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Chapter 3

Biosafety, Consumer Protection and International Trade

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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 various positive contributions from this technology. They argue that it will reduce pressure on over-utilized and degraded soils and arable lands, decreasing the need to expand the agricultural frontier to areas such as fragile ecosystems; the less crops will be lost to pests and weeds; that agricultural products will be able to contain better nutritional value; and that there will be reduced use of energy and chemical pesticides.

However, modern agricultural biotechnology also represents unprecedented risks to human health and the environment, raises serious ethical questions, and may have significant international implications. The creation of 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* (UN CBD), an international treaty signed buy over 160 nations, which is designed to ensure the conservation and sustainable use of a broad range of living organisms and ecosystems which sustain the planet. Specifically, Article 8 (g) of the UN CBD 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 implemented internal legislation even before the UN CBD entered into force. The UN CBD *Cartagena Protocol on Biosafety*[4] has set down new rules for the international community, and these will be binding for countries enacting national laws. The following chapter tries to piece together, from a critical perspective, the institutional and legal puzzle in the Americas on these issues.

Concerns Related to Modern Biotechnology

There are serious environmental, health, socio-economic and ethical concerns related to the development and use of genetically engineered, or genetically modified (GM) organisms, in particular for food crops.

Environmental Concerns

It is a major challenge for scientists to identify the precise nature of potential environmental risks posed by GM crops. Different GM crops may present different risks, depending on a wide variety of factors including the characteristics of the crops and the location in which they are tested or grown commercially. Margaret Mellon and Jane Rissler, from the Union of Concerned Scientists, recently outlined two of the most significant and well-understood categories of environmental risk.[5] These are first, the environmental risks related to GM plants themselves, and second, the risks associated with the movement of transgenes (foreign genes spliced into plants) into other plants, including other species of plants.[6]

Health Concerns

Proponents of biotechnology maintain that GM 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 GM 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 GM 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 GM potatoes modified to express

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[3] *United Nations Convention on Biological Diversity*, 5 June 1992, 1760 U.N.T.S. 79, 31 I.L.M. 822 (entered into force 29 December 1993) at 8(g).

[4] *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*, 29 January 2000, 39 I.L.M. 1027, available online: <http://www.biodiv.org> (entered into force 11 September 2003).

[5] J. Rissler & M. Mellon, *The Ecological Risks of Engineered Crops* (Cambridge, MA: MIT Press, 1996).

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

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 GM potatoes.[7] Dr. Stanley Ewen, a consulting histopathologist at the University of Aberdeen Medical School, built on Pusztai's studies and found even more disturbing results. Ewen found that the adverse health effects from the GM 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 GM potatoes. The CaMV promoter has been widely used in making GM tomatoes, corn and soybean cultivars, which are already in the marketplace.[8]

Socio-Economic Considerations

Multinational biotechnology companies are rapidly developing GM agricultural products for international markets. They maintain that these products will help to address food shortage problems in developing countries. One global firm, 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.[9]

The suggestion that GM 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.[10] GM crops may do little to alleviate hunger until these political and economic problems are addressed.[11] In fact, GM crops may actually worsen the plight of third world farmers, for several reasons.

Many critics of GM 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.[12] Hybrid seeds typically cost three times as much as traditional seeds and patented GM 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

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[7] "Biotech: The Pendulum Swings Back" (May 6, 1999) 649 Rachel's Environment and Health Weekly, at 2 online: <http://www.rachel.org>. Pusztai's results sparked a storm of criticism from proponents of GMOs 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.

[8] A. Clark, "Genetic Engineering in Field Crops: Ethics and Academia" (Presented to the Annual Meeting of the Saskatchewan Institute of Agrologists, April 1999).

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

[10] Union of Concerned Scientists, "Biotechnology and the World Food Supply," online: <http://www.ucsusa.org/agriculture/index.html>.

[11] *Ibid.*

[12] *Ibid.*

chemicals and water.[13] 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."[14]

These costs may also be compounded by patent fees. Many biotechnology companies place patents on GM 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 over all transgenic cotton plants and seeds until the year 2008.[15] Such a 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 is 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.[16]

Premium prices, technology fees and royalties may make GM crops too expensive for small, resource-poor farmers. Moreover, such crops may be impractical for small farmers in developing countries. Critics of GM products 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. Certainly, some of these crops do. But 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."[17]

Instead, most of the GMOs 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 $US 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.[18]

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[13] "Against the Grain" (February 11, 1999) 637 Rachel's Environment and Health Weekly, online: <http://www.rachel.org>.

[14] Union of Concerned Scientists, *supra* note 8.

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

[16] RAFI, "Control of Cotton: The Patenting of Transgenic Cotton" Communiqué, July/August 1993.

[17] M. Winfield, "Agricultural Biotechnology and Sustainable Development" (Notes for presentation, June 1997).

[18] As noted in A. Clark, "Debunking the Myths of Genetic Engineering in Field Crops" (Presented to Alternatives, Kitchener, Ontario, 2 March 1999), online: <http://www.plant.uoguelph.ca/research/homepages/eclark/myths.htm>.

Control over the Agricultural Sector

The development and sale of GM agricultural products gives the biotechnology industry increasing 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.[19]

Control over production is, in fact, the goal of many biotechnology companies. As the Vice-President of the American biotechnology company Calgene, has stated: "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."[20]

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.[21] 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 $US 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.[22]

Social and Ethical Issues

Genetic engineering raises many significant ethical concerns and questions. While these issues cannot be extensively explored within the scope of this chapter, they should be briefly raised.

First, there are major ethical concerns regarding the impact that this technology may have on the health and welfare of animals. Some societies and individuals see plants and animals as utilitarian objects that can be legitimately modified and manipulated for human purposes. To others, though, plants and animals are culturally and/or religiously significant beings evoking respect. These groups see the manipulation of the genetic material of other species as a violation of species integrity and the laws of nature, and fundamentally disagree with many applications of modern biotechnology for reasons of dignity and respect for other species.

Genetic engineering also raises serious ethical concerns about the patenting of living organisms. In 1980, the United States Supreme Court granted the first patent

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[19] "In the Mill" *The Economist* (March 20, 1999), 64-65.
[20] B. Kneen, *From Land to Mouth: Understanding the food system* (Toronto: NC Press, 1995) at 140.
[21] "In the Mill", *supra* note 19.
[22] *Ibid.*

on a life form.[23] Since then, patents have been granted on plant and animal strains, as well as on individual genes. To others, though, the patenting of life is profoundly unethical. As one critic noted, "I never imagined that people would patent plants and animals. It's fundamentally immoral... [it] violates the integrity of life itself, and our deepest sense of morality."[24] Patenting life forms also raises questions regarding intellectual property rights. Genetic material, such as plants used in traditional societies 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 GM products discovered in this way.[25]

Several other ethical questions often raised concerning modern biotechnology include who owns genetic information, is ownership of genetic material a right, and what are the implications of this kind of ownership. In addition, others ask whether there is truly a need for GM food. Still others ask whether animals should be used in genetic experimentation, and whether, when a plant receives an animal gene, vegetarians should have a right to be informed. Who will pay for failed technology, and who is responsible or liable for potential adverse environmental or health reactions? Finally, many have asked whether societies truly believe that private companies, like insurance companies, should 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, and should take place openly in courts. Until recently, however, ethical concerns were ignored by many governments. Governments should facilitate open debates in society around these issues, and demonstrate a willingness to act on the consensus that develops.

The Relationship between the Cartagena Protocol on Biosafety and International Trade Agreements

The development of the Protocol was mandated in the UN CBD, which was adopted at the 1992 Rio Earth Summit. The drafters of the Convention were conscious of the looming commercialisation of GM crops, fish, animals and micro-organisms, 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 after six negotiating sessions, were to have been concluded at an Extra-Ordinary Conference of the Parties to the Convention in Cartagena, Colombia in February 2000.

However, discussions collapsed in the face of intense opposition from a group of six countries (the so-called 'Miami Group'), five of which are leaders in the FTAA negotiations (Canada, the United States, Australia, Uruguay, Chile and Argentina). The

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[23] A. Clark, *supra* note 18 at 7.

[24] I. Acosta, President of the Guaymi General Congress, as quoted in B. Mausberg, M. Press-Merkur & P. Coutinho, *The Citizen's Guide to Biotechnology* (Toronto: CIELAP, 1995) at 37.

[25] M. Press-Merkur & M. Winfield, *Enabling Biotechnology? An analysis of the report of the Biotechnology Council of Ontario* (Toronto: CIELAP, 1995).

Miami Group emerged from the Cartagena meeting with two major objectives with respect to the Protocol. First, they wanted exemptions from the rules established through the Protocol for transboundary movements of modified organisms that are commodities for use in food, feed or processing. Second, they wanted the rules of the Protocol to be subordinated to the WTO international trade rules, to prevent the Protocol from being used to justify 'disguised protectionism.' These 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 except in accordance with WTO rules.

Negotiations for the Cartagena Protocol were eventually concluded in February 2000 in Montreal. The final text does not really settle the question of how the Protocol relates to the WTO and other international agreements. In fact, it appears to be a conflict postponed, rather than avoided. The question of primacy of one set of rules over another is only important if the two sets of rules conflict, however. In the case of a conflict between the WTO and a multilateral environmental agreement (MEA), one of the most important issues is in which forum the dispute would be heard. On the face of it, there seems to be no direct conflict between WTO rules and the Protocol's 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. But this point becomes more contentious, and important, in the context of the Protocol's labelling and precautionary provisions.

Labelling and Consumer Information

The main conflict between the Biosafety Protocol and WTO rules may arise from attempts by governments to apply precautionary or consumer information restrictions to GM foods. Presently under the Protocol, governments can only require a label that says a product "may contain" living modified organisms intended for direct use as food or feed, or for processing (LMO-FFPs), and it does not address other GM labelling requirements. However, in many countries, consumers want to be informed if products *do* contain LMOs. Those who are concerned about health risks, have particular allergies, or do not support the development of this technology, want their governments to respect their right to know what is in their food. However, a law requiring labels containing such information could be found inconsistent with international trade law, especially the WTO Agreements.

First of all, GM producers claim that GM foods and non-GM foods are "like products". In a way, for the normal consumer in the market, it is almost impossible to determine the difference between and GM tomato and a traditional one. To determine if products are sufficiently similar to be considered 'like', international trade law considers different factors, including the physical characteristics of the product and consumer tastes and preferences. In the *Japan - Alcohol* case,[26] different liquors were considered 'like', as consumers bought them inter-changeably, though their

[26] *Japan - Taxes on Alcoholic Beverages* (1996) WTO Doc. WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, AB-1996-2 (Appellate Body Report).

physical characteristics were quite distinct. But in the *EC – Asbestos* case,[27] carcinogenic white chrysotile asbestos was considered not to be a 'like-product' with non-asbestos substitutes due to the health risks associated with asbestos, which were taken into account in considering the physical characteristics. A WTO Panel might rule either way, but in the current environment, it could find that GM food and normal food are alike.

In this case, any labelling or other requirements that mean a different sort of treatment for GM products may violate GATT, Article III, which commits countries not to pass laws that will discriminate between 'like products.' In such a case, the measure would need to seek justification in one of the exceptions. GATT, Article XX (b) may provide a ground for defence, as it creates an exception for laws necessary for the protection of human, plant or animal health, but the burden of proof, in an area where science is still very uncertain, will fall on the government seeking to defend the environmental measures in direct violation of the precautionary principle.

Even should a labelling measure pass muster this way, it would still face challenges in either the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) or the Agreement on Technical Barriers to Trade (TBT). According to these instruments, such measures should only be taken after a risk assessment with sufficient scientific evidence supporting it. In the *EC – Growth Hormones* case,[28] it became clear that the SPS Agreement only has a little space for precautionary measures. In the recent *Japan – Apples* case,[29] a fairly high bar was confirmed for sufficient scientific evidence, and specific requirements were detailed for risk assessments. While the Cartagena Protocol provides more detailed criteria, it is not clear that it can help in the matter. Reasoning based on the *US – Shrimp /Turtle* cases,[30] suggests that the WTO panels will show deference to measures taken in compliance with multilateral environmental agreements, such as the Convention on Biological Diversity (UN CBD), such respect is mainly valid when an agreement exists between parties to the UN CBD. A challenge could be brought by a non-party. Furthermore, the Protocol, in its current form may even work to declare the measure unjustifiable as it does not provide for such labelling.

As such, it is possible that any compulsory labelling scheme for LMO-FFPs would be found inconsistent with trade rules. This would run contrary to the precautionary principle, and also violate consumers' right to know what is in their food.

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[27] *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products* (2001), WTO Doc. WT/DS135/AB/R (Appellate Body Report), WT/DS135/R (Panel Report).

[28] *European Communities - Measures Concerning Meat and Meat Products (Hormones)* (1998) WTO Doc. WT/DS26/AB/R, WT/DS48/AB/R (Appellate Body Report), WT/DS26/R/USA, WT/DS48/R/CAN (Panel Report).

[29] *Japan - Measures Affecting the Importation of Apples* (2003), WTO Doc. WT/DS245/AB/R (Appellate Body Report), WT/DS245/R (Panel Report).

[30] *United States - Import Prohibition of Certain Shrimp and Shrimp Products: Recourse to Article 21.5 of the DSU by Malaysia* (2001), WTO Doc. WT/DS58/AB/RW (Appellate Body Report), WT/DS58/RW (Panel Report).

Mutual Supportiveness

There are not always conflicts between the international trade rules and the Cartagena Protocol. These can also be mutually supportive. For instance, the Protocol complements the SPS Agreement rules in relation to the precautionary approach in the several important ways. First, the SPS Agreement does not spell out exactly what a risk assessment entails, but the Protocol does so, in detail, in Annex II. Second, the SPS Agreement mentions risk assessment but not risk management. The Protocol (in Articles 15 and 16) makes it clear that both exercises are necessary, defining the former as the gathering of the data, and the latter as the building of a regulatory regime based on that data. The Protocol further sets out certain guidance in creating such a regulatory 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. Third, the Protocol explicitly requests Parties to take into account socio-economic considerations in making their decisions whereas the SPS Agreement says nothing on the subject. Fourth, the Protocol is specific about the process for review of decisions in the light of new evidence (Article 12) while the SPS Agreement is ambiguous about how to treat measures adopted provisionally in the face of uncertainty. Fifth, the provisions in Article 15 of the Protocol 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 issue, the SPS Agreement is silent. An argument could be made that the Protocol is, in fact, *lex specialis* in the area of LMOs, and as such has precedence and complements the SPS Agreement.

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.[31] 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 contain LMOs.

A Consumer's Right to Know

Genetic modification has important implications in the spheres of health policy, the environment, ethics, religious beliefs and the economy. Consumers have the right to full information on the safety of the technology, and should be able to identify the products whose genetic structure has been altered. The consumer's right to know has been recognised on both regional and global levels. For instance, it was recognised by the UN General Assembly when it adopted the UN Guidelines for Consumer Protection. Article 3(c) of the Guidelines recognises the need for consumers to have

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31 *Ibid.*

"[a]ccess... to adequate information to enable them to make informed choices according to individual wishes and needs."[32]

Information should be readily available to consumers. This includes full disclosure of all aspects of the safety evaluation of GM foods, as well as clear and truthful labelling of any approved products that come onto the market, particularly when there is uncertainty about the risks. GM foodstuffs have reached the market unlabelled in many countries, though surveys have shown there is a strong consumer demand for full labelling of such products. 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 are able to decide for themselves whether to buy products created as a result of this new technology and accept the uncertain risks.

International Risk and Liability for Biosafety

Trade liberalization opens borders to more and more products with less and less government oversight. However, as demonstrated by the spread of hoof-and-mouth disease, free trade is not always the best policy. Some degree of oversight and some controls on the movement of goods are warranted.

The Cartagena Protocol on Biosafety[33] itself is an indication that the world community has recognised the need for some degree of oversight and control on the movement of genetically modified organisms (GMOs). The Protocol's reference to the precautionary principle is significant, given that the health and environmental impacts of GMOs are uncertain. Insurance companies treat risks with unknown consequences as potentially catastrophic. Unfortunately, the Protocol's negotiators failed to finalize terms for liability and compensation if the premature spread of this experimental technology results in actual damage. Recent events provide evidence of the risks associated with the absence of such liability mechanisms.

StarLink: A Case Study

Shortly after the conclusion of Biosafety negotiations, the infamous 'StarLink scandal' unfolded. StarLink (a genetically modified corn) was grown on approximately 10,000 acres in the US in 1998, some 250,000 acres in 1999, and more than 350,000 acres in 2000. This variety of genetically-engineered corn had not been approved by the United States of America for human consumption. It contained the Bacillus thuringiensis subspecies tolworthi Cry9C protein and the DNA necessary to produce this protein. Significant evidence was found that Cry9C is heat stable and resistant to degradation in gastric juice, the two most important indicators of allergenicity. On 18 September 2000, a coalition of non-governmental groups known as "Genetic Engineering Food Alert" announced the detection of StarLink in corn taco shells sold on grocery shelves in the US, and raised concerns regarding its allergenic properties. This finding was subsequently confirmed by testing done by food processing companies and the US Environmental Protection Agency. Attorneys immediately filed

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[32] *United Nations Guidelines for Consumer Protection*, 1985, UNGA Res. 39/85 at 3, online: <http://www.un.org/esa/sustdev/sdissues/consumption/english.pdf>.

[33] *Supra* note 4.

claims across the US as affected parties began to sue, seeking recovery for their damages.

Within the US, the presence of StarLink in US-processed foods and corn exports raised serious liability issues. The US Food and Drug Administration was forced to post a recall on 297 brand-name corn products while the US Department of Agriculture announced a buyback program of StarLink from US farmers, to be reimbursed by Aventis.[34] Efforts to segregate StarLink after co-mingling were estimated to cost between $US 100 million and $US 1 billion. However, the buy-back was not able to address all the costs incurred by elevators, distributors, food processors and retailers, nor the losses in farmers' markets and reputation due to the contamination, nor the cost of settling liability claims resulting from contamination of non-StarLink farms due to cross-pollination, or lawsuits arising from allergenic reactions to StarLink.

Outside the US, the situation degenerated rapidly. The patent-holder Aventis CropScience had, in spite of concerns raised by consumers groups, been allowed to sell its corn to farmers. It was grown commercially, harvested and commingled with the rest of the United States' corn crop. On 26 October 2000 the US Department of Agriculture proceeded to approve StarLink for export, and attempted to shift liability for the product's safety by notifying exporters that "they have responsibility to take all appropriate measures to ensure that this product is used only for approved purposes."[35] Upon later independent DNA testing, the StarLink protein was found in a variety of consumer products in the USA, Japan and South Korea. Because the US commodities system has few provisions to keep bulk grains separated, it was likely to be found in any country that imports corn from the US.

The ensuing media attention and international concern opened markets for non-StarLink producers, a gap that other agricultural countries hastened to fill. The EU had not purchased corn from the US for several years, to avoid all genetically engineered varieties. Japan, which usually bought approximately 30 percent of US corn exports worth some $US 1.5 billion, asked the US government to ensure that shipments do not include StarLink.[36] And many Japanese companies were driven by consumer concern to looking elsewhere – to China, South Africa and Argentina – for supplies, even at a premium price. The US was forced to send trade delegations around the world to try to calm importers' concerns about contamination.

When the corn was found to be a potential allergen, the patent-holder Aventis was forced to absorb millions of dollars of costs within the United States. But a principal legal issue concerns international liability for costs to farmers, country elevators, distributors, food processors, retailers, exporters, and overseas entities in the corn-products food chain: who will be held responsible to rid the global food supply of the product?

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[34] See C. Raghavan, "Call for Ban on Import of US GM Corn" (Third World Network), online: <http://www.twnside.org.sg/title/corn.htm>.

[35] See, e.g, "Starlink" (2000) Independent Organic Inspector's Association *The Inspector's Report* 9:4, online: <http://www.google.ca/search?q=cache:mQbpgQ59HIoJ:www.ioia.net/v9n4good.pdf+Starlink+Export+Ban+Lifted+2000+AG+Net&hl=en>.

[36] *Ibid.*

Is the US responsible for its StarLink exports? An argument could be made for this solution. Indeed, under customary international environmental law, States have a duty to ensure their actions (and the activities of legal persons situated in their territory) do not cause harm in other states, and the right to seek compensation from another state responsible for any damages – whether to persons, property, the environment, or economy.

However, *ad hoc* claims and negotiated settlements can be costly, time-consuming and seldom result in payments going to those most affected by damage, who often cannot afford recourse. Enforceable liability treaties exist to govern oil pollution, nuclear material, space objects and hazardous waste. Perhaps the best features of these treaties could be adopted to protect importing countries from the imported risks of GMOs. With the food security of the Americas hanging in the balance, such a course of action would gain credibility and persuasiveness. A better solution perhaps would be for negotiations advance swiftly on a liability and compensation regime for GMOs under the Cartagena Protocol on Biosafety. And under this global treaty, much could be done within regional contexts. A regional agreement is one appropriate response to risks that can move from plant to plant, field to field, and ecosystem to ecosystem.

Access to compensation may become important in other countries where efforts to identify and segregate StarLink corn from corn destined for human consumption will become extremely costly. Under customary international law, states have the right to seek compensation from another state responsible for damages – whether to persons, property, the environment, or economic. [37] While states have shown themselves, over time, to be reluctant to invoke international liability claims against other states, there have been cases in which compensation has been negotiated without reference to legal liability (such as when the US paid Japan $US 2 million as compensation for injuries caused by nuclear testing in the Marshall Islands). Countries also have the right to impose civil liability on private actors – such as Aventis – in their own courts or in the courts of the country where the act was done.

This would seem to indicate that the US Government is liable for what could be characterized as reckless and negligent failure to ensure the segregation of corn it has not approved for human consumption – because it could cause allergies – from corn that is destined for human use.

Negligence is bad enough. But there may also be a valid claim based on intentional harm. Once the contamination was discovered (not by government inspectors, but by non-governmental organizations opposed to genetically-engineered

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[37] States have a duty under customary international law to ensure their actions do not cause harm in other states. Evidence of its status as a customary norm is found in the 1941 "Trail Smelter" arbitration. The principle is further elaborated in the 1972 *Stockholm Declaration* and the 1992 *Rio Declaration*, as well as several rulings of the International Court of Justice (ICJ). In 1996, the ICJ issued an advisory opinion regarding the legality of nuclear weapons noting that: *"the environment is not an abstraction but represents the living space, the quality of life and the very health of human beings, including generations unborn. The existence of the general obligation of States to ensure that activities within their jurisdiction and control respect the environment of other States or areas beyond national control is now a part of the corpus of international law relating to the environment."* See *Legality of the Threat or Use of Nuclear Weapons* (Request by the General Assembly), [1996] I.C.J. Rep. 226 at 241-242.

foods), the US Department of Agriculture moved to get rid of the unwanted product by officially approving StarLink for export – placing the burden on importing countries to object to StarLink imports and to test their current supplies. Meanwhile, efforts are underway to gain approval for StarLink as a human food in the US. The US may hope these actions will be construed by the courts as immunization from liability; could they not also be construed as wilful and intentional disregard for public health and international law?

Potential for a Global or Regional Liability Regime

Numerous international agreements have been negotiated to deal with liability and compensation that may be caused by risky business. For example, in the case of oil pollution at sea, liability rests with the private sector, backed up by an international oil pollution compensation fund. In the case of nuclear damage, the duty to compensate rests on the operator of the nuclear installation, exonerating all other parties who may have been involved in the development of this high-risk form of energy.

The *Convention on International Liability for Damage Caused by Space Objects* places the liability on states, but only for personal injury and not damage to or loss of property. Under the *Basel Protocol on Liability and Compensation for Damage Resulting from Transboundary Movements of Hazardous Wastes and their Disposal* (Basel Protocol), the liability lies with the carrier, shipper, or other party found to be at fault. Where fault cannot be proved, strict liability is placed on the exporter for transportation incidents or on the disposer should damages occur after receipt. All potentially liable parties are required to carry insurance, bonds, or other financial guarantees covering liability in advance.

Do any of these models properly allocate the liability for environmental, human health or socio-economic damage that may be caused by GMOs? In cases in which signatories properly implement the Biosafety Protocol and damage results nonetheless, there may be one answer. What about cases in which signatories may not properly follow the global biosafety rules? And what of cases involving non-parties?

Ironically, it may be the private sector that cannot wait for the Cartagena Protocol's liability negotiations to reach fruition. Because the technology is so new, there is no way as yet to properly evaluate the risks so, in effect, the consequences for insurers range anywhere from near zero to near catastrophic levels. Insurance companies in most markets are covering these unknown risks under existing liability policies and are thus over-exposed. Insurance companies find that genetic engineering is changing the risk profiles of the pharmaceuticals, agricultural and nutritional sectors permanently, without it being possible to predict the risk potential. In this case, the decisive factor is not whether it is dangerous, but rather how dangerous it is perceived to be.

As the months march by, the perceived risk seems to be growing. Not only the EU and Japan, but also Korea, Australia, New Zealand, Brazil, Egypt, Sri Lanka and China have joined the list of countries regulating GMOs to one degree or another. Thanks to the StarLink fiasco, the US has had considerable difficulty maintaining that its regulatory system is adequate. Soon, the biotech industry itself may opt for a coordinated international system rather than trying to find its way through a maze of

varied national regulations. A regional approach might provide opportunities to move forward.

GMO Commodities Regulation and GMO-Free Markets

Clearly, the US government is unsettled by the impact of multiple import restrictions on its agricultural exports. The US has again raised the subject of GMOs in recent negotiations to reform the WTO Agreement on Agriculture. Other less familiar settings for international deal-making have also put the issue of GMOs on their agendas. For example, the *Codex Alimentarius* Commission, which once set guidelines and provided technical assistance on food safety, but was anointed by the WTO in 1995 as the presumptive standard-setting body – has set up an "ad hoc Intergovernmental Task Force on Foods Derived from Biotechnologies." The FAO's Commission on Genetic Resources for Food and Agriculture has established another intergovernmental group to develop a "Code of Conduct on Biotechnology" and the Trans-Atlantic Economic Partnership was set up to devise executive level "Mutual Recognition Agreements" to harmonise US and EU regulations, bypassing the normal regulatory processes of each country. With ever-greater public awareness in both the US and the EU, and a continuing intercontinental trade war – including US threats to dispute European regulations governing GMOs at the WTO – a pre-emptive Multilateral Recognition Agreement on GMOs seems unlikely for now. But the over-riding issue – how to harmonize multiple national policies and international agreements covering genetic engineering – remains unresolved.

At its most fundamental level, the debate over genetic engineering reflects the wider public debates over globalization and global governance. There is a growing sense that not only the WTO, but also all of the entrenched bureaucracy of corporate globalization, is vulnerable to citizen action. In many countries, citizens are becoming more aware, more alarmed and more organized in their objections to GMOs. In response, companies are taking steps to develop GMO-free products including Gerber's and Heinz's baby foods, McDonald's and Burger King's potatoes, Frito-Lay, Seagram's liquor, and all of Novartis's food products. Many supermarkets in Europe are advertising their own brands GMO-free products. ADM is offering premiums to farmers that can supply the company with GMO-free corn. More and more farmers are opting to plant non-GMO seeds.

In 1999, the world's first global class action suit was filed in US federal court against Monsanto and other agribusiness corporations on behalf of all farmers everywhere.[38] The suit contends that Monsanto hastened the introduction of genetically engineered organisms into markets without sufficiently assessing environmental or human health impacts, and that the corporations deliberately sought to create a cartel in order to monopolize the global corn and soybean markets. The suit is brought by a coalition of prominent law firms specializing in antitrust litigation on a contingency basis (they will only be paid if they win). A victory would hold Monsanto and the other companies liable for environmental damages, negative

[38] See *Higginbotham et. al.* v, *Monsanto Company*, Civil No. 1:99cv03337 (CK-K) Civil No. (US District Court for the District of Columbia).

consequences to public health, and any costs incurred by farmers around the world resulting from genetic contamination.

Food Security in the 21st Century

The experience with StarLink suggests it would be prudent to establish an independent, equitable liability regime for GMOs immediately. Existing international law provides scope for states to seek compensation and otherwise defend themselves from StarLink contamination and resulting economic dislocation, but it is less likely, in practice, to be used.

It will likely be years before the parties to the Cartagena Protocol on Biosafety negotiate a liability regime. It is possible that a regional approach to liability could be achieved somewhat sooner, given the immediacy of the challenge. Many GMOs are self-replicating, and can spread quickly across significant geographic distances. In the 2001 seed stock, US officials and seed company representatives were dismayed to find the StarLink protein in non-StarLink seed corn – and they still are unsure how the contamination occurred. Mexico, a centre of origin for maize (meaning its wild and cultivated stocks are used to replenish the maize gene pool) is particularly vulnerable due to its large quantity of corn imports from the US and the geophysical proximity of the two states.

Ultimately, the issue coalesces around global food security concerns. While the industry promotes genetic engineering as the solution to hunger, others believe it presents threats to agro-biodiversity and the planet's capacity to regenerate life. For one thing, there is little convergence between the destination of export crops in the global marketplace and areas where people are suffering from malnutrition. Less than 0.3% of total corn exports from the United States, for example, went to the 25 countries listed by the FAO as the world's most severely undernourished. [39] Then again, a diversified production system based on locally adapted seeds and integrated cropping is likelier to feed the world of the 21st century.

After the floods in Southern Africa in 2000, a group of scientists from the region, including plant breeders, geneticists, and biotechnology experts, issued a public letter dated March 2000 in which they requested relief organizations *not* to send genetically engineered or patented seed. Instead, they urged the international community to "support efforts to reconstitute locally adapted planting material and quality seed material/varieties, like indigenous land races or farmers' varieties appropriate to the various ecosystems." [40] They insisted that this solution is best not only for the immediate regeneration of production systems after the severe flooding, but also for the medium and long term. In every case, they emphasized that farmers know how to use locally adapted seed; they don't need cash or chemicals to use them; and they can be re-sown and spread readily for continual adaptation under local conditions. Recently, the FAO published a document affirming this point of view:

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[39] See "Feeding the World: Battle of 21st Century agriculture" (ASEED Europe), online: <http://www.aseed.net/un-corporated/un-reader-ge.htm# top>

[40] See "Open Letter from the Southern African region addressed to regional and international bodies in disaster relief and developmental assistance", online: <http://home.snafu.de/usp/SeedLett.htm>.

> "Conventional systems of production have generated high environmental costs in many cases, and their reliance upon externally supplied inputs creates barriers to access amongst the poorest segments of the population... Organic agricultural production based upon cheap, locally available materials and technologies provides an important alternative in the search for an environmentally sound and equitable solution to the problem of food security."[41]

Which approach will prevail? In 1997, US Secretary of Agriculture Dan Glickman described biotechnology and the patenting of life as "the Battle Royale of 21st century agriculture."[42] Clearly, the principal debates of the 21st century on this issue not over yet. It will be important that the negotiators of the "Free Trade Area of the Americas" find careful ways to handle food safety, GMOs and patented seeds. Their decisions will decisively influence food security, biological diversity and the future of humankind.

Other Mechanisms of Cooperation on Biosafety: The *Codex Alimentarius* and Consumers

The Eleventh Session of the Conference of the FAO in 1961 and the Sixteenth World Health Assembly in 1963 both adopted resolutions to establish the *Codex Alimentarius* Commission. The Commission was created with the primary task of establishing scientific standards on food safety. It 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.

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[41] See D. Brough, "FAO says Organic Farming Can Reduce Hunger" (GRID-Arendal News, March 6, 2001).

[42] K. Dawkins, "Biotech - From Seattle to Montreal and Beyond: The Battle Royale of the 21st Century" (February 2000), online: <http://www.biotech-info.net/developments.html>.

Importance to International Trade

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 WTO SPS and TBT Agreements 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.

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 organization. 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 as mentioned above, in 1985 a UN General Assembly Resolution gave rise to the *Guidelines for Consumer Protection*, published in 1986 and updated in 1999. 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.[43]

While open to participation from all governments, few developing countries can afford to monitor the Codex process closely. Meetings are generally dominated by developed countries — especially North Americans and Europeans, whose national delegations tend to push a commercial agenda, according to 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 Bovine Somatotropin (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.[44] Nearly all industry representatives came from large global corporations: small businesses and

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[43] *Supra* note 32.

[44] Codex Alimentarius, online: <http://www.fao.org>

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.

Conclusions

The Cartagena Protocol on Biosafety is a significant step forward. It contains some important victories for many developing countries, and for 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, certain provisions of the Protocol also put the consumer's right to know at risk.

Ways must be found to enable the public to participate in decision-making about genetically engineered foods. Such activities are very clearly necessary in the Americas. With five of the six members of the 'Miami Group' leading the FTAA, any biosafety provisions proposed for the FTAA must be analysed very carefully. Of course, not all the potential human health or environmental problems will occur. But some may. Not enough research has been done to identify the highest priorities; a cautious and above all independent examination is needed.[45] It is clear that consumer lawyers and other representatives of the international public interest still have much homework to do.

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[45] L. Harvey, "Human Health and GMOs (September – December 2000) 25 *Ecology and Farming* 10.