governments today.

The environmental and health risks associated with biotechnology are recognized in the 1992 United Nations Convention on Biological Diversity (CBD), an international convention signed by over 160 nations, which is designed to protect the broad range of living organisms and ecosystems which sustain our planet.[2] Specifically, article 8(g) of this convention stipulates that each contracting party must:

Establish or maintain a means to regulate, manage or control the 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.[3]

Many countries have implemented internal legislation even before the CBD. After the adoption of the Protocol to the CBD in January 2000 have set down new rules that will have to be observed by the international community when enacting national laws. The following study intends to put together the institutional and legal puzzle around this subject.

**SECTION I: THE DEFINITION OF BIOTECHNOLOGY**

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[1] This paper constitutes part of the findings reached by a three year law project executed by and the Canadian Institute of Environmental Law and Policy (Canada) and Ambio Foundation (Costa Rica), with funding from the Canadian International Development Agency.

[2] *United Nations Convention on Biological Diversity*, June 1992, Can. T.S. 1993, No. 24

[3] *Ibid*, Article 8(g).

Biotechnology covers a wide range of processes from fermentation to the latest reproduction methods, such as cloning and genetic engineering. Biotechnology may, therefore, be broken down into two categories for clarification: traditional biotechnology and modern biotechnology.

Examples of traditional biotechnology techniques include plant cultivation, animal husbandry, the selective breeding of plants and animals, and gene transfer within the same species. In these processes, "human intervention appears as the manipulation of processes that are otherwise occurring in nature routinely".[4]

Modern biotechnology is, however, quite distinctive from traditional techniques as it entails inter-species transfer, a process which does not occur spontaneously or frequently in nature. Specifically, modern biotechnology involves recombinant-DNA technology (rDNA - also known as genetic engineering) which is "the process of artificially moving genes among unrelated organisms, across normally impenetrable species barriers, which specifically excludes conventional plant breeding or genetic improvement within a species".[5]

Even though there is no universally accepted definition of biotechnology, in the Biosafety Protocol it means the application of:

(a) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or;
(b) fusion of cells beyond the taxonomic family that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

## SECTION II: CONCERNS ABOUT MODERN BIOTECHNOLOGY

### *Environmental Concerns*

Identifying the potential environmental risks posed by genetically engineered (GE) crops is a major challenge for scientists. Different GE crops may present different environmental risks, depending on a wide variety of factors including the characteristics of the GE crops and the location in which they are planted. Margaret Mellon and Jane Rissler from the Union of Concerned Scientists have outlined two of the most significant and well-understood categories of environmental risk in The Ecological risks of Engineered Crops.[6] These are: 1) risks related to GE plants themselves, and 2) risks associated with the movement of transgenes (foreign genes spliced into plants) into other plants.[7] Both of these categories are explored below.

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[4] Dr. William Leiss. *Biotechnology in Canada Today: Not more regulation, but more credible regulation,* a presentation to the House of Commons Standing Committee on Environment and Sustainable Development, June 1996, p. 12

[5] Clark, Ann. *Environmental Risks of Genetic Engineering*. Presented to the NAEC workshop: Factoring in the Environment for Decisions on Biotechnology in Agricultural Production, July 1998.

[6] Rissler, Jane and Mellon, Margaret. *The Ecological Risks of Engineered Crops*, Cambridge, MA: The MIT Press, 1996.

[7] For a more detailed discussion of these categories, see ibid and also J. Rissler and M. Mellon, *Perils Amidst the Promise: Ecological Risks of Transgenic Crops in a Global Market*, Union of Concerned Scientists, December 1993.

*Environmental Risks of GE Plants*

Genetic engineers have specific goals in mind when they splice transgenes into plants, such as enabling a plant to ripen faster or to survive in harsh climates. In addition to these expected effects, though, a new gene may alter the characteristics of a plant in other, less predictable ways.

An example of this phenomenon occurred in the United States' Mississippi Delta in the summer of 1997 when farmers experienced serious problems with Monsanto's Round-up Ready cotton. This cotton was genetically engineered to resist the pesticide company's best-selling weed killer, Roundup. However, approximately 30,000 acres which had been sown with these GE crops failed to produce cotton bolls or produced bolls that were deformed, reducing yield by nearly 40%.[8]

Another unintentional outcome of genetic modification is the possibility that transgenes may enhance a crop's capacity to become a weed; that is, to persist unwanted in a field or pasture, or invade a wild habitat.[9] This risk is particularly problematic because, according to Ann Clark, Professor of Plant Agriculture at the University of Guelph in Canada, "The potential for a GE entity...to become invasive cannot be predicted without targeted study."[10]

Once a GE organism becomes a weed, other problems relating to weediness may arise, including ecosystem disturbances. A simple example of a GE organism's potential to disrupt an ecosystem is described below:

...genetic engineering's potential to ultimately alter community structure might begin with transgenic salt-tolerant rice planted near coastal wetlands. It is conceivable that the rice could invade the salt-water ecosystems, displacing native salt-tolerant species. As the native populations declined, other organisms typically associated with them - algae, microorganisms, insects, other arthropods, amphibians, birds - might not be compatible with the invading rice. Different organisms, new to the salt-water marsh, might find homes in the new rice-dominated ecosystem.[11]

Some transgenic crops may also pose problems to non-target species. Plants genetically modified to resist certain insects or pests may, for instance, result in harm to beneficial organisms

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[8] Myerson, Allen R. "*Seeds of discontent: cotton growers say strain cuts yields*", in New York Times, Nov. 1997. Several farmers who planted the cotton asked the Mississippi Seed Arbitration Council to cover their losses. This Council ruled that Monsanto's product failed to perform as advertised and recommended payments of nearly $2 million to three cotton farmers who suffered severe losses.

[9] See, for example, M. Crawley. *The ecology of genetically engineered organisms: assessing the environmental risks*. In Introduction of Genetically Modified Organisms Into the Environment, ed. Mooney and Bernardi, NY: John Wiley and Sons, 1990, pp. 133-50. Also, M. Williamson, *Environmental risks from the release of genetically modified organisms - the need for molecular ecology*, in Molecular Ecology, vol. 1, pp. 3-8.

[10] Clark, Ann . *Risks of Genetic Engineering in Agriculture*, adapted from a speech to the annual meeting of the National Farmers Union, Nov. 1997, (www.oac.uoguelph.ca/www.CRSC/faculty/eac/risks.htm)

[11] J. Rissler and M. Mellon, supra endnote 7.

that feed off these plants. Several recent studies point to troubling and unexpected effects of GE insect-resistant crops on beneficial insects:

Scientists at Cornell University in the United States have discovered that GE corn crops may threaten the survival of the monarch butterfly. In laboratory studies, these scientists mimicked the natural process of pollen from one plant dispersing onto the leaves of nearby plants. They powdered milkweed plants, the exclusive food upon which monarch larvae feed, with pollen from GE corn which had been modified to exude a natural pesticide, bacillus thuringiensis (Bt), to kill corn-boring caterpillars. The scientists studied the growth and survival of monarch butterfly larvae that fed on the GE powdered milkweed leaves and found that 56% died, while none of the larvae fed on leaves powdered with natural corn pollen died.[12]

Scientists at the Scottish Crop Research Institute found that ladybird beetles (ladybugs) which fed on aphids reared on transgenic potatoes experienced reproductive problems and failed to live as long as ladybugs fed aphids from ordinary potatoes. The potatoes were engineered to produce insecticidal lectins, which are proteins from the snowdrop plant that bind to the surface of insect cells causing the cells to stop functioning.[13]

Swiss scientists from the Federal Research Station for Agroecology and Agriculture found similar results in their studies of green lacewing insects, which play a critical role in maintaining the equilibrium of insect populations. These researchers found that the mortality rate of lacewing larvae increased significantly after eating corn borers reared on GE corn.[14]

None of these studies have been extended to field situations, so it is unclear whether the laboratory results will reflect what might happen in nature. However, if field results do show similar effects, use of GE crops may have serious implications for biological diversity.

In addition to the possibility that some GE crops may become weeds or endanger non-target organisms, farmers may also have to deal with some less direct impacts of GE crops; mainly, changes to their farm management practices. For instance, transgenic crops containing bacillus thuringiensis, may have a deleterious impact on the efficacy of Bt, a relatively safe biological insecticide often used in organic farming. Scientific studies show reason for concern that widespread use of crops containing Bt could accelerate the development of insect pest resistance to Bt, rendering this natural insecticide useless.[15] The loss of Bt's effectiveness would cause serious problems for farmers, particularly organic farmers who have relied on this natural pesticide for decades.

GE crops could also increase farmers' dependency on herbicides and pesticides. Many of the GE crops that have recently been commercialized (corn, soybean, cotton and potato) are

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[12] See Losey, John E. and , Raynor, Linda. *Transgenic pollen harms monarch larvae*, in Nature, May 20 1999, pp. 399-214; and *Altered Corn Called Threat to Butterfly*, in The Toronto Star, May 20, 1999, p. A16.

[13] The Physicians and Scientists for the Responsible Application of Science and Technology, *Genetically Engineered Crops May Threaten Beneficial Insects*, Aug. 31, 1998, (www.psrast.org/insects.htm)

[14] *Ibid*.

[15] Clark, Ann. *Debunking the Myths of Genetic Engineering in Field Crops*, March 1999, (www.oac.uoguelph.ca/www/CRSC/faculty/eac/myths.htm).

herbicide tolerant plants, which are designed to withstand lethal doses of weed and pest sprays. These herbicide resistant plants allow farmers to apply broad-spectrum, non-selective herbicides several times throughout a season, rather than just once during pre-planting. Thus, these GE crops promote an increase in farmers' use of herbicides and, as a result, may increase the amount of residues from that herbicide on the harvested crop and in ground water.[16]

*Risk of Gene Flow to Other Plants*

Another major category of risk associated with large-scale releases of GE crops is that the transgenes in these crops may be transferred, by wind, water or other natural means, to other wild plants which may then become weeds (known as 'gene transfer' or 'outcrossing'). As Professor Joy Bergelson from the University of Chicago explains, "Crops engineered to contain genes that give them resistance to pests or the ability to produce lots of seeds, could pass these genes to their weedier cousins, producing hybrid strains of superweeds."[17]

These 'superweeds' would present risks similar to those posed by the transgenic crops themselves. For example, if corn (which is a grass) crossed with timothy grass, an abundant weed, resulting in a weedy, pest-resistant hybrid, it could outcompete beneficial plants for water and nutrients upsetting ecosystem structure and function.

Evidence summarized in the New Scientist journal in 1997 shows that genetically modified traits can readily move into adjoining populations.[18] For example, research has demonstrated the ease of trait transfer from oilseed rape into a wild weedy relative.[19] Also, studies of transgenic oilseed rape and wild radish have demonstrated potential for rapid spread of herbicide resistance into wild populations.[20]

Proponents of biotechnology argue that the risk of outcrossing is negligible because there are no known weedy or naturalized relatives of the crops which are currently being modified.[21] This argument has some validity, because the majority of crops grown in North America and, hence, their wild, weedy ancestors, evolved elsewhere (for example, maize, beans, potatoes, and cotton evolved in South America).[22]

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[16] *Ibid*.

[17] *Engineered Plants May Spread Genes to Weeds*, in Nature (U.K.), September, 1998.

[18] Gledhill, M. and P. McGrath. *Call for a Spin Doctor*, in New Scientist, November 1997.

[19] Mikkelson, Thomas R.and Jorgensen, Anderson. *The risk of crop transgene spread*, in Nature, vol. 380, March 7, 1996.

[20] Chevre et al., in Nature, 1997.

[21] See Canadian decision documents authorizing commercial release of genetically engineered field crop cultivars. For example: Decision Document DD96009. Determination of Environmental Safety of Event 176 Bt Corn (Zea mays L.) developed by Ciba Seeds and Mycogen Corporation: "The biology of corn...indicates that there are no wild relatives in Canada that can freely hybridize with Zea mays L....AAFC therefore concludes that gene flow from Event 176 to corn relatives is not possible in Canada."

[22] Clark, Ann., *supra* endnote 10.

But, despite the fact that most crops did evolve elsewhere, many of the wild or weedy relatives for important crops now exist in North America. Moreover, the risk of outcrossing will increase as the variety of crops being genetically modified continues to expand. Ecological geneticist Norm Ellestrand from the University of California predicts that outcrossing "...will probably happen in far less than 1% of [GE] products, but within ten years we will have a moderate-to-large scale ecological or economic catastrophe, because there will be so many [GE] products being released."[23]

Furthermore, industrialized countries that are developing and exporting GE crops must recognize the global risks involved. As Professor Clark explains, "the risk of outcrossing is amplified, with potentially devastating repercussions for germplasm conservation, when transgenic crops are grown in developing countries, where most food crops evolved."[24] Selling GE crops, like corn and alfalfa, in the regions from which they evolved could affect the survival of wild, weedy ancestors, whose genes are needed for agricultural production around the world. According to the Union of Concerned Scientists, "these plants are the genetic basis of the world's future food supply. They are the source of new genes that plant breeders and genetic engineers use to adapt crops to changing environmental conditions."[25] Is it not, therefore, in the best interest of all countries to avoid inadvertently obliterating these valuable genes?

Finally, recent scientific evidence indicates that we must not only be cautious of gene transfer between related organisms, but also between unrelated organisms via horizontal gene transfer. In 1996, a database search of mainstream journals for horizontal gene transfer yielded 75 references between 1993 and 1996, of which all but two gave direct evidence of outcrossing.[26] For example, scientific studies conducted in 1996 reported the movement of antibiotic resistant genes from GE rapeseed, black mustard, thorn apple and sweet peas into a soil fungus.[27] Therefore, the potential for transgenes to move into much broader ecological communities appears to be significant.

*Health Concerns*

Proponents of biotechnology maintain that GE crops are not substantively different from conventional food products and that they should, therefore, be regulated in the same manner. Several recent scientific studies suggest, however, that a more precautionary approach to regulating GE crops may be necessary as these crops may pose unique and substantial health risks.

In February 1999, for example, the first evidence of the potential for GE food to cause health damage emerged. Dr. Arpad Pusztai, an internationally respected senior scientist at the Rowett Research Institute in Scotland, presented evidence that rats fed with GE potatoes modified to

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[23] As quoted in James Kling, "Could Transgenic Supercrops One Day Breed Superweeds?", in Science, vol. 274, October 11, 1996, pp. 180-181.

[24] Clark, Ann *supra* endnote 10.

[25] Rissler and Mellon, *supra* endnote 8, p. 69.

[26] Mae Wan Ho and B. Tappeser. *Transgenic transgression of species integrity and species boundaries*, Presented at the Workshop on Transboundary Movement of Living Modified Organisms Resulting from Modern Biotechnology, Denmark, July 1996. (http://userwww.sfsu-edu/~rone/GEEssays.html)

[27] Clark, Ann *supra* endnote 10.

express snowdrop lectin experienced shunted growth, damaged immune systems, and damage to several major organs. In contrast, unmodified potatoes had a much milder effect on the rats. >From this evidence, Pusztai tentatively attributed the adverse responses to the transgenes in the GE potatoes.[28]

Dr. Stanley Ewen, a consulting histopathologist at the University of Aberdeen Medical School, furthered Pusztai's studies and found even more disturbing results. Ewen found that the adverse health effects from the GE potatoes may not have come from the lectin transgenes, but from the promoter genes (derived from cauliflower mosaic virus, CaMV) which were used to drive the expression of the transgene within the GE potatoes. The CaMV promoter has been widely used in making GE tomatoes, corn and soybean cultivars which are already in the marketplace.[29]

*New Allergens in the Food Supply*

Genetically modified crops could bring new allergens into foods that sensitive individuals would not know to avoid, unless these foods were appropriately labelled.
Empirical evidence regarding the generation of allergenic foods through GE is limited, since few of these foods have been thoroughly tested for allergenicity.[30]

However, one example of allergenicity has already surfaced involving Pioneer Hybrid's GE soybeans. The company developed soybeans with nutritionally balanced amino acid composition by genetically engineering the beans' DNA to contain the gene for a brazil nut storage protein. Scientists discovered, though, that soybeans set off a strong, potentially deadly, allergic reaction in people sensitive to Brazil nuts.[31] Pioneer Hybrid thus decided to terminate plans to commercialize this product.

*Anitibiotic Resistance*

Another health concern about some GE crops, such as corn used for animal fodder, is that these crops may include a gene for antibiotic resistance that could create antibiotic resistant pathogens. Antibiotic resistance genes are used to track the uptake of modified genes in GE crops. Some scientists fear that these antibiotic resistance genes could jump into bacteria in the guts of livestock, creating antibiotic resistant pathogens.

Proponents of GE have argued that there is no risk of this happening because modified genetic material breaks down so quickly. Recent Dutch research casts doubt on these assurances, though. Studies conducted by Robert Havenaar and his colleagues at the TNO Nutrition and Food Research Institute in the Netherlands showed that DNA can, in fact, linger in the intestine.

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[28] Rachel's Environment and Health Weekly, *Biotech: The Pendulum Swings Back*, May 6, 1999, no. 649, p. 2. Pusztai's results sparked a storm of criticism from proponents of GE and Pusztai was forced to resign from the Institute. He was, however, exonerated when an international group of 22 scientists attacked the behaviour of the institute and re-affirmed the scientific soundness of Pusztai's conclusions.

[29] Ann Clark, *Genetic Engineering in Field Crops: Ethics and Academia*, Presented to the Annual Meeting of the Saskatchewan Institute of Agrologists, April 1999, (www.oac.uoguelph.ca/www/CRSC/faculty/eac/ethics.htm)

[30] Fagan, John. *Safety Concerns About Allergenicity*, (http://www.psrast.org/jflabel.htm) p. 6.

[31] Norlee, Julie et al., *Identification of a Brazil Nut Allergen in Transgenic Soybeans*, New England Journal of Medicine, March 14, 1996.

Thus, they concluded that it is possible for genetically modified bacteria to transfer their antibiotic resistance genes to bacteria in the gut.[32]

*International Implications*

Multinational biotechnology companies are rapidly developing GE agricultural products for international markets. They maintain that these products will help to address food shortage problems in developing countries. Monsanto, for instance, suggests that biotechnology can contribute to higher productivity and efficiency on the farm, thereby increasing food supply and helping to solve the world hunger crisis.[33]

The suggestion that GE crops can alleviate world hunger by increasing food production is, however, quite problematic. As the Union of Concerned Scientists explains, there are many complex reasons for food shortages, including lack of income to buy food, trade and land-use policies that disadvantage farmers in the developing world, and lack of appropriate inputs such as fertilizer.[34] GE crops may do little to alleviate hunger until these political and economic problems are addressed.[35] In fact, GE crops may actually worsen the plight of third world farmers, not only because of the environmental implications outlined above, but also for the reasons outlined below.

*High Cost of GE Crops*

Many critics of GE argue that genetically modified products are unlikely to benefit resource-poor farmers because these products are too expensive. Biotechnology companies need to sell their products at premium prices in order to cover their high research and development costs.[36] Hybrid seeds typically cost three times as much as traditional seeds and patented GE seeds can cost up to five times more than regular seeds. Moreover, new genetically engineered seeds often require high-quality soils, large investments in machinery and fertilizer, and increased use of chemicals and water.[37] In short, "these products are of virtually no value to hungry farmers...who cannot afford the products of traditional technology, much less these expensive genetically engineered products."[38]

These costs may also be compounded by patent fees. Many biotechnology companies place patents on GE products which prohibit farmers and other individuals from using these products unless they pay royalties. Agracetus Inc. (a subsidiary of W.R. Grace and Co.) has, for instance, received a patent for genetically engineered cotton that will give the company monopoly control

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[32] Mackenzie, Debora. *Gut Reaction*, (www.newscientist.com). See also, *Doubts Raised on Genetically Altered Food*, in Globe and Mail, January 27, 1999.

[33] See, for example, Monsanto's advertising campaign, "Let the Harvest Begin".

[34] Union of Concerned Scientists, "Biotechnology and the World Food Supply", (www.ucsusa.org/agriculture/index.html)

[35] *Ibid*.

[36] *Ibid*.

[37] Rachel's Environment and Health Weekly, "Against the Grain", February 11, 1999, (www.rachel.org).

[38] Union of Concerned Scientists, supra endnote 34.

over all transgenic cotton plants and seeds until the year 2008.[39] This patent gives Agracetus the right to decide when and if it chooses to license its technology and under what conditions. Cotton is a self-pollinating crop and farmers in many parts of the world save seeds from their harvest to re-plant. Under industrial patent law, however, it will be illegal for farmers to save seeds from transgenic cotton plants without payment of royalties to the patent owner. The company has similar patent applications pending in countries such as Brazil, China and India.[40]

Premium prices, technology fees and royalties may make GE crops too expensive for small, resource-poor farmers. Moreover, these crops may be impractical for small farmers in developing countries. Critics of GE argue that if these crops were meant to feed the hungry, they would have special characteristics to help poorer farmers, such as the ability to grow on marginal soil, or to produce more high-quality protein, with increased yields and without expensive inputs. However, as Mark Winfield, Research Director at the Canadian Institute for Environmental Law and Policy explains, "the two leading applications of GE crops in North America, herbicide tolerance and pest resistance, are simply not relevant to the challenges facing the world's foods supply, particularly in the developing south."[41]

Instead, most of the GE products in development are intended to mainly serve large farming operations in developed countries and wealthy producers in less developed regions. Monsanto, for example, recently announced that it will spend $550 million in Brazil to build a factory to produce Roundup pesticide for use in Roundup Ready soybeans. It is unlikely that this factory will benefit the poor, though, as "most rural Brazilians are subsistence farmers who do not grow soybeans", but will only serve wealthy farmers serving export markets.[42]

*Control Over the Agricultural Sector*

Another issue which arises from the development and sale of GE agricultural products is the biotechnology industry's growing control over farmers and the food production process. Many small and medium-sized farming operations are concerned that biotechnology will further centralize power over agricultural production into the hands of a few large multinational companies. They worry that as agricultural biotechnology companies develop interlinked products, such as herbicides and herbicide tolerant seeds, farmers will become dependent on their products, increasing the ability of these companies to gain control over the food production process.[43]

Control over production is, in fact, the goal of many biotechnology companies. As the Vice-President of the American biotechnology company, Calgene, has stated:

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[39] U.S. Patent No. 5,159,135, October 27, 1992.

[40] RAFI Communique, "Control of Cotton: The Patenting of Transgenic Cotton", July/August 1993, (www.rafi.org/communique/19934.html).

[41] Winfield, Mark. *Agricultural Biotechnology and Sustainable Development*, CIELAP, notes for presentation, June 1997.

[42] As noted in Clark, Ann. *Debunking the Myths of Genetic Engineering in Field Crops,* (www.oac.uoguelph.ca/www/CRSC/faculty/eac/myths.htm)

[43] *In the Mill*, in The Economist, pp. 64-65, March 20th, 1999.

Our objective is to control production with our partners from the production of foundation seed to the sale of the oil to our customers. We want complete control...The way you capture value added is selling oil -- value-added oil at a premium to customers, period. So we and our partners will maintain complete control of the process."[44]

Consolidation of the agricultural biotechnology industry is happening at a rapid rate. For instance, according to a recent article in The Economist, DuPont, one of America's leading producers of chemical pesticides, has recently announced its purchase of Pioneer HiBred, the world's largest seed company.[45] The two companies have had a long-standing joint venture in the production of GE grains. Monsanto has also been rapidly taking over seed companies. The company has, in fact, paid over $8 billion in the past four years to buy companies such as Delta and Pine Land, and Holden Seeds, putting it in command of roughly 80% of American cotton-seed production.[46]

*Threats to Traditional Agricultural Practices*

GE products may not only be unaffordable and impractical for many poorer farmers in developing countries, but they may also threaten traditions on the farm. This is the case with a new seed product created by the United States Department of Agriculture and Pine Land Company. This product is deemed "terminator technology" by its opponents because its purpose is to kill off the second generation of plants by rendering seeds sterile after one planting. Terminator technology thus obliges farmers to buy more seed on a yearly basis, rather than saving seed for re-planting. According to developers, the rationale for creating these seeds is that companies do not want to give products away after sinking substantial funds into their research and development.

However, GE seed designed to prevent farmers from saving seed could have adverse implications for resource poor farmers in developing countries. Pat Mooney of the Rural Advancement Foundation International (RAFI) explains that, "If they [poorer farmers] can't save seed and do plant breeding to adapt the seed to their own growing conditions, then they can't be farmers. They can't afford to buy seed every year."[47] Up to 1.4 billion resource poor farmers in the South depend on farm-saved seed and seeds exchanged with farm neighbours as their primary seed source.[48] Mooney argues that "A technology that threatens to restrict farmer expertise in selecting seed and developing locally adopted strains is a threat to food security and agricultural biodiversity, especially for the poor."[49]

Moreover, terminator technology may endanger other crops through outcrossing. Pollen from Terminator Technology can move substantial distances away from a GE field, inadvertently fertilizing plants in neighbouring fields and rendering their seeds sterile.[50] Ann Clark notes that

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[44] Manitoba Cooperator, March 23, 1993, in B. Kneen, >From Land to Mouth, p. 140.

[45] The Economist, *supra* endnote 43.

[46] *Ibid*.

[47] Pat Mooney, as quoted in *Genetic Engineering Threatens Traditions on the Farm*, Globe and Mail, November 16, 1998, p. A13.

[48] Mooney, Pat. *The Terminator Technology*, in RAFI Communique, March/April 1998.

[49] *Ibid*.

[50] *Ibid*.

"with 80% of crops in the developing world sown from farmer-saved seed, genetic pollution from Terminator-enhanced fields could exacerbate, rather than reduce, world food deficits."[51] The terminator technology research apparently has come to a halt due to international pressure on the company. Nevertheless, this shows very well how aware we have to be.

*Social and Ethical Issues*

Genetic engineering raises many significant ethical concerns and questions. These issues cannot be explored in detail within the scope of this paper, but following is a brief overview of some these issues.

A major area of ethical concern regarding GE is the impact that this technology may have on the health and welfare of animals. For some people, plants and animals are seen as utilitarian objects that can be legitimately modified and manipulated for human purposes. For others, though, plants and animals are culturally and/or religiously significant beings evoking respect. These individuals see the manipulation of the genetic material of other species as a violation of species integrity and the laws of nature. They thus fundamentally object to many applications of modern biotechnology.

Genetic engineering also raises serious ethical concerns about the patenting of living organisms. In 1980, the United States Supreme Court granted the first patent on a life form.[52] Since then, patents have been granted on plant and animal strains, as well as on individual genes. For some people, though, the patenting of life is unethical. As one critic noted, "I never imagined that people would patent plants and animals. It's fundamentally immoral...[and] violates the integrity of life itself, and our deepest sense of morality."[53] Patenting life forms also raises questions regarding intellectual property rights. Genetic material, such as plants used in traditional society for medicinal purposes, are now being collected from indigenous peoples by multinational biotechnology companies. This activity raises many complex issues, such as how and if consent to use these materials should be obtained, who owns such material and knowledge, and if and how indigenous societies should receive royalties from any GE products discovered in this way.[54]

Several other ethical questions often raised concerning modern biotechnology include:

- Who owns genetic information?
- Is ownership of genetic material a right?
- What are the implications of this kind of ownership?
- Do we need genetically altered food?
- Should animals be used in genetic experimentation?
- When a plant receives an animal gene, should vegetarians be informed?
- Who will pay for failed technology?
- Who is responsible for potential adverse environmental or health reactions?

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[51] Clark, Ann *supra* endnote 29, p. 6.

[52] Clark, Ann, *supra* endnote 41, p. 7.

[53] Acosta, Isodro. President of the Guaymi General Congress, as quoted in The Citizen's Guide to Biotechnology, CIELAP, p. 37.

[54] Press-Merkur, Maureen and Winfield, Mark. *Enabling Biotechnology? An analysis of the report of the Biotechnology Council of Ontario*, CIELAP, 1995.

- Do we want private companies, like insurance companies, to have access to genetic information?

Although these questions are difficult to answer, open discussion of the ethical issues regarding genetic engineering should be encouraged and supported by governments. Until recently, however, ethical concerns were ignored by many governments, specially by Canada and the United States. This behaviour contrasts sharply with the approach taken by a number of Western European governments, which have facilitated societal debates around these issues, and demonstrated a willingness to act on the results of such decisions.

**SECTION III. THE REGULATION IN THE BIOSAFETY PROTOCOL**

*Introduction*[55]

At 5AM Saturday, January 29, representatives of more than one hundred and thirty countries, gathered in Montreal adopted a Protocol on Biosafety under the United Nations Convention on Biological Diversity (CBD). The early morning conclusion of the Extra-ordinary Conference of the Parties to the Convention brought three years of negotiations on the Protocol to a close.

Although the Protocol suffers from a number of significant gaps and ambiguities, its conclusion represents a major achievement for countries and societies around the world concerned about the impacts of modern biotechnology on their well-being. The outcomes of the biosafety negotiation also have significant implications for the future relationship between international trade and environmental protection agreements.

*The Road To Montreal*

The development of the Protocol was mandated through the CBD, completed at the Rio Conference on Environment and Development in 1992. The drafters of the Convention were conscious of the looming commercialization of genetically engineered crops, fish, animals and microorganisms, and the potential threat that this could pose to the environment and human health. The actual negotiations on the Protocol began in July 1996, and following six negotiating sessions, were to have been concluded at an Extra-Ordinary Conference of the Parties to the Convention in Cartagena, Colombia in February of last year.

However, the negotiations in Colombia collapsed in the face of intense opposition from a group of six countries (Canada, the United States, Australia, Uruguay, Chile and Argentina) called the Miami Group. The Miami Group emerged from the Cartagena meeting with two major objectives with respect to the Protocol: the exemption of transboundary movements of modified organisms that are commodities for use in food, feed or processing from the rules established through the Protocol; and the subordination of the Protocol to the World Trade Organization (WTO) rules regarding international trade. These six countries had invested heavily in agricultural biotechnology, and wanted to ensure that the Protocol did not permit countries to refuse imports of genetically engineered foods and other products on anything other than the extremely restrictive rules established by the WTO. An attempt to restart the negotiations in Vienna in September 1999 again failed in the face of the Miami Group's intransigence.

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[55] Winfield, Mark. *Reflections on the Biosafety Protocol Negotiations in Montreal,* document circulated by email, March 2000.

*The Montreal Negotiations*

The process was chaired by Juan Mayr, the Colombian Minister of the Environment, and Chair of the Cartagena Ex-COP. The process operated on the basis of the so-called 'Vienna process,' where negotiations took place in contact groups, in which each of the five camps into which the negotiating process had split (the Miami Group; the European Union (EU); the Central and Eastern European (CEE) Group; the Compromise Group (made of up of non-EU, non-Miami Group OECD Countries including Switzerland, Norway, New Zealand, Mexico, Korea, and Japan); and the Like Minded Group (LMG) (developing countries), had two spokespersons. The focus of the negotiations was the so-called Cartagena text, the draft Protocol proposed by Chairman Mayr, and left on the table at the Colombia meeting.

**Key Elements**[56]

*The Advance Informed Agreement Procedure*

This procedure is the backbone of the Protocol. As noted below, however, it only applies to a small percentage of traded LMOs. The Party of export is obliged to notify (or ensure notification) in writing to the Party of import, before the first intentional import of any given type of LMO. The Party of import then has 90 days to acknowledge receipt of the notification, and advise that it intends to proceed with the Protocol's decision procedure, or according to its domestic regulatory framework.

The decision procedure works as follows. A risk assessment must be carried out for all decisions made (see discussion below). Within 90 days of notification, the Party of import must inform the notifier that either it will have to wait for written consent, or that it may proceed with the import without written consent. If the verdict is to wait for written consent, the Party of import has 270 days from the date of notification to decide either to:

- Approve the import, adding conditions as appropriate, including conditions
- for future imports of the same LMO;
- Prohibit the import;
- Request additional information, or;
- Extend the deadline for response by a defined period.

The Protocol establishes an Internet-based Biosafety Clearing-House, to which all decisions must be relayed. The first meeting of the Parties will elaborate procedures and mechanisms to help Parties make such decisions.

*Exclusions*

Five types of LMOs are not subject to the AIA:

- Most pharmaceuticals for humans;
- LMOs in transit to a third Party;
- LMOs destined for contained use;
- LMO– FFPs (discussed below), and;
- LMOs that have been declared safe by a meeting of the Parties.

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[56] Due to its concise and clear content, most of this section has been taken in its entirety from Burgiel, Stas, Writer, The Cartagena Protocol on Biosafety: An analysis of results (A International Institute for Sustainable Development Briefing Note, *Earth Negotiations Bulleti*n, www.iisd.ca).

These exclusions (particularly the exclusion of LMO– FFPs) mean that the AIA covers only a small percentage of traded LMOs—basically, only those destined for direct introduction to the environment of the importer, such as seeds and microorganisms.

*Living Modified Organisms Used for Food, Feed or Processing (LMO– FFPs)*

LMO– FFPs are not subject to the AIA procedure that covers other LMOs, but are covered by a separate, less restrictive, procedure outlined in Article 11. Parties making a final decision about the domestic use of an LMO must notify the other Parties of the decision through the Biosafety Clearing-House. Thus, while the AIA procedure lays first responsibility on the Party of export to notify its intent to export, the procedure for LMO– FFPs lays first responsibility on potential importers to develop and announce regulations proactively. The result is less onerous for the exporters, who will not have to wait for the Parties of import to respond to their notifications. As well, exporters of LMO– FFPs do not face the burden of proof established for exporters of other LMOs, who may have to conduct and finance risk assessments in support of their notifications. Shipments of commodities, however, that contain, or may contain, LMO– FFPs must be identified as such in their accompanying documentation. The details of this procedure still remain to be worked out, and are supposed to be settled within two years after the Protocol enters into force. Such shipments must also be accompanied by a list of other information, including the identity and relevant traits and characteristics of the LMOs, any requirements for safe handling, storage, transport and use, and information about the importers and exporters.

These requirements are helpful to countries that are enacting domestic labeling schemes for LMOs and products thereof. But they are unwelcome for exporters, who will be forced either to segregate LMO and non-LMO commodities, or to label all exports "may contain LMO– FFPs" and likely pay the penalty in lower prices.

*Labelling and segregation*

LMO-FFPs have to be accompanied by documentation that "clearly identifies that they "may contain" [LMOs] and are not intended for intentional introduction into the environment, as well as a contact point for further information." This text does not fulfil the provisions of many existing national labelling laws and fails to provide clear information.[57] The parties to the Protocol Are supposed to decide on a more detailed procedure including specifying identity and unique identification within two year of the protocol coming into force.

*Precautionary principle*

The Protocol contains string provisions on the precautionary principle. Article 10 (6) states that the lack of cientific uncertainty... shall not prevent a party from taking a decision, as appropriate, with regard to the import of the living modified organisms in question...". A similar clause is contained in Article 11, which covers the commodities. The precautionary approach is formulated as a right, not as an obligation. Therefore, it is limited by the obligation on Article 12 that imposes on the importing party the obligation to review its decision in the light of new scientific evidence on request of the exporting party.

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[57] Meyer, Hartmut, The Cartagena Protocol on Biosafety, in Biotechnology and Development Monitor, No. 43, September 2000 (www.pscw.una.nl/monitor).

*Relationship to the WTO*

The final text does not settle the question of how the Protocol relates to the WTO and other international agreements. In fact it looks like a conflict postponed, rather than a conflict avoided. The question of primacy of one set of rules over another, however, is only important if the two sets of rules conflict. In the case of the WTO vs. an MEA, it might also be important in determining where an MEA-related trade dispute would be heard. On the first question, there seems to be no conflict between WTO rules and the Cartagena Protocol provisions. In fact, the wording of the two preambular passages would suggest that both the WTO rules and the Protocol have to be read as mutually supportive and not conflicting. As we will see later, this point becomes important in the context of the Protocol's precautionary provisions.

## SECTION IV. THE REGULATION IN THE 1994 GATT

The WTO Agreements are complex since they deal with a wide variety of activities, such as agriculture, textiles, services, telecommunications, public tendering and intellectual property. We will briefly study the most important rules related to our topic.

### The relevant rules

*1. Article III*

Article III of the GATT establishes the national treatment principle and it is one of its core disciplines. It regulates the application of domestic policies to imported products and ensures for them treatment no less favorable than accorded to like national products of domestic origin. Article III: 1 provides that internal taxes and other charges, laws, regulations and requirements that affect the sale and distribution of products shall not be applied so as to afford protection to domestic products. These laws, regulations and requirements are also subject to a more stringent test under Article III: 4, which provides that imported products must be afforded treatment no less favorable than that given to like domestic products.[58]

A similar sort of provision applies to taxes and other charges under Article III: 2. The first sentence of this article prohibits the imposition of direct or indirect charges on imported goods which are in excess of those imposed on like domestic products. The second sentence repeats the obligation contained in Article III: 1. In particular, taxes and charges may not be used to protect domestic production. This is extended to include not only like products but products that are directly competitive or substitutable with each other.[59] Moreover, Article III: 2, first sentence, cannot be interpreted to protect expectations on export volumes. Rather, it protects expectations vis-à-vis the competitive relationship between imported and domestic products. Thus, a change in the competitive relationship must consequently be regarded *ipso facto* as a nullification or impairment of benefits accruing under the General Agreement[60]

Article III does not require formally equal treatment but only a no-less favorable one. This allows parties to treat domestic and imported products differently. Yet, to prevent abuse, Article III can be breached by measures having no protective purpose or consequences. In relation to taxes, the presence of a protective application need not to be established separately from the specific

[58] See Article III: 4 of GATT, Agreement Establishing the World Trade Organization, April 15, 1994, 33 I.L.M. 1144.

[59] See Interpretative Note Ad Article III, GATT Annex I, para. 2.

[60] See European Communities Regime for the Importation, Sale and Distribution of Bananas, Report of the Appellate Body, 9 September 1997, WT/DS27/AB/R, at. 252.

requirements that are included in the first sentence of paragraph two in order to show that a tax measure is inconsistent with the general principle set out in this first sentence.[61] Only in the context of the second sentence of the same paragraph, reference to the existence of protective application is required.[62] However, it is the effect and not the aim which was to be addressed.

**The likeness of products**

The issue of whether products are "like" is central to the question of whether differentiation is consistent with Article III. If products are not alike, then any differentiation will be consistent. However, if they are alike, then differentiation (e.g., for environmental purposes) can only be consistent if it neither protection to domestic production (protective effect) nor less favorable treatment to imported products.[63] Stated differently, the answer to this question is important because the treatment of imported domestic products as like products under Article III may have significant implications for the scope of obligations under the General Agreement. It is also paramount for the regulatory autonomy of contracting parties with respect to their international tax laws and regulations. Under these circumstances, it has been stated that "…it is imperative that the like product determination in the context of Article III be made in such a way that it not unnecessarily infringe upon the regulatory authority and domestic policy options of contracting parties."[64]

It is in this context that regulations that differentiate between products on the basis of factors other than physical characteristics have been ruled to violate Article III.[65] This has been stated implicitly as early as 1952 in the *Belgian Family Allowances* Case. This case addressed a charge imposed by Belgium on imported products purchased by public bodies when these goods originated in a country whose system of family allowances did not meet specific requirements. In that context, the panel considered that "the Belgian legislation on family allowance was not only inconsistent with the provisions of Article I, but was based on a concept which was difficult to reconcile with the spirit of the General Agreement".[66]

[61] See *Japan – Custom Duties, Taxes and Labeling Practices on Imported Wine and Alcoholic Beverages*, adopted 1 November 1996 GATT, BISD 34S/83, [hereinafter *Japan – Alcohol* Case], Appellate Body Report at 241. This is a clear rejection of the aim and effect test. It suggests that unless the aim and effect of a trade restrictive environmental measure was to provide an advantage to the competitive domestic industry, the terms of Article III were not contravened. The origin of it is the *U. S. Alcohol*, at 5.24, 5.71-5.75. According to this precedent, the aim and effect of the trade measure, as well as its focus on the features inherent in the product concerned, should receive attention.

[62] *Ibid*, Appellate Body Report at 246.

[63] *Ibid*, at 5.5.

[64] *Ibid*, at 5.72.

[65] See *United States – Restrictions on Imports of Tuna*, Report of the Panel, GATT Document DS21/R (3 September 1991), (not adopted), BISD 40S/155, at 5.11-5.15, reprinted in (1991) 30 International Legal Materials 1594, [hereinafter *1991 Tuna – Dolphin* Case]; *United States – Restrictions on Imports of Tuna*, GATT Document DS29/R (16 June 1994), (not adopted), at 5.8-5.9, reprinted in (1994) 33 ILM 842, [hereafter *1994 Tuna – Dolphin* Case]; See *U. S. Alcohol Case*, *supra* note 10 at 5.19; *United States – Taxes on Automobiles*, GATT No. DS31/R (11 October 1994), (not adopted), at 5.57, reprinted in (1994) 33 ILM 1399, [hereinafter *U. S. Automobiles* Case], at 5.52-5.54.

[66] See *Belgian Family Allowances Case*, G/32, 7 November 1952, 1S BISD Supp. 59 (Mar. 1953) at 8.

Generally, it is true that "likeness" is usually expressed by reference to physical similarity and that "tuna is tuna", no matter how it has been caught.[67] In spite of this, however this issue is not as clear as it has been presented. The term "like products" is used throughout the GATT but for different purposes.[68] In some cases, the finding of likeness has been easy. In the *Superfund* Case, the compared products for the purposes of import taxation consisted of different types of oil, gasoline and other liquid hydrocarbon products.[69] The domestic and imported products in question where either identical or had almost the same end-uses.[70] Consequently, the panel had little problem in characterizing them as like products for the purposes of article III: 2.[71]

In contrast, in the *Japan–Alcohol* Case, which dealt with the problem of comparing different kinds of alcoholic beverages for taxation purposes, the task proved not so easy. The European Community argued that gin, vodka, whiskey, grape brandy, fruit brandy, sparkling wine and still wine had been grouped together in such a way as to afford domestic protection.[72] In relation to the first sentence of this Article, after noting the importance of focussing on whether the item possessed essentially the same physical characteristics,[73] the Panel found that the items were like products for the purposes of the first sentence of Article III: 2. However, the second sentence of this article prohibits taxation to protect domestic products, not only in relation to like domestic products, but also on directly competitive or substitutable products.[74] Applying this rule, the panel submitted that the focus had to be laid on the elasticity of substitution, an element not related to the intrinsic characteristics of a commodity.[75] It then grouped gin, vodka and brandy together as imported and domestic distilled liquors. Alternatively, imported and domestic unsweetened and sweetened still wines were put into a separate group, as were imported and domestic sparkling wines.[76] Under this analysis, the Panel found that spirits competed directly against each other whereas still and sparkling wines did not.[77]

As might be expected, the Panel recognized that even the most restrictive term of "like product" could be interpreted in several different ways. It has been suggested that the concept should be defined on a case to case basis according to different criteria. For example, it has been suggested guidelines such as the similarity of the product's end-use in the market, objective

[67] Of course, this is a reference to the *1991 Tuna – Dolphin* Case, at para. 5.33.

[68] See Cheyne, I., *Environmental Unilateralism and the WTO/GATT System*, 24 Georgia Journal of International and Comparative Law 433, 1995, p. 438.

[69] See *United States – Taxes on Petroleum and Certain Imported Substances*, GATT, BISD 34S/136, at 5. 1. [hereinafter *U. S. Taxes on Petroleum* Case].

[70] See Cheyne, I., op. cit., p. 439.

[71] See *U. S. Taxes on Petroleum* Case, at 5.1.1.

[72] See *Japan – Alcohol*, at 3.a.

[73] *Ibid.*. at. 6.21.

[74] Interpretative Note Ad Article III, GATT Annex I, at. 2.

[75] See *Japan – Alcohol*, at 6.28-6.32.

[76] See Cheyne, I., op. cit., p. 439.

[77] See *Japan – Alcohol*, at 5.7.

criteria such as compositions and manufacturing processes and consumer preferences, which vary country by country.[78] The question remains whether these criteria relate to the elemental characteristics of the product as such.

But if criteria not related to the product itself occasionally have been used, why has this not been applied to environmental trade measures? This writer contends that the Panels have not been ready to include in their definition of the product environmental aspects due to the political implications for the trading system. Whatever reason is, it is certainly not because the term "like product" has an inherent meaning that has been "unveiled" and can not be defeated.

In conclusion, in order to satisfy the test of Article III, a Panel will examine:[79] (1) whether the trade measure focuses in the imported product's intrinsic characteristics and attributes (if the measure targets production and processing methods, the fact that the measure is origin neutral does not prevent incompatibility with the article); (2) whether the measure affects expectations regarding competition between products and not particular trade volumes (the fact that there is no intention to affect trade flows is irrelevant); (3) the relation to the second sentence of Article III paragraph two, whether different treatment is applied to competitive products in conjunction with protective application.

*2. Article XI*

Article XI prohibits quantitative restrictions such as quotas, bans and licenses on imported or exported products. Other than through the article's specific exemptions, the only way a quantitative restriction can conform to GATT is by falling within one of the exceptions enumerated in Article XX. However, the contracting party enforcing the quantitative restriction must observe the most favored nation principle as well as the national treatment obligation.[80] By prohibiting non-tariff barriers, the ban on quantitative restrictions also prevents Member States from instituting environmental restrictions such as a conservation ban imposed on exports of resources (unless justified under Article XX).[81]

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There have been many debates as to whether Articles XI or III apply to environmental regulations. [82] Some general remarks can be made. It has been traditionally understood that while Article XI applies to measures affecting the *act of importation* of any merchandise from

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[78] *Ibid.*. See *Spain – Tariff Treatment of Unroasted Coffee*, Panel Report, 11 June 1981, BISD 28S/ at 4.8; Report of the Working Party on "Border Tax Adjustments", GATT, BISD 18s/97, adds nature and quality of the product.66.

[79] See Zedalis, R., *Product v. Non-Product Based Distinctions in GATT Article III Trade and Environment Jurisprudence: Recent Developments*, in European Environmental Law Review, April 1997, p. 112.

[80] See GATT Article XIII.

[81] See Housman, R. and Zaelke, D., *Trade, Environment and Sustainable Development: A Primer*, in 15 Hastings International and Comparative Law Review, 1992, p. 542.

[82] A measure falling under Article III can not be jointly considered under the aegis of Article XI, because it is either internal or external, but not both. Concerning this, see Mathis, J., *Trade Related Environmental Measures in the GATT*, in 2 Legal Issues of European Integration 119, at 55. See also *Canada – Administration of the Foreign Investment Review Act*, (L/5504), 30 BISD, 7 February 1984, at 5.14.

other territory, Article III regulates those measures affecting products *after* importation. [83] Since the conduction of product tests and the certification of stocks in order to control their compliance with national requirements are activities conducted *after* import, these are considered as internal requirements for the purposes of Article III.[84] Additionally, the Note to Article III extends the scope of this article to domestic measures enforced *at the time or point* of importation.[85]

However, it has been affirmed that an import restriction, even if it has an equivalent measure which applies to domestic marketing or manufacturing, can not be typified as a domestic regulation if it aims to target the production–process technique of the imported and the like domestic good.[86] As a result, Article XI will be the pertinent legal norm inasmuch it can be a quantitative restriction. In other words, Article III can only be invoked in respect of a measure that affects imported products and the like domestic product *as product*.[87] Thus, in many instances most important than the point or time at which the measure is implemented, it is the *target* of the measure what will determine the correct legal ground. If it targets the product as such, then the appropriate legal ground will be provided by Article III. If it aims to regulate the process, the it will be caught by Article XI.

*3. Article XX*

Once a measure has been found to be in breach of either Article III or XI, the enacting country can look for a safe haven under the arrangements of several exceptions. Currently, there are four environment-specific exceptions to the general principles of the GATT: Article XX (b)(g), the Agreement on the Application of Sanitary and Phytosanitary Measures and the Agreement on

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[83]See Mathis, J., *External Legal Aspects of the Transatlantic Marketplace*, March 12, 1998, p. 8 and 32, to be published yet. Mathis suggests that GATT Article XI can be the appropriate legal ground for internal regulations amounting to quantitative restrictions applied after importation, if we adopt the ruling of the European Court of Justice in the landmark *Dassonville* Case. In this case, it was established that "all trading rules enacted by Member States which are capable of hindering, directly or indirectly, actually of potentially, intra-Community trade are to be considered as measures having an effect equivalent to quantitative restrictions." If we apply this interpretation of "measure having equivalent effect" to GATT Article XI's "other measures", then environmental regulations would constitute measures having equivalent effect to quantitative restrictions, every time they hinder trade. It follows that the legal basis in this case would be Article XI instead of Article III. Indeed, this was an issue in the *1991* and *1994 Tuna - Dolphin* Cases, where the complainants argued that the measure taken by the U.S. amounted to quantitative restrictions and not internal laws because a border measure was merely a convenient way of enforcing the internal measure (limiting the incidental killing of dolphins) but could not be a substantially different measure (restricting the landing of tuna and tuna products as such.). In the end, the Panel gave the reason to the complainants under its own reasoning.

[84] Of course, there has to be an analogous discipline on domestic sale or production

[85] The Note reads: "[a]ny internal tax or other internal charge, or any law, regulation or requirement of the kind referred to in paragraph I which applies to an imported product and the like domestic product and is collected or enforced in the case of the imported product at the time or point of importation, is nevertheless to be regarded as an internal tax or other internal charge, or law, regulation or requirement of the kind referred to in paragraph I, and is accordingly subject to the provisions of Article III."

[86] This is the conclusion to which one must arrive after studying the Panels arguments for rejecting the U. S. insistence in Article III as the appropriate rule applicable to its embargo. See the *1991Tuna – Dolphin* Case, at 5.8-5.16 and *1994 Tuna – Dolphin* Case, at 5.6-5.10.

[87] See *1994 Tuna – Dolphin* Case, at 5.8.

Technical Barriers to Trade.[88] This section focuses in the exceptions of Article XX, inasmuch as it is the most common defense ground used so far. Article XX provides that:

> Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between 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 parties of measures:
> b) necessary to protect human, animal or plant life or health;
> g) relating to the conservation of exhaustible resources if such measures are made effective in conjunction with restrictions on domestic production or consumption;

The mechanics of this article operate as follows. After the finding of an infringement by a national measure, it is analyzed: (1) whether the policy purportedly embodied in the national measure serves to achieve one the objectives established in the ten exceptions; (2) whether the national measure is necessary to achieve the policy objective; and (3) whether the measure complies with the chapeau of Article XX.[89] If the internal disposition meets survives all these successive tests, then it is considered to be justified under GATT.[90]

**a. The Preamble**

Only after a measure falls within one of the ten exception listed in article ten then the preamble is considered. It is the application of the measure and not the measure itself which the chapeau addresses.[91] The chapeau contains the requirement to avoid arbitrary or unjustifiable discrimination between countries where the same conditions prevail,[92] or a prevent the enforcement of disguised restriction to international trade. This obligations are different from most-favored-nation and national treatment stated in Articles I and III.[93] As confirmed by the Appellate Body of the *U. S. Gasoline* Case,[94] these requirements have to be understood as a *sui generis* type of discrimination:

> The provisions of the chapeau cannot logically refer to the same standard(s) by which a violation of a substantive rule has been determined to have occurred. To proceed down the path would be

[88] See Meier, M., *GATT, WTO and the Environment: To What Extent Do GATT/WTO Rules Permit Member Nations to Protect the Environment When Doing So Adversely Affects Trade?*, in Colorado Journal of International Environmental Law and Policy, 1997, Vol. 8, No. 2, p. 244.

[89] See GATT Secretariat, *GATT/WTO Dispute Settlement Practice Relating to Article XX, Paragraphs (b), (d) and (g) of GATT*, WT/CTE/W/53, 30 July 1997, p. 5 and *U. S. Gasoline* Case, at 22. Nevertheless, in the recent *United States – Import prohibition of Certain Shrimp and Shrimp Products*, (*Shrimp* Case) 15 May 1998, WT/DS58/R, at 34, the Panel expressed in citing the *U. S. Gasoline* Case: "However, as the conditions contained in the introductory provision apply to any of the paragraphs of Article XX, it seems equally appropriate to analyze first the introductory provision of Article XX."

[90] See Mathis, J., *Trade Related Environmental Measure in the GATT*, p. 48. See also Meier, M., op. cit., p. 252.

[91] See *United States – Imports of Certain Automotive Spring Assemblies*, 26 May 1983, BISD 30S/107, at 56; *U. S. Gasoline* Case, at 22; *Shrimp* Case, at 29.

[92] The phrase "between countries where the same conditions prevail" has not been addressed properly yet.

[93] See GATT Secretariat, op. cit., p. 6.

[94] See *U. S. Gasoline* Case, at 22.

> both to empty the chapeau of its contents and to deprive the exceptions in paragraphs (a) to (j) of meaning. Such recourse would also confuse the question of whether inconsistency with a substantive rule existed, with the further and separate question arising under the chapeau of Article XX as to whether that inconsistency was nevertheless justified. One of the corollaries of the "general rule of interpretation" in the Vienna Convention is that interpretation must fine meaning and effect to all the terms of a treaty. An interpreter is not free to adopt a reading that would result in reducing whole clauses of paragraphs of a treaty to redundancy or inutility". [95]

This is a clear statement of the validity of the principle of effectiveness in GATT interpretation. However, this argument did not prevent the Appellate Body from making a redundant interpretation of the chapeau's key terms. In fact, later it was ruled that the preamble's three conditions should be read side-by-side, since they impart meaning to one another:

> "It is clear to us that 'disguised restriction' includes disguised discrimination in international trade. It is equally clear that concealed or unannounced restriction or discrimination in international trade does not exhaust the meaning of disguised restriction[96]…the kinds of considerations pertinent in deciding whether the application of a particular measure amounts to 'arbitrary or unjustifiable discrimination', may also be taken into account in determining the presence of a 'disguised restriction' on international trade. The fundamental theme is to be found in the purpose and object of avoiding abuse or illegitimate use of the exceptions to substantive rules available in Article XX." [97]

To say that the same considerations apply in determining whether there is a disguised restriction or an unjustifiable discrimination makes the use of the three concepts redundant. The problem with this approach is that the term 'discrimination' focuses on how a measure affects the *status* of an import in relation to domestic goods while a disguised restriction focuses more on a hidden intent behind the measure and the *effect* of the measure on the flow of imports.[98]

In spite of the side-by-side reading of the chapeau, the question remains whether the exact meaning of 'arbitrary discrimination or unjustifiable discrimination' and 'disguised restriction' in GATT case law can be determined. The meaning of a 'disguised restriction' has yet to be properly defined. Previously, it had been interpreted to refer to cases where a claimed regulatory purpose was found to be of so little importance or so little served that it could be called a disguise.[99] As examined, the *U. S. Gasoline Case* did not explore further its meaning, beyond indicating that a concealed or unannounced restriction or discrimination does not exhaust the meaning of the concept.

In relation to the term "unjustifiable", the *Shrimp* Case pretended to further clarify its meaning:[100]

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[95] *Ibid.* at 23.

[96] This is a rejection of previous GATT panels, suggesting that a restriction is not disguised if it is not concealed. See *United States: Prohibition on Imports of Tuna and Tuna Products from Canada,* GATT Doc. L/5198, BISD, Supp.29, 22 February 22, 1982, at 48.

[97] *Ibid.* at 25.

[98] See Strom, T., Pouring Fuel on Fire? The WTO's Reformulated Gasoline Case, in Annuare Canadien de Droit International 1996, Vol. XXXIV, Tome XXXIV, p. 264.

[99] See United *States: Canada's Landing Requirements for Salmon and Herring* (1991), at 7.11.

[100] See *Shrimp* Case. The facts of the case are as follows. *Pursuant* to the US Endangered Species Act of 1973 (hereafter "ESA"), all sea turtles that occur in US waters are listed as endangered or threatened species. Research programmes carried out by the United States have led to the conclusion that incidental capture and drowning of sea turtles by shrimp trawlers is a significant source of mortality for sea turtles.

"…discriminatory treatment is applied to shrimp from non-certified countries. Pursuant to the chapeau of Article XX, a measure may discriminate, but not in an "arbitrary" or unjustifiable" manner. We therefore move to consider whether the US measure conditioning market access on the adoption of certain conservation policies by the exporting Member could be considered as "unjustifiable" discrimination. While the ordinary meaning of "unjustifiable" confirms that Article XX is to be applied within certain boundaries, it does not explicitly address the issue of whether Article XX should be interpreted to contain any limitation on a Member's use of measures conditioning market access on the adoption of certain conservation policies by the exporting Member. For that reason, it is essential that we interpret the term "unjustifiable" within its context and in the light of the object and purpose of the agreement to which it belongs."[101]

**b. Article XX (b)**

The case law providing the analytical framework for this article is less than the number of cases for Article XX (g). A measure has been considered to be necessary if there is either no alternative measure consistent with the Agreement or less inconsistent with it, that could reasonably be expected to be employed by the imposing state.[102] This is to say that under GATT, a Member has to use the least inconsistent measure available when such inconsistencies are unavoidable.[103] Finally, a measure necessary to protect the life and health of animals,

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The United States National Marine Fisheries Service has developed, within a programme aimed at reducing the mortality of sea turtles in shrimp trawls, turtle excluder devices (hereafter "TEDs"). In 1987, the United States issued regulations under the ESA whereby shrimp fishermen are required to use TEDs or tow time restrictions in specified areas where there is a significant mortality of sea turtles in shrimp trawls. Since December 1994, these regulations have eliminated the option for small trawl vessels to restrict tow times in lieu of using TEDs.

In 1989, the United States enacted Section 609 of Public Law 101-162 (hereafter "Section 609"). Section 609 provides that shrimp harvested with technology that may adversely affect certain sea turtles protected under US law may not be imported into the United States, unless the President annually certifies to the Congress that the harvesting country concerned has a regulatory programme governing the incidental taking of such sea turtles in the course of such harvesting that is comparable to that of the United States, that the average rate of that incidental taking by the vessels of the harvesting country is comparable to the average rate of incidental taking of sea turtles by United States vessels in the course of such harvesting, or that the fishing environment of the harvesting country does not pose a threat of incidental taking to sea turtles in the course of such harvesting.

In April 1996, the Department of State extended the scope of Section 609 to shrimp harvested in all countries. The Department of State further determined that, as of 1 May 1996, all shipments of shrimp and shrimp products into the United States must be accompanied by a declaration attesting that the shrimp or shrimp product in question has been harvested "either under conditions that do not adversely affect sea turtles ... or in waters subject to the jurisdiction of a nation currently certified pursuant to Section 609."

Thailand, Malaysia, Pakistan and India requested the establishment of a panel. According to them, the US measure breached Articles I, III, XI and XIII of the GATT. This body ruled that the measures in question amounted to quantitative restrictions and could not be justified under Article XX (b) relaying in previous case law and an examination of the meaning of "unjustifiable". According to the Panel, "it appears to us that, in light of the context of the term "unjustifiable" and the object and purpose of the WTO Agreement, the US measure at issue constitutes unjustifiable discrimination between countries where the same conditions prevail and thus is not within the scope of measures permitted under Article XX."

[101] See *Shrimp* Case, at 33-34.

[102] See *Thailand Restrictions on Importation of and Internal Taxes on Cigarettes*, DS/10R, adopted 7 November 1990, BISD 37S/200, at 74-75. *1994 Tuna – Dolphin* Case, at 5.35.

[103] See *United States-Section 337 of the Tariff Act of 1930*. L/6439, 7 November 1989, at 5.26.

humans and plants may not include measures forcing other countries to change their policies within their jurisdictions or which require such changes to be effective.[104]

The second addition to the concept of 'necessary' is problematic. "Necessary", according to Oxford's, means "essential for a purpose". In the context of the Tuna - Dolphin Cases, it is difficult to understand how the restriction in the consumption of tuna of the world's biggest consumer is not essential for the purpose of preventing the depletion of the associated species killed during the fishing. Granted, the measure amounts to commercial coercion and as such should be dealt with in the appropriate legal ground, for example because it is discriminatory. But to import into the acceptation of the word 'necessary' concepts which have nothing do with it under any generally understood meaning in order to deal with the problem of unilateralism and protectionism, creates a picture that only adds judicial uncertainty.

In conclusion, GATT case law has settled that to test the validity of a national measure in relation to Article XX (b), a Panel will examine: (1) whether the measure serves to protect human, animal, plant life or health; (2) whether the measure is necessary, within the meaning already explained; and (3) whether the measure is consistent with the chapeau.

**c. Article XX (g)**

Article XX (g) provides another exception for environmental purposes. "Relating to…" has been interpreted to mean, "primarily aimed at"[105]. Recently there has been further guidance instructing how the "relating to" is to be applied. It has been declared that if the relationship between the conservation goal and the trade measure at issue is 'substantial', then the "relating to' requirement would be satisfied.[106] Such an interpretation is broader than that which has been applied by previous panels. Alternatively, the article covers import and export restrictions when accompanied by domestic restrictions on consumption or production.[107] This second clause should be read disjunctively; an environmental measure may be directed at domestic production *or* consumption.[108]

In the *U. S. Gasoline* Case, the Appellate Body ruled that in the case of this Article XX (g), the measure is not required to be necessary in order to be justified, as had been stated by the Panel.[109] In other words, the fact that another less-trade restrictive measures could be used equally and more efficiently to encourage the conservation of exhaustible natural resources does not imply that the measure could not be justified under the article. In reaching this conclusion, the Appellate Body noted that the Panel had not taken into consideration one of the pillars of treaty

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[104] See *1994 Tuna - Dolphin* Case, at 5. 38.

[105] See *Canada – Measures Affecting Exports of Unprocessed Herring and Salmon*, L/6268, 22 March 1988, BISD 35S/98, at 4.4 [hereafter *Herring and Salmon* Case]; *1991 Tuna – Dolphin* Case, *supra* note 33, at 5.33; *1994 Tuna – Dolphin* Case, *supra* note 33, at 5.35; *U. S. Automobiles* Case, at 5.57; *U. S. Gasoline* Case, at 6.39.

[106] See *U. S. Gasoline* Case, at 19. Such an interpretation is broader than that applied by previous panels.

[107] See Mathis, J., *Trade Related Environmental Measure in the GATT*, p. 51.

[108] See *U. S. Gasoline* Case, at 20-22.

[109] See *U. S. Automobiles* Case, at 5.63.

interpretation: Article 31.1 of the Vienna Convention.[110] Unlike other paragraphs of Article XX, "necessary" is not used in the context of Article XX (g) and to require its use would demand disregarding the actual words of the Article. While the context (in terms of GATT's substantive provisions) and the object and purpose were important factors in arriving at the decision, the Appellate Body emphasized that the words used by the WTO parties to express their intent and purpose should not be disregarded.[111]

Furthermore, the measure must be primarily aimed at conservation and not merely related to that purpose.[112] In other words, a trade measure can only be considered to be made effective "in conjunction with" production or consumption restrictions if it is primarily aimed at rendering these restrictions effective.[113] The fact that the rule may impact upon domestic and foreign producers differently is irrelevant to this particular aspect of the inquiry, as "there is no textual basis for requiring identical treatment of domestic or imported products".[114]

Therefore, a Panel will employ a three-step analysis to examine this article: (1) whether the policy purportedly embodied in the measure is a policy to conserve the resources; (2) whether the national measure is primarily aimed at the conservation of resources and whether it is implemented "in conjunction" with restrictions in domestic production or consumption; and (3) whether the measure conforms with the introductory clause of Article XX.

The evolution of the phrase "primarily aimed at" in the GATT jurisprudence is an interesting study. According to the *1994 Tuna-Dolphin* Case, "measures taken so as to force other countries to change their policies, and that were effective only if such changes occurred, could not be primarily aimed either at the conservation of an exhaustible natural resource, or at rendering effective restriction on domestic production of consumption."[115] The hidden assumption here is that such measures primarily serve to exclude *a priori* other members' products. Then, a fourth element of analysis was to be considered when reviewing a national measure: whether it forces other members to change their own policies within their jurisdiction. However, in the *U. S. Gasoline* Case, the Appellate Body declined to consider this factor within its framework of analysis.[116] Perhaps this same evolution could also be seen in relation to this issue in Article XX (b), already discussed above.

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[110] See *U. S. Gasoline* Case, at 16-17.

[111] *Ibid.*, at 18.

[112] Mathis, J., *Trade Related Environmental Measure in the GATT*, p. 52.

[113] *Ibid.*, p. 51, citing the Panel Report on Unprocessed Herring and Salmon.

[114] See *U. S. Gasoline* Case, at p. 625. The Panel there added that "[t]he fact that imported gasoline received less favorable treatment than domestic gasoline in terms of Article 3:4 was immaterial to this particular aspect of the inquiry." Of course, different treatment will be question in relation to the introductory clause of Article XX.

[115] See *1994 Tuna* Case, at 5. 39

[116] This does not mean that the Appellate Body condoned unilateral actions. As the *1994 Tuna-Dolphin* had also hinted, the Appellate Body suggested again the importance of attempts to conclude ancillary international agreements. Nevertheless, the subjective element, those that some call "environmental imperialism" should not be considered as a part of the analysis anymore.

*A Short Note on the Associated Agreements*

The Agreement on Technical Barriers to Trade[117] and the Agreement on the Application of Sanitary and Phytosanitary Measures[118] are ancillary agreements within the GATT/WTO framework. The first is prevents a protective application of technical standards, while the second one provides rules for food safety and animal and plant health. Even though these instruments have not played a crucial role in this debate, they could prove strategic in the near future. Both Agreements provide that in that when national legislation is based in international norms, they are *prima facie* presumed GATT consistent. ON the contrary, if the depart from the international standards, theu burden of proof fall on the enacting party, since it will have to prove that they are GATT consistent. Therefore, a short analysis of both agreements is provided below.

**a. The Agreement on Technical Barriers to Trade**

The TBT Agreement prevents the creation of unnecessary obstacles to trade by means of technical regulations, standards and conformity assessments. It covers process and production methods related to the characteristics of the product itself.[119] The Preamble recognized the Member's right to take measures necessary for the protection of human, life, animal or plant life or health and for the protection of the environment. The regulations enacted should not constitute a disguised restriction to international trade or a means of arbitrary discrimination between countries were the same conditions prevail. Furthermore, The TBT Agreement's Article 2. 1 requires that standards be applied on a most favored nation basis, meaning no less favorable treatment for "like" products.

The TBT overrides other WTO rules in case of conflict.[120] Therefore, a national measure would be legal when, failing to qualify for as a GATT Article XX exception, it meets the TBT's requirements. In the *Gasoline* Case, the Panel considered unnecessary to examine the TBT since the Gasoline Rule, according to the Panel, did not qualify for exemption under Article XX.[121] Taking in consideration that the TBT Agreement is more flexible than Article XX in allowing exceptions to the GATT,[122] we would have expected a consideration of whether the Gasoline rule would qualify as for a TBT exception.[123]

[117] Agreement on Technical Barriers to Trade, April 15, 1994, Agreement Establishing the World Trade Organization, Annex 1A, (hereinafter TBT Agreement).

[118] Agreement on the Application of Sanitary and Phytosanitary Measures, April 15, 1994, Agreement Establishing the World Trade Organization, Annex 1 A, (hereinafter SPS Agreement).

[119] According to the Annex I. 1 of the TBT Agreement, a technical regulation is a "[d]ocument which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory."

[120] See General Interpretative Note to Annex 1A, April 15, 1994, Agreement Establishing the World Trade Organization, Annex 1A.

[121] See Meier, M., *GATT, WTO and the Environment: To What Extent Do GATT/WTO Rules Permit Member Nations to Protect the Environment When Doing So Adversely Affects Trade?*, p. 279.

[122] For example, according to the TBT Agreement's Article 2.2, a Member can enforce technical regulations based on legitimate objectives such as *inter alia*, national security requirements, the prevention of deceptive practices, protection of human health or safety, animal or plant life or health, or the environment. GATT Article XX does not provide for some of these.

[123] *Ibid*.

**b. The Agreement on the Application of Sanitary and Phytosanitary Measures**

Since Article XX (b) lacks detailed standards, the SPS Agreement establishes technical rules to which national environmental and health rules should conform to. Specifically, it regulates measures used by governments to ensure that human and animal food is safe from contaminants, toxins, disease-causing organisms and additives. Besides, it covers measures to protect human health form pests or diseases carried by plants or animals. Such measures should be taken only to the extent necessary for health protection, on the basis of scientific principles and evidence.

The SPS Agreement prevails over the GATT in cases of conflict.[124] Consequently, an environmental measure contrary to GATT Article XX (b) but in conformity with the SPS would be legal. While Article XX (b) offers only exception to rules protecting human, animal and plant life, the SPS Agreements has a broader scope. It provides an exception for all qualified sanitary and phytosanitary measures.[125] Therefore, the measures covered by Article XX (b) are comprised within the SPS.

One of the main differences between the SPS and the TBT Agreement is that in the first one, regulations can be applied disregarding the most favored nation principle. The SPS permits Members to impose different sanitary and phytosanitary measures provided that these do not arbitrarily discriminate between countries where identical or similar conditions prevail.[126] This is due to differences in climate, diseases and food safety conditions.

The SPS provides that measures should be taken based on a riks assessment with concluding scientific information supporting the norm. There small room for countries that don´t have concluding evidence but want to act based on precautionary approach. However, as we will see later, the Biosafety Protocol has widened the room for maneuver in respect to the LMO under its scope. .

**SECTION V: CONFLICTS AND RELATIONSHIPS BETWEEN THE PROTOCOL AND THE 1994 GATT**

*Conflicts*

**Labelling**

The main conflict comes from most important source of conflicts may arise from the application of the restrictions to the LMO-FFPs

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[124] See General Interpretative Note to Annex 1A, April 15, 1994, Agreement Establishing the World Trade Organization, Annex 1A.

[125] Article 1. 1 indicates that the "Agreement applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade. Such measures shall be developed and applied in accordance with the provisions of this Agreement."

[126] Article 2. 3 of SPS Agreement provides: "Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade."

Presently states can only require a label that says “may contain” LMO-FFPs. But what happens is a country decide to rule that all products containing LMOs should have a labelled saying that it do contains those organisms? Probably the rule will be declared inconsistent with the WTO Agreements.

First of all, GM producer say that GM foods and traditional foods are “like products”. In a way, for the normal consumer in the market, there is no way for him to determine the difference between and GM tomato and a traditional one. We have seen that do determine if products are similar they have resorted to the physical characteristics plus consumer tastes and preferences. In the Japan alcohol case we saw how different liquors were considered alike based on consumer criteria and not their physical characteristics. Probably a Panel will rule that GM food and normal food are alike.

In this case, any differentiation would violate Article III, constituting a quantitative restriction according to Article XI. In such a case, the measure should seek justification in one of the exceptions. Article XX (b) may provide a ground for defence. However, according to the SPS Agreement the measure should be taken after a risk assessment with concluding scientific evidence supporting it. We have seen that the SPS does not have a lot of room for precautionary measure, but is the Biosafety Protocol the one that provides more detailed criteria. Nevertheless, the Biosafety Protocol will not help in the matter. It may even work to declare the measure unjustifiable since it does not allow such a labelling. We will have to conclude that probably a compulsory labelling for LMO-FFPs will be GATT inconsistent. This might run contrary to the consumers´s right to know.

**Consumers' Right To Know**

Genetic modification has important implications in the spheres of health, the Environment, ethics, religious beliefs and the economy. Consumers have the right to full information about the safety of the technology and about products whose genetic structure has been altered.

The consumer's right to know has been established and accepted, notably by the UN General Assembly when it adopted the Guidelines for Consumer Protection. Article 3 cites one of the legitimate needs the guidelines are intended to meet as being the "access of consumers to adequate information to enable them to make informed choices according to individual wishes and needs".

Information readily available to consumers must include the full disclosure of all aspects of the safety evaluation of genetically modified foods, and the clear and truthful labelling of any approved products that come on to the market. Genetically modified foodstuffs have already reached the market unlabelled, but surveys have shown there is a strong consumer demand for full labelling of such foods. Labelling would give those consumers who wish to buy or to avoid genetically altered food the information that they need to do so. With proper labelling, consumers would be in a position to decide for themselves whether to buy products created as a result of this new technology.

*Supportiveness*

There are not only conflicts between the international trade rules and the biosafety protocol, since they can also be mutually supportive For instance, the Protocol complements the SPS Agreement rules in relation to the precautionary approach in the following ways:[127]

- The SPS does not spell out exactly what a risk assessment entails, but the Protocol does so in detail in Annex II.
- The SPS does not mention risk management, but only risk assessment. The Protocol (in Articles 15 and 16) makes it clear that both exercises are necessary, defining the latter as the gathering of the data, and the former as the building of a regulatory regime based on that data. It further sets out some guidance in creating that regime; for example, asking Parties to try to ensure that any LMO should undergo an appropriate period of observation commensurate with its life-cycle or generation time before it is put to its intended use.
- The Protocol explicitly allows Parties to take into account socio-economic considerations in making their decisions, whereas the SPS says nothing on the subject.

[127] Stas, Writer, Op. Cit., p. 9.

- The Protocol is specific about the process for review of decisions in the light of new evidence (Article 12), whereas the SPS is ambiguous about how to treat measures adopted provisionally in the face of uncertainty.
- The provisions in Article 15 go some distance toward laying the onus on the exporter to establish the harmless nature of the LMO in question. Paragraphs 2 and 3 state that the party of import may require the exporter to carry out the risk assessment, and it may require the notifying party to foot the bill. Again, on this question, the SPS is silent.

The significance of the Protocol's precautionary provisions seems to be that they fill in some of the gaps in the SPS Agreement. They enrich the SPS by adding details that help implement the precautionary principle in the context of LMOs.[128] It is my submission that even though the Protocol does not require a risk assessment for LMO-FFPs prior to importation, countries can require it. Even more, if the assessment is not completely concluding, they can rely on the precautionary principle to enact legislation. This is different from the labelling requirements, since the Protocol clearly precludes labelling stating that the products <u>contain</u> LMOs.

**SECTION VI: THE CODEX ALIMENTARIUS COMMISSION AND CONSUMERS[129]**

The Eleventh Session of the Conference of FAO in 1961 and the Sixteenth World Health Assembly in 1963 both passed resolutions to establish the Codex Alimentarius Commission. Therefore, the Commission was created with the primary task of establishing scientific standards on food safety. The Commission meets every two years, alternately at FAO headquarters in Rome and at WHO headquarters in Geneva. Plenary sessions are attended by as many as 500 people. Representation at sessions is on a country basis. National delegations are led by senior officials appointed by their governments. Delegations may, and often do, include representatives of industry, consumers' organizations and academic institutes. Countries that are not yet members of the Commission sometimes attend in an observer capacity.

A number of international governmental organizations and international NGOs also attend in an observer capacity. Although they are "observers", the tradition of the Codex Alimentarius Commission allows such organizations to put forward their points of view at every stage except in the final decision, which is the exclusive prerogative of Member Governments.

To facilitate continuous contact with member countries, the Commission, in collaboration with national governments, has established country *Codex Contact Points* and many member countries have *National Codex Committees* to coordinate activities nationally.

*Importance*

The Codex Alimentarius has relevance to the international food trade. With respect to the ever-increasing global market, in particular, the advantages of having universally uniform food standards for the protection of consumers are self-evident. It is not surprising, therefore, that the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) and the Agreement on Technical Barriers to Trade (TBT) both encourage the international harmonization of food standards. A product of the Uruguay Round of multinational trade negotiations, the SPS Agreement cites Codex standards, guidelines and recommendations as the preferred international measures for facilitating international trade in food. As such, Codex standards have become the benchmarks against which national food measures and regulations are evaluated within the legal parameters of the Uruguay Round Agreements.

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[128] Id.

[129] See www.fao.org

*Participation*

Since its beginning, the Commission has welcomed the participation of consumers, whose organizations have been represented at its sessions since 1965. The involvement of consumers in the Commission's work has been the subject of explicit discussions within the Commission. Consumers' participation in decision-making in relation to food standards and the Joint FAO/WHO Food Standards Programme, for instance, was an item on the agenda of the 20th Session of the Codex Alimentarius Commission, where it was agreed that it is necessary to continue working in close cooperation with consumers' organizations.

The highest priority of the Codex Alimentarius Commission, as stated in Article 1 of its statutes, is to protect the health of consumers and ensure fair practices in the food trade.
Other UN bodies have also recognized the importance of consumer protection, and in 1985 a UN General Assembly resolution gave rise to the *Guidelines for consumer protection*, published in 1986. These guidelines identify food as one of three priority areas that are of essential concern to the health of consumers, and the document specifically identifies the Codex Alimentarius as the reference point for consumer protection with regard to food.

While open to participation from all governments, few developing countries can afford to monitor the Codex process closely, and meetings are generally dominated by the developed countries — especially North America and Europe, whose national delegations tend to push a "commercial agenda," says Sri Ram Khanna of India's VOICE consumer group. Last year, Consumers International protested the "unacceptable influence of business interests" following revelations that a US consultant to the Codex committee assessing BST safety had passed confidential documents to Monsanto, the company that sells the controversial bovine milk hormone.

Industry voices predominate over public interest groups. A 1993 analysis of Codex representation found that 49% of the accredited US delegates were from industry, 44% of the Japanese, 31% of the British and 61% of the Swiss. Nearly all industry representatives came from large global corporations: small businesses and farmers were virtually absent. Just 0.4% of the total delegates came from consumer and public interest groups. Codex has since taken steps to increase consumer participation, but the balance remains skewed.[130]

**Final remarks**

Some general comments on the Protocol

The Protocol is a significant step forward. It contains some important victories for the non-Miami Group world and civil society. These include the absence of a WTO override clause, and the inclusion of references to the precautionary principle as a basis for decision-making, including with respect to commodities.

However, the Protocol also suffers from some significant ambiguities and weaknesses. For example, a clause was included so that socio-economic impacts (with specific reference to impacts on indigenous peoples) could be considered when deciding whether an import will be allowed or not. However, it is limited to risk management, and is subject to other international obligations, which may limit its utility in relation to the WTO. Provision was not made for a social or cultural impact assessment regarding the introduction of an LMO, or the consequences of such impacts for the conservation and sustainable use of biological diversity. Finally, it also puts the consumer's right to know at risk.

[130] See www.consumersinternational.org

Ways must be found to enable the public to participate in decision-making about genetically engineered foods.  Not all the potential human health problems will certainly occur.  But some may.  We don´t know which ones since we have not bothered to look.[131]  It is clear that consumer lawyers and the international society have much homework to do.

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[131] Harvey, Linda.  Human Health and GMOs, in Ecology and Farming, No. 25, Septmeber – December 2000, the International Magazine of the International Federation of Oorganic Agriculture Movements (IFOAM), p 10.

## DERECHOS DE LOS CONSUMIDORES[132]

**DERECHOS DE LOS CONSUMIDORES[133]**

Las organizaciones de consumidores, por lo general, no rechazan de manera categórica la modificación genética. Sí exigen seguridad y derecho a tomar decisiones informadas.

Las siguientes son algunas de las demandas y recomendaciones planteadas por grupos, algunos científicos, organizaciones ambientalistas y consumidores:

A. Protección del ambiente

- Que se declare una moratoria en el cultivo comercial de productos transgénicos hasta no contar con el consenso científico, o al menos con un acuerdo razonable, sobre los potenciales efectos ambientales a largo plazo. (Informe preliminar de la British Medical Association, mayo de 1999).
- Que se establezcan protocolos de seguridad más estrictos para las pruebas en terreno de organismos transgénicos. (Gene Campaign, India).
- Que se declare una moratoria inmediata a todos los ensayos en terreno y a la comercialización de cultivos transgénicos, durante al menos cinco años (World Scientists' Statement, Sitio web: www.i-sis.dircon.co.uk).

B. Salud y seguridad

- Que se declare una moratoria indefinida a los cultivos transgénicos hasta no contar con suficientes estudios sobre nuevas alergias provocadas por éstos, la propagación de genes resistentes a los antibióticos y los efectos del ADN transgénico. (British Medical Association).
- Que se promulgue la prohibición inmediata del uso de genes marcadores resistentes a los antibióticos en alimentos transgénicos. (Gene Campaign, India).
- Que se establezcan sistemas más estrictos de vigilancia de enfermedades para enfrentar la potencial aparición de nuevas enfermedades asociadas a productos transgénicos. (British Medical Association).

C. Producción y venta de alimentos

- Que la segregación se lleve a cabo en el origen, para posibilitar la identificación y el rastreo de los alimentos transgénicos. (British Medical Association).

- Que se exija el etiquetado de los productos transgénicos importados, y se ordene la prohibición de su comercialización si no llevan etiquetas. (British Medical Association).

- Que se realicen pruebas acuciosas de seguridad a los alimentos transgénicos previo a su comercialización. (Campaign for Food Safety (EEUU)

- Que las empresas que demuestran un compromiso en la comercialización de alimentos no transgénicos dispongan de instalaciones separadas para la producción de estos alimentos. (Food Magazine, Gran Bretaña, setiembre 1999).

- Que a los consumidores se les asegure una oferta garantizada de productos no transgénicos. (Bureau Européen des Unions de Consommateurs).

D. Etiquetado obligatorio

- Que los gobiernos establezcan la obligatoriedad del etiquetado para todos los alimentos e ingredientes transgénicos y la realización de un seguimiento completo a los organismos modificados genéticamente durante

[132] Esta parte forma parte de la Bioseguridad: guía para consumidores, en preparación y próxima publicación por parte de la FUNDACION AMBIO.

[133] ¿Alimentos transgénicos en boca de todos?
Debate y acción desde los consumidores ISBN: 956-7665-14 Consumers International © 2000
Título en Inglés: Our Food, Whose Choice?

todo el proceso de elaboración y distribución. (Transatlantic Consumer Dialogue, abril de 1999. Sitio web: www.tacd.org).

- Que los países exportadores establezcan la obligatoriedad del etiquetado en todos los productos exportados para distinguir los transgénicos de aquellos que no contienen dichos organismos. (Consumers Union de Japón).

- Que se establezca el etiquetado obligatorio para todos los alimentos que contengan más de un 1% de material transgénico. (Consumers Union de Japón).

- Que se exija el etiquetado obligatorio para los alimentos transgénicos e información sobre sus ingredientes para detectar los alergenos e identificar el origen de las alergias provocadas por dichos alimentos. (Campaign for Food Safety (EEUU).

E. Patentes y comercialización

- Que sean revocadas y prohibidas todas las patentes sobre organismos, células y genes vivientes. (World Scientists' Statement).

- Que los países tengan derechos internacionales, bajo el principio de precaución, sobre la prohibición o el control de importaciones y el uso de organismos transgénicos, así como el derecho a establecer acuerdos previos para el traslado de estos organismos entre un país y otro. (Greenpeace ).

F. Consultas públicas

- Que se realicen consultas públicas e independientes acerca de la seguridad agrícola y alimentaria del futuro, tomando en cuenta los estudios científicos realizados, así como sus implicaciones socioeconómicas y éticas. (World Scientists' Statement).

G. La posición de Consumers International[134]

Consumers International apoya el principio según el cual los alimentos genéticamente modificados deben ser tan seguros como sus homólogos convencionales. CI recomienda tomar muchas precauciones al declarar que un alimento genéticamente modificado es sustancialmente equivalente a un alimento convencional. El proceso que consiste en declarar algo sustancialmente equivalente debería ser transparente y accesible a expertos.

- Evaluación de la toxicidad: Debido a los efectos que puede tener la ingeniería genética sobre las toxinas en los alimentos, CI considera que debe darse prioridad al desarrollo de nuevos sistemas de pruebas para evaluar la toxicidad de los alimentos genéticamente modificados.
- Evaluación del carácter alergizante: Considerando que el problema de las alergias alimentarias podría agudizarse por la alteración genética de los alimentos, CI recomienda que los organismos que causan alergias no se utilicen como fuentes de material genético para ser insertado en otros organismos usados como alimento, a menos que pruebas en seres humanos demuestren que la proteína transferida no causa alergia.
- Resistencia a antibióticos: El uso de genes marcadores antibióticos en microorganismos presenta problemas para la salud. CI recomienda prohibir el uso de genes de resistencia antibiótica en microorganismos para alimentos. CI también recomienda el desarrollo y uso de alternativas a los genes marcadores de resistencia antibiótica para la transformación de plantas.
- Reglamentaciones de seguridad y etiquetado: CI pide que se refuercen las reglamentaciones de seguridad y etiquetado sobre los alimentos genéticamente modificados, a nivel nacional e internacional.

La reglamentación de los alimentos genéticamente modificados debe tener un amplio alcance y debe incluir:

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[134] "Alimentos transgénicos y la posición de los consumidores", por Karla Irigoyen, Oficina Regional para América Latina y el Caribe (CI, 1999).

H. Pautas básicas para los consumidores

Las normas actuales de protección de los consumidores se basan en los ocho derechos fundamentales que se detallan a continuación. Cuatro de ellos son pertinentes al debate sobre los alimentos transgénicos.

- ***El derecho a la satisfacción de las necesidades básicas:*** Acceso a productos y servicios básicos y esenciales: alimentos nutritivos, vestimenta, vivienda, servicios de salud, educación y sanidad.
- ***El derecho a la seguridad:*** Protección contra productos, procesos de producción y servicios que puedan perjudicar la salud o atentan contra la vida.
- ***El derecho a la información:*** Acceso a la información necesaria para tomar una decisión informada y protegerse contra la publicidad o el etiquetado deshonesto o engañoso.
- ***El derecho a elegir***: tener la posibilidad de elegir entre una gama de productos, ofrecidos a precios competitivos, con garantías de calidad satisfactoria.
- ***El derecho a la representación:*** representar los intereses de los consumidores en el diseño e implementación de políticas gubernamentales, y en el desarrollo de productos y servicios.
- ***El derecho a la reparación:*** recibir una resolución justa por reclamos justificados, incluyendo indemnización por la mala representación, productos de mala calidad o servicios insatisfactorios.
- ***El derecho a la educación del consumidor***: adquirir los conocimientos y habilidades necesarios para tomar decisiones informadas sobre productos y servicios, y al mismo tiempo estar consciente de los derechos y responsabilidades básicos del consumidor y cómo ejercerlos.
- ***El derecho a un ambiente saludable:*** vivir y trabajar en un ambiente que no amenace el bienestar de las actuales y futuras generaciones.
- ***El derecho a la seguridad:*** "Ya no bastan los argumentos de autoridad como garantía de la seguridad en los alimentos", señala Stephen Leeder, experto australiano en salud pública. Los consumidores ya no aceptan que les impongan qué es bueno o conveniente para ellos: quieren participar en el proceso que determina cuáles son los criterios de seguridad.

Los consumidores ya no están dispuestos a poner en riesgo su salud y su seguridad a largo plazo, la evaluación de la seguridad en relación a los alimentos transgénicos deber ser acuciosa, sería ingenuo suponer que, dada la etapa en que el desarrollo de estas nuevas tecnologías se encuentra todavía, hayan sido ya identificados todos los posibles riesgos para la salud humana

- ***Derecho a la información + derecho a elegir = derecho a tomar decisiones informadas***

La información no garantiza la seguridad, pero facilita la comprensión y la decisión de qué se va a comprar, y qué no. Una información completa sobre el proceso de producción permite a los consumidores más precavidos elegir sus alimentos con mayor cuidado, y también hace posible detectar posibles riesgos para la salud.

Sin duda, los alimentos transgénicos deben ser etiquetados como tales, pero esta simple identificación no es suficiente. La etiqueta debe incluir además información sobre cómo y por qué el producto fue modificado genéticamente; esta información debe ser también accesible por otros medios, como letreros en los escaparates, folletos o líneas telefónicas de información al consumidor.

No proporcionar esta información constituye una práctica comercial engañosa y deshonesta. La inexistencia de etiquetas terminará por perjudicar a algún sector de la industria alimenticia.

- ***El derecho a un ambiente saludable y sostenible***

Es la demanda lo que determinará finalmente cuáles alimentos transgénicos serán cultivados. Esta aceptación se extiende asimismo al uso de productos transgénicos en alimentos para animales, ya que gran parte de estos cultivos está destinada a ellos y no a los seres humanos. El impacto ambiental, en todo caso, es el mismo.

Al ser cada vez más evidente que estos cultivos afectan los ecosistemas, es posible que antes de pagar, los consumidores tomen su decisión de acuerdo con el "principio de precaución". Para las agrupaciones de consumidores, el impacto de estos productos sobre el medio ambiente y las normas elaboradas para protegerlo pueden constituir un buen punto de partida para las campañas que desarrollan en sus respectivos países. Los activistas pueden también vigilar y monitorear la posición que tienen sus gobiernos en las negociaciones del Protocolo de Bioseguridad y en otros tratados internacionales relativos a productos transgénicos y temas ambientales.