

Splitting Genes:

The Future of GMO's in the Wake of the WTO/Cartagena Standoff

By

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DISCLAIMER This paper refers to a Preliminary Ruling issued by the WTO. While several reputable news outlets have reported on the draft ruling it has not been authorized for release by the WTO. The full copy relied upon in this paper was “leaked” and provided by a potentially biased organization, Friends of the Earth.² Its authenticity is assumed but not proven.

Introduction

On February 7, 2006 the World Trade Organization (WTO)³ issued a preliminary ruling indicating that the European Communities (EC)⁴ had violated their WTO obligations by permitting several member states to erect “de facto” barriers to trade against certain GM (genetically modified) products previously approved by the umbrella organization and by failing to enforce its own mandates.⁵ This decision amounted to the realization of fears long held by environmentalists around the globe including members of The United Nations (UN), national governments and private advocacy groups.⁶ This paper will address whether this decision can be reconciled with the Cartagena Protocol (CP) on Biosafety⁷ and other GMO specific legislation. The respective views of both parties to the WTO dispute, the United States (US) (joined by Canada and Argentina,

² http://www.foeeurope.org/biteback/WTO_decision.htm (NOTE: All websites referenced were accurate as of 5/9/06)

³ “The World Trade Organization (WTO) is the only global international organization dealing with the rules of trade between nations. At its heart are the WTO agreements, negotiated and signed by the bulk of the world’s trading nations and ratified in their parliaments. The goal is to help producers of goods and services, exporters, and importers conduct their business.”
http://www.wto.org/english/thewto_e/whatis_e/whatis_e.htm

⁴ A list of EC Member Countries is available at http://www.mywebcalls.com/pop_up_ec.php – The name European Communities and the name European Union (EU) will be used synonymously throughout the paper. The European Communities entered into Maastricht Treaty in February, 1992 which led to the creation of the EU. The European Communities make up one of the three “pillars” of the EU. For more on the history of the EC/EU see http://en.wikipedia.org/wiki/European_Community

⁵ <http://www.ictsd.org/biores/06-02-17/story1.htm>

⁶ Nelkin, Dorothy, Sands, Philippe and Stewart, Richard B. Genetically Modified Organisms: Foreword the International Challenge of Genetically Modified Organism Regulation 8 N.Y.U. Env’tl. L.J. 523

⁷ <http://www.biodiv.org/biosafety/default.aspx>

sometimes referred to as the “Miami Group”⁸) and the European Communities (EC) will be compared. The EC is a party to the Cartagena Protocol. The US is not, however it has signed (but has not ratified) the 1992 Rio Convention on Biodiversity (CBD) which authorized the CP and is a party to several other international agreements.⁹

The Basics

GMO’s (genetically modified organisms) are the products of recombinant DNA technology, essentially splicing favorable genetic traits from one organism and adding them to another to produce a superior organism.¹⁰ Other terms used include “genetically engineered” (GE) “living modified organism” (LMO) and “transgenic.”

There are several major benefits and potential detriments regarding the production and use of GMO’s. The benefits include increased and faster food production as well as resistance to certain pests, degeneration and diseases. Certain health benefits such as higher vitamin content can be achieved as can the removal of less desirable traits.¹¹

The most prominent drawbacks are the limited scientific data on potential health risks, the potential loss of biological diversity, ethical and moral concerns surrounding the consumption of “Frankenfood”¹² as it has been referred to by its detractors and the potential for adverse economic consequences to local farmers and industries in

⁸ <http://www.greenpeace.org/international/campaigns/genetic-engineering/biosafety-protocol/the-miami-group-the-bad-guys>

⁹ For a recent and informative overview of the ramifications of signing but not ratifying international treaties (especially helpful for readers unfamiliar with international law) see: The United States Senate Republican Policy Committee’s “Unratified and Unsigned Treaties Still Constrain U.S. Action” 5/16/2006 at http://rpc.senate.gov/_files/May1605UnsignedTreatiesMS.pdf

¹⁰ Wei, George An Introduction to Genetic Engineering, Life Sciences and The Law Singapore University Press, 2002 Pg. 32, and Sophia Kolehmainen, IN DEPTH: GENETICALLY ENGINEERED AGRICULTURE: PRECAUTION BEFORE PROFITS: AN OVERVIEW OF ISSUES IN GENETICALLY ENGINEERED FOOD AND CROPS, 20 Va. Env’tl. L.J. 267

¹¹ A comprehensive list presenting the basic benefits and detriments is available at: <http://www.ifap.org/about/wfcbiotech.html>

¹² Miller, Henry I. & Conko Gregory The Frankenfood Myth: How Protest and Politics Threaten the Biotech Revolution Praeger Publishing, 2004 Pg. 29

developing nations in favor of large multinational biotech corporations. The primary disagreements among the parties center on safety, health concerns, labeling, traceability, and production methods.¹³

Another factor that cannot be ignored is public opinion. Public access to environmental issues is vital towards both the initial acceptance and continued reliance on new technologies and projects. The absence of public participation can lead to widespread displeasure. Certain governments and private businesses alike have used a “clean green” marketing image in order to garner public support for their policies on GMO’s.¹⁴ Greenpeace, while potentially biased, has conducted surveys throughout Canada and the US showing that when presented with the issue a majority of those polled support labeling of GM food as such as well as the removal of GM products from certain foods. Additionally, certain areas in the United States often considered to be more environmentally friendly such as Vermont and California were considering the establishment of localized GMO free zones in 2005.¹⁵ Whether this view is shortsighted or not is not the ultimate point. If GMO’s are going to gain widespread acceptance people must perceive them as safe and nutritious rather than artificial and dangerous. The best way to accomplish such a goal would be to prove that GMO’s can be produced and consumed safely without causing an adverse effect to the environment.

Is There a Right to Food?

1. Is there a naturally inherent right?

¹³ <http://www.gmofoodforthought.com/2005/11/>

¹⁴ Stewart Jr. C Neal, Genetically Modified Planet Oxford University Press, 2004 Pg. 40

¹⁵ http://action.web.ca/home/gpc/alerts.shtml?x=74472&AA_EX_Session=f31cbe36cb860b396c22d3043d0fe77b

In the abstract one might say there is a right to food but this is contradicted by the very laws of nature. Darwinian terms like “natural selection” and “survival of the fittest” lose all meaning if there exists an inherent right. If there is indeed any right to food it is likely one imposed on us through morality and compassion towards fellow human beings.¹⁶

2. Is there a legal right?

While several sources of law may be considered, Article 11 of the UN International Covenant on Social, Economic and Cultural Rights provides the basic obligations imposed on governments. Section 1 states that governments should “recognize the right of everyone” to “adequate food” while Section 2 states that there is a “fundamental right of everyone to be free from hunger.”¹⁷ Section 2 further states that nations should cooperate in order “to improve methods of production, conservation and distribution of food by making full use of technical and scientific knowledge.”¹⁸ From this broad language it is nearly impossible to identify what if any affirmative obligations governments have to combat world hunger and leaves open the question of through what means may these goals be accomplished. A strict interpretation would indicate that feeding the population is paramount to any other concern however there are many subsequent agreements that pertain specifically to the production of food and the conservation of the environment.

Is There a Need for GM Food?

¹⁶ http://en.wikipedia.org/wiki/Survival_of_the_fittest

¹⁷ Dias, Clarence & James, Paul “Developing the Human Right to Food as a Legal Resource for the Rural Poor. Some Strategies for NGO’s” in Alston, P & Tomasevki, K (editors) The Right to Food Stichting Studie, 1984 p. 203

¹⁸ <http://www.hrweb.org/legal/escr.html>

Americans and Europeans alike are fortunate in that they have not experienced wide scale hunger in more than half century. The reality is that despite improved production and the process of globalization a disproportionate number of people go hungry each day.¹⁹ In 2002 the African nations of Zambia and Uganda initially rejected an offer of food aid from the US because it contained GM maize. They relented only when the maize was milled prior to importation. The reasons behind this go straight to the heart of the debate. Both nations feared that acceptance of GMO's might taint their future potential crops for export to the EU and other GM wary nations. In 2003 the Southern African Development Community (SADC)²⁰ adopted a resolution to incorporate the mandates of the Cartagena Protocol in regards to accepting agricultural imports including food aid thereby accepting the "precautionary principle."²¹

A simple web search for "GMO" will reveal that a seeming majority of self published public opinions agree with groups like GMO-Free-Europe which advocate for the immediate cessation of GMO use and research.²² The presumption is that the US view is that of its major biotech firms, most notably Monsanto, Syngenta, Dow, Bayer and DuPont (The Big Five) and that any other justifications are merely screens for what is an assertion of economic dominance.²³ In a damning new book Paul Smith claims that Monsanto Corporation is involved in a worldwide conspiracy and along with the assistance of both Bush presidents seeks to gain worldwide dominance in the agricultural market before nations have time to adopt substantive regulations. Tactics include getting

¹⁹ http://www.usaid.gov/locations/sub-saharan_africa/initiatives/ieha.html

²⁰ <http://www.sadc.int/>

²¹ http://www.unctad.org/en/docs/itcdtab30_en.pdf

²² www.gmofree-europe.org/

²³ Stewart Jr. Pg. 214

“a foot in the door” by selling to GM friendly countries such as Poland who are trying to gain favor with the US.²⁴

While definitive proof to the contrary is not available there are certainly viable justifications for exploring the potential uses of GMO’s as a solution for both short terms hunger issues and long term environmental concerns. The primary objectives set forth in both the Rio Convention and subsequent Cartagena Protocol are the protection of biodiversity and sustainable development for the future. Genetic diversity and biological diversity are two vastly different concepts. While genetic diversity relates to the number of separate species, biological diversity takes into account the relationship between species.²⁵ Fears relating to “super-weeds” running rampant appear speculative however the threat that an integral part of the food chain may be adversely affected or that pests and viruses may become immune to preventative measures causing greater damage are very real.²⁶ The simplest analogy is that of the big fish and the little fish. If the little fish disappears so does the big fish. The big fish therefore has a vested interest in keeping enough of the little fish around.

The greatest threat to biodiversity is mankind’s over-exploitation of available resources, often times in a manner far from their most optimal use. The World Wildlife Fund (WWF) maintains the Living Planet Index (LPI) which indicates that species are being lost at a rate consistent with the mass extinctions of the past. The WWF also calculates the “ecological footprint” of persons living across the world. In 1999, based on an approximate world population of six billion the WWF calculated that there are 1.9 productive hectares per person. World consumption was 2.3 hectares per person meaning

²⁴ Smith, Paul Seeds of Destruction PublishAmerica, 2006 Chapter 3

²⁵ Norton, Bryan G. Why Preserve Natural Variety? Princeton University Press, 1987 Pg. 260

²⁶ Stewart Jr. Pgs. 40-41

that the world is consuming more than the planet is capable of sustaining. The biggest culprits are the two parties to the WTO debate. Western Europeans utilize 5.0 hectares per person while a North American's "ecological footprint" is an unfathomable 9.6 hectares per person.²⁷ When one considers the U.N.'s estimate that the world's population could reach 10.9 billion people by 2050 it becomes impossible to ignore the immediate need for action.²⁸

To compound the problem, desertification as a result of human activities is becoming an even greater problem. The 1996 Convention to Combat Desertification (UNCCD)²⁹ recognizes that the phenomenon disproportionately affects the poor, most notably in Africa, South America and parts of Asia. Biological hotspots (25 distinct areas comprising 1.4% of the Earth's available land but home to an estimated 35% of its distinct species)³⁰ such as mangroves in South America are leveled in favor of agricultural crops which fair poorly in the mineral depleted soil left behind while cattle attempt to graze across barren plains in Africa.³¹ Although the Montreal Protocol³² focused on another important issue, depletion of the Ozone layer, it states that "lack of full scientific certainty shall not be used as a reason for postponing cost effective measures to prevent environmental degradation" and precautions should be limited to "threats of serious or

²⁷http://www.panda.org/news_facts/publications/key_publications/living_planet_report/about_lpr/index.cfm

²⁸ U.N. Population Division, *World Population Prospects: The 2000 Revision, Vol. III Analytical Report*, at 5, ST/ESA/SER.A/200 (2002)

²⁹ <http://www.unccd.int/convention/menu.php>

³⁰ Wilson, E. O. "Hotspots. Preserving Pieces of a Fragile Biosphere" in *National Geographic*. January, 2002

³¹ World Resources Institute, *World Resources 2000-2001: People and Ecosystems: The Fraying Web of Life* 2001, Pg. 30

³² The Montreal Protocol on Substances That Deplete the Ozone Layer available at ozone.unep.org/pdfs/Montreal-Protocol2000.pdf

irreversible damage”.³³ If GMO’s can be grown safely and effectively at an increased rate and potentially reduced cost they should at the very least be considered. The problem is already upon us. We cannot protect an environment if we leave nothing to protect. Great reward however is coupled with great risk. With this mind we can approach the issues presented in the US/EC WTO debate.

The Issue Presents Itself: The WTO Verse the Cartagena Protocol

The WTO was established in 1995 following the Uruguay Round, a nearly ten year series of trade negotiations culminating in Marrakesh in 1994. Its principle rules are found in the GATT (General Agreement on Tariffs and Trade) which was established in 1948.³⁴ The WTO’s purpose is to facilitate free trade amongst the nations of the world. Through such terms as “most favored nation status” the WTO seeks to help producers and consumers by way of internationally agreed up standards to eliminate barriers to trade and to establish new markets. The WTO claims to be sensitive to government’s social and environmental objectives as set forth in the preamble to the agreement establishing the WTO.³⁵ Nevertheless it has been constantly chastised as environmentally insensitive and solely reliant on the principles of a free market rather than genuine concern for the people that the agreements effect. Whether or not this sentiment is true is of little consequence. The WTO rules are focused on trade concerns with certain environmental safeguards. Therefore it is important to recognize from the outset that any WTO violation is strictly a violation of trade and not one of environmental policy.

³³ Kimball, Lee A. Treaty Implementation: Scientific and Technical Advice Enters a New Stage ASIL, 1996 Pg. 127

³⁴ <http://www.gatt.org/>

³⁵ http://www.wto.org/english/docs_e/legal_e/legal_e.htm

On May 13, 2003 the United States submitted a Request for Consultations with the World Trade Organization's dispute resolution body regarding certain policies on GMO's enacted by the European Communities.³⁶ It alleged that a de facto moratorium was established by several member states in defiance of EC protocol and in violation of the following WTO rules: Articles 2, 5, 7 and 8, and Annexes B and C of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)(relating to food safety and animal and plant health measures); Articles I, III, X and XI of GATT, Article 4 of the Agreement on Agriculture (Agriculture Agreement); and Articles 2 and 5 of the of the Agreement on Technical Barriers to Trade (TBT Agreement).³⁷

The SPS Agreement in relevant part seeks to prevent “arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade.” It is the most important and viable claim made in the Request. Article 4 of the Agriculture Agreement prohibits the use of measures that would otherwise be converted to standard custom duties. The TBT seeks to eliminate technical barriers to trade unless they accomplish a “legitimate objective.” Article 2(2) states that “protection of human health or safety, animal or plant life or health, or the environment” qualify as such objectives.³⁸ The GATT seeks to prevent discrimination between domestic and imported products with certain exceptions.

An analysis of the Request and a reading of the applicable WTO provisions indicate that there are three primary causes of action. First, the failure on the part of the EU to consider applications for approval of new GMO's approved prior to 1998 have

³⁶ Dispute DS291, EC — Approval and Marketing of Biotech Products at http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds291_e.htm

³⁷ Id.

³⁸ http://www.wto.org/english/docs_e/legal_e/17-tbt.doc

adversely affected imports from the US, Canada and Argentina. Second, WTO rules have been violated because product-specific bans have not been scientifically justified and there has been undue delay in processing applications for approval. As such they qualify as technical bans. Lastly, the individual member state bans have stymied new development in a field that offers substantial benefits despite the accepted proof of safety by the EC regarding many of the individual products listed in the Annex to the Request.

On February 7, 2006 a three member panel of the WTO issued a preliminary ruling seemingly in favor of the United States and other producers of GM products.³⁹ The final text of the decision is not expected until the end of 2006 however several news articles as well as the interim conclusions and recommendations of the panel are available. The panel ruled that the “de facto” moratorium did not constitute an SPS measure in and of itself, but had "resulted in a failure to complete individual procedures without undue delay," thereby violating Article 8 and Annex C of the SPS Agreement. Additionally, failure to consider for final approval 24 of 27 GMO's constituted a violation. Furthermore, allowing individual member nations the right to implement SPS measures is not of itself a violation however failure to conduct risk assessment when reliable scientific data was available constituted a violation.

While the preliminary ruling sides with US position in a few regards it strongly suggests that nations are free to conduct risk assessments along the lines of the “precautionary principle” based on scientific evidence as long as they do not cause undue delay and/or act as “de facto” moratoriums. The WTO explicitly choose no to investigate whether GMO's are safe, whether they are “equivalent” to non GMO's, and whether certain EC regulations violate the WTO rules. Nevertheless many EC members and

³⁹ <http://www.tradeobservatory.org/library.cfm?refid=78475>

interested independent groups have reacted with dismay and continue to protest further imports of GMO's.⁴⁰ While this reaction is partly justifiable it is important to remember that the EC is a party to both the CP and the WTO. The fact that the US has not yet ratified Rio raises questions relating to true motive however in the end the WTO may be more closely aligned to general principles of humanitarianism as they are given credit for. Historically, taxation of agriculture has been a "brutal mechanism" through which resources were allocated unfairly and inefficiently.⁴¹ In a truly free market, if the United States and others could produce cheaper food faster world hunger could potentially be alleviated. The WTO provides some exemptions for environmental safeguards. While this is not to say that they are the noblest of organizations the approach taken is one that allows for some accommodation. Perhaps the US failure to ratify Rio is a product of an apparent lack of accommodation. This is not meant to serve as a justification; it is simply a suggestion as to why a controversial decision was made.

The Cartagena Protocol

The timing of the WTO Request was obviously an attempt at mitigating the effects of the Cartagena Protocol on Biosafety. The Protocol was designed specifically to address the transboundary movement of GMO's. It was adopted as a supplement to the CBD on January 29, 2000 in order to apply the goals and objectives of the CBD to GMO's.⁴²

Three primary affirmative duties are required under the Protocol. The first centers on the Advanced Informed Agreement (AIA) in Articles 7-10 and 12 which

⁴⁰ In some instances protesters have destroyed test plots for GMO crops. See Anita Manning, *Altered Floor Might Mutate Trade*, USA TODAY, Jul. 14, 1999, at A7

⁴¹ The Right to Food Pg. 179

⁴² <http://www.biodiv.org/biosafety/default.aspx>

provides that Countries exporting GMO's for intentional introduction into the environment will have to give prior notification of the initial shipment to the importing country that is a party to the Protocol. Appropriate information, both general and scientific, will need to be provided by the exporting country in order for the importing country to make an informed decision as to whether to accept the product. The second is that parties to the Protocol will have access to and be required to utilize the Biosafety Clearinghouse (BCH). The BCH is primarily web based and is designed to facilitate communication amongst the parties. It will be made available to non-parties as well in some situations. Lastly, any shipment containing a GMO must be clearly identified as such and reference with specificity the identity and characteristics of the product(s). Article 19(3) acts as a catch all identifying the need for appropriate procedures for the "safe transfer, handling and use of any living modified organism resulting from biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity."⁴³

The Protocol sets the minimum standards to be adhered to by the Parties. Parties must therefore establish their own substantive regulations in conformity with the protocol. Developing nations are permitted to make use of the Protocol prior to establishing national policies on GMO's. Parties to the Protocol are required to adhere to its mandates when engaging in trade with nations which are not a Party to the Protocol.

Article 15 of the Protocol states that Parties will decide whether to ban GMO's on the basis of risk assessment "to be undertaken in a scientific manner based on recognized risk assessment techniques" however the absence of such techniques would leave the potential importer free to deny the import without any factually based reason.

⁴³ <http://www.biodiv.org/doc/legal/cartagena-protocol-en.doc>

Perhaps the most important part of the Protocol, for the purposes of this debate, is found in Article 22(1) of the CBD which states that the CBD supersedes any other agreement including WTO agreements if abiding by them “would cause serious damage or a threat to biological diversity.”⁴⁴ Neither the CBD nor the Protocol provide for a dispute resolution procedure regarding the use of GMO’s.

Contrast and Comparison: Regulatory Schemes in The US and The EC

The United States

The Food and Drug Administration (FDA) as well as several other federal agencies including the Department of Agriculture (USDA) and Environmental Protection Agency (EPA) oversee the domestic food supply.⁴⁵ There are two key sections of the Federal Food, Drug, and Cosmetic act of 1938 (the Act) that would relate to genetically modified food:

1. §402(a)(1) – Defines “adulteration”⁴⁶
2. §409 - Defines “food additive”⁴⁷

These provisions provide that if an added substance is “poisonous or deleterious” the FDA can take action. The FDA has established “action levels” for certain substances and can decide not to act under certain circumstances such as when an offending substance is determined to be de minimis. In order for a substance to be de minimis it must be a naturally occurring substance none of which was added by way of human

⁴⁴ <http://www.biodiv.org/doc/legal/cbd-un-en.pdf>

⁴⁵ 22 Temp. Env'tl. L. & Tech. J. 171

⁴⁶ Statutory Supplement: Federal Food, Drug, and Cosmetic Act and Related Sections of Additional Statutes, FDLI 2005, Pg. 27

⁴⁷ Id. Pg. 58

intervention.⁴⁸ Any potentially harmful manually added substance must be approved. How a GMO would fit into these definitions is debatable as the term “added” is left open to interpretation. That said the Courts have been deferential to the FDA’s decision to pursue actions based on what the agency feels is “necessary for the protection of public health.”⁴⁹ In the context of GMO’s however the FDA, subject to political pressure, has chosen not to act.

In 1992, following public comments by the first Bush administration relating to the need to utilize GMO technology in order to combat world hunger, most notably in Africa, the FDA stated that “the agency is not aware of any information showing that foods derived by these new methods differ from other foods in any meaningful or uniform way.”⁵⁰ Essentially the FDA relies on a presumption that GMO’s are safe or GRAS (generally recognized as safe). They are not considered to be any different than their counterparts produced through natural means. As such there is no requirement that a GMO be labeled as such nor are there any mandatory tracking or production mechanisms in place. These administrative guidelines allow producers entry to the market with out any mandatory GMO safety testing. Some critics have suggested that this causes a “race to the bottom” in that The Big Five will rush their products to market without adequate safety testing.

In 1999 the FDA clarified their position by way of an appearance by James H. Maryanski, Ph.D before the House Committee on Science Subcommittee on Basic

⁴⁸ *United States v. Anderson Seafoods, Inc.*, 622 F.2d 157 (5th Cir.-OLD 1980) Holding that the FDA could regulate mercury levels in swordfish when some mercury was naturally occurring and some was a product of human action.

⁴⁹ *Young v. Community Nutrition Institute*, 476 U.S. 974 (U.S. 1986)

⁵⁰ *Statement of Policy: Foods Derived From New Plant Varieties*,” Federal Register vol. 57, No. 104 at 22991. May 29, 1992

Research. In short, The FDA retains the authority to proceed against a specific article if it is deemed to be unsafe. Additionally, the FDA has conducted several tests on GM varieties and has established an informal procedure through which producers can submit a summary of their safety assessment for agency review. While not a binding procedure the FDA maintains that “all firms” have voluntarily complied with this request for plant varieties that have been commercialized and this has aided the goal of providing an “expedited procedure” to get safe GMO’s to the market.⁵¹

In 2001 the FDA proposed new rules regarding GMO’s including the changing of the notification system from voluntary to mandatory. To date, these rules have not been enacted. In order to quell some fears, especially those present overseas, the federally funded National Research Council stated in 2000 that “there is no evidence suggesting that bioengineered food is unsafe to eat.”⁵² Apparently a lack of evidence having nothing to do with production methods or biodiversity was insufficient to win over the skeptics. That said the US has no affirmative labeling requirements for GMO’s however there are guidelines that must be met before an article can be certified organic.⁵³

The issue came to a head in *Alliance for Bio-Integrity v. Donna Shalala* in which plaintiffs sued claiming that the FDA’s policy statement was not subject to public comments, that the FDA failed to file an Environmental Impact Statement⁵⁴ in violation of the National Environmental Protection Act, the FDA’s GRAS⁵⁵ (generally recognized

⁵¹ <http://www.fda.gov/ola/1999/plant2.html>

⁵² www.cfsan.fda.gov/~dms/fdbioen2.html

⁵³ <http://www.ams.usda.gov/nop/Consumers/brochure.html>

⁵⁴ Environmental Impact Statements are required by § 102(2)(C) of the National Environmental Policy Act of 1969. They require federal agencies to consider probable environmental effects of projects prior to any undertaking. <http://www.epa.gov/compliance/nepa/index.html>

⁵⁵ §§ 201(s) & 409 of the Food Drug and Cosmetic Act for an explanation see <http://www.cfsan.fda.gov/~dms/grasguid.html#Q1>

as safe) standard and labeling requirements were “arbitrary and capricious”⁵⁶ (the standard for administrative agency review) and were in violation of the Religious Freedom Restoration Act. The DC Circuit held that the agencies statement merely set forth a “rebuttable presumption” and was not a final agency determination and as such was not arbitrary and capricious.⁵⁷

In a more recent case, the District Court in the Southern District of Illinois held that a contractual provision used by Advanta Inc. designed to prevent “seed saving” was permissible under the Plant Variety Protection Act. Seed saving is the practice of planting a GMO crop and replanting the reproduced seeds the following season.⁵⁸ The courts in several other cases have upheld the FDA’s GRAS standard but at the same time have enforced copyright violations regarding GMO’s.⁵⁹ It seems contradictory to hold that on the one hand an agency policy stating that the final products are no different is valid but the seeds are subject to copyright laws. These decisions are from 2004 and 2005 respectively. The issue is upon us and as these and other cases illustrate there is domestic dissention suggesting that the current regulatory scheme is insufficient to deal with the issues surrounding GMO’s.

Before continuing it is important to note that the US is not a Party to either the CBD or CP and cannot be admonished for failure to comply from a legal perspective. The conflicts between US policy and failure to ratify CBD and CP are addressed later on.

The European Communities

⁵⁶ 5 USC. 706(2)(A), see also *Natural Resources Defense Council, Inc. v. United States EPA*, 966 F.2d 1292 (9th Cir. 1992)

⁵⁷ 116 F.Supp. 2d 166

⁵⁸ 2004 U.S. Dist. Lexis 28066

⁵⁹ *Syngenta Seeds Inc. v. Monsanto Co.* 409 F.Supp. 2d 536

Unlike the US, the EC has developed GMO specific legislation. Like the Cartagena Protocol it sets a floor in some cases rather than a standard leaving it to the individual member states to craft their own substantive law.

EC Directive 90/220/EEC controls “deliberate release” of GMO’s. The mandate that “all appropriate measures are taken to avoid adverse effects on human health and the environment” in Art. 4(1) is a sweeping concept that has allegedly precluded many GMO’s from entering the EC market according to the US. To approve a GMO for initial release a member state must first conduct a risk analysis regarding potential human health and environmental impacts, confirm that the product complies with EC product regulations and ensure that the product has undergone a risk assessment.⁶⁰

Once these procedures have taken place to the satisfaction of the member state a favorable opinion is forwarded to the EC which alerts the other member states. If no objection is raised the application is approved and the product may proceed to market. A member state with “justifiable reasons to consider” that human health or the environment are at risk must notify the EC and can temporarily restrict the product from entering its territory. If after further review the dissenting nation is still not satisfied it may for “justifiable reasons” prohibit the GMO from entering its territory.⁶¹ The term “justifiable reasons” has not been interpreted by the EC yet it provides for potentially broad leeway to nations like France which are especially wary of importing GMO’s. Hypothetically speaking, if a nation does not want a certain GMO to enter its territory it may utilize alternate political means through which to accomplish this goal. This ambiguity may in fact cause “unjustifiable delay” in violation of the WTO rules. The review process under

⁶⁰ Brown Weiss, Edith & Jackson John H. (editors), Reconciling Environment and Trade Transnational Publishers Inc. 2001 Pg. 633

⁶¹ Id. 635

the mandates of Cartagena is a valid attempt towards reaching a justifiable goal but only if the member states act within the confines of the process. To arbitrarily refuse an import would most likely be an unjustifiable restriction. Additionally, leaving individual states free to disregard the affirmative review of another member state defeats the goals of shared information as stated in the CP.

Labeling and traceability are governed by Regulation EC No 1831/2003 (formerly 2001/18) which again provides broad mandates. The regulation applies to food as well as “food derivatives” (containing a GMO). A “unique identifier” (Art. 8) must be established in order to provide traceability.⁶² While certain information pertaining to the GMO must be present on the label, member states are free to go above and beyond those requirements. The United States assumed position is that such requirements act as technical barriers to trade in violation of the TBT Agreement.⁶³ Plausible arguments exist on both sides. On the one hand, labeling may add expenses however they may also satisfy an increasingly wary public's concerns which otherwise may not have purchased a product containing a GMO. The TBT simply states that a technical barrier must meet a “legitimate objective.” The WTO recognizes that environmental concerns are within the purview of each government. As such labeling requirements should not be a per se violation however a long-winded dispute over the length and or content of such labeling may in fact be a violation.

A recent source of debate has emerged in the form of Article 3(4) of EC Regulation 258/97. That provision sets forth a simplified procedure if a novel food or ingredient is “substantially equivalent to existing [foods] as regards their composition,

⁶² http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00240028.pdf

⁶³ http://www.wto.org/English/tratop_e/tbt_e/tbt_e.htm

nutritional value, metabolism, intended use and the level of undesirable substances contained therein."⁶⁴ Monsanto and other GMO producers have sought to use this provision to their advantage.

The EC's GMO policy on the transboundary movement of GMO's is codified in Regulation (EC) 1946/2003.⁶⁵ It was the first such regional agreement enacted following the passage of the Cartagena Protocol. In accordance with the "precautionary principle" emphasized in both Rio and Cartagena it provides for an unprecedented level of safety measures as well as early notification system if a nation so much as thinks a GMO may have crossed a national boundary. More importantly, the regulations regarding transboundary movement govern exportation to other nations. Any nation, whether or not they are a party, is free to use the BCH in determining whether or not to accept a GMO. If an EC member is of the opinion that exporting a GMO to a country unable to control the resource may result in harm they may be able to withhold approval. If such an issue were to present itself such conduct may act as a "technical barrier to trade" under the TBT agreement. While no such charge has been brought yet this potential represents the mounting tension between safety and the obligation to assist developing nations.

While several other EC regulations are applicable four key points, approval for introduction, labeling requirements, traceability requirements and restrictions on transboundary movement remain constant

Contradiction

Conflicts of Law

⁶⁴ http://www.tjg.co.uk/topical/life_sciences/1103_gene.html

⁶⁵ [http://72.14.203.104/search?q=cache:e6MmP6yfAb4J:europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_287/l_28720031105en00010010.pdf+\(EC\)+1946/2003&hl=en&gl=us&ct=clnk&cd=1](http://72.14.203.104/search?q=cache:e6MmP6yfAb4J:europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_287/l_28720031105en00010010.pdf+(EC)+1946/2003&hl=en&gl=us&ct=clnk&cd=1)

Despite the reaction to the WTO's Preliminary Ruling an investigation into the policies and practices of the respective parties indicates that there is room for negotiation. Because the United States has not ratified the Cartagena Protocol and the European Union is a party to both the WTO dispute and the Protocol if any cognizable legal arguments are to be made it must be within the context of existing internationally binding agreements or domestic legislation.

International Law as Applied to Both WTO Parties

Several additional UN sponsored agreements may be applicable to the current GMO dispute. In order for a nation to be bound they need to be a party absent an overriding international custom. Two conventions in particular, the Stockholm and Espoo are especially relevant.

One of the most influential and all-encompassing pieces of environmental legislation is the Stockholm Declaration of the United Nations Conference on the Human Environment to which the United States and many European nations are parties. Principle 1 sets forth certain basic guidelines including that no environmental tactics should be used to gain leverage over less developed nations. Principle 2 requires the safeguarding of natural resources, Principle 11 deals with domestic environmental policy and Principle 18 states that science and technology must be applied to the "identification, avoidance and control of environmental risks."⁶⁶ As GMO's had not been introduced in 1972 there are no specific references to GMO's in the Stockholm Declaration however the principle dealing with science and technology are still valid. The US presumption that GMO's are safe appears to run afoul of this principle as it fails to establish any control over what is a

⁶⁶ Stockholm Declaration of the United Nations Conference on the Human Environment in Guruswamy, Lakshman D. Supplement of Basic Documents to International Environmental Law and World Order West Group, 1999 Pgs. 103-107

perceived environmental risk. Certain members of the EC can be said to have violated the principle by attempting to eliminate rather than identify and control the true risks if they feel such risks exist.

In 1998, under the mandate of the Stockholm Declaration, The Convention on Access to Information, Public Participation in Decision Making and Access to Justice in Environmental Matters (The Aarhus Convention) was passed.⁶⁷ The United States is not a party, the European Community is. A special Working Group on Genetically Modified Organisms was established. Article 6 of the Aarhus Convention references GMO's and states that there is a need for "transparency" and public participation as well as oversight by a competent state authority.⁶⁸ The U.N. has identified a need and placed affirmative burdens on member states to regulate GMO's.

While the United States has refused to join these conventions they remain a party to the Stockholm and signer of Rio Conventions. Simply because they do not cover GMO's specifically does not (or should not) absolve parties of their general obligations and responsibilities. The United States has an obligation to at least investigate new techniques which may affect the environment. Conversely, the European Community has an obligation to pursue advancements that may preserve or improve the human environment. Both parties can be said to have violated their responsibilities in some way. The US and EC are both powerful political forces. While it is unlikely to occur it would be interesting to see a party attempt to enforce these obligations.

⁶⁷ www.unece.org/env/pp/documents/cep43e.pdf

⁶⁸ Article 6.11 specifically excludes GMO's from the public participation provisions of the Aarhus Convention. An Ecoforum (under the Economic Commission for Europe) Position Paper dated May 2003 presents an informative argument as to why this position is incorrect. See <http://www.unece.org/env/pp/gmo/lbecoforum.doc>

The Espoo Convention on Environmental Impact Assessment in a Transboundary Context (EIA) entered into force in 1997 as the GMO controversy was beginning to gain momentum. Both the US and the EU are parties to the EIA. The EIA was created to address the interrelationship between economics and the environment, Article 5 of the EIA provides for mandatory consultation amongst the parties regarding the potential transboundary impact of a proposed activity.⁶⁹ Whether this convention applies here in light of the more recent Protocol is debatable. While the activity of producing GMO's and exporting them may not be considered an activity for the purposes of the EIA, Article 1 specifically states that activities related to health and safety are covered. While the applicability of the EIA is debatable neither side stands to lose much by engaging in consultations.

GMO's are a cutting edge topic however many nations have enacted at least some form of GMO specific regulation. Despite the fact that it is early on the process an argument can be made, now or in the future, that the unrestricted use of GMO's is a violation of international custom. The *Trail Smelter Arbitration* set forth a remarkable standard, "no state has the right to use or permit the use of its territory in such a manner as to cause injury" to another.⁷⁰ While that case dealt with air pollution it set forth a standard of liability for transboundary pollution. Oddly enough the US was the complaining party. If GMO's ever gain status as pollutants the US may come to regret that victory.

Domestic Law and Customs of the United States Contradicting the Current Policy on GMO's

⁶⁹ <http://www.unece.org/env/eia/eia.htm#article5>

⁷⁰ *United States v. Canada* Trail Smelter Arbitration, 3 R.I.A.A. 1938 (1941)

An analysis of domestic statutory and case law reveals that the United States' policy relating to GMO's may conflict with broader environmental and social policies that predate the 2003 WTO Request and 1992 FDA statement. Using existing domestic legislation to influence international legislation is a commonly employed tactic of many environmental groups and other NGO's. As GMO's have been granted an exemption from regulation the argument will be difficult but not impossible.

In *United States Public Interest Research Group v. Atlantic Salmon of Maine, LLC* the Court of Appeals for the First Circuit held that non-native species of salmon were a pollutant under the Clean Water Act.⁷¹ Aquaculture or fish farming is accomplished by holding a large number of fish in an enclosed pen within a natural body of water. These fish which have often been fed bioengineered feed or in some cases have been bioengineered themselves occasionally escape and cross-breed with the native population potentially causing adverse affects on biodiversity. In response the First Circuit granted an injunction banning further breeding of non-native species. It would seem that if one bioengineered or non-native product could be regulated as a pollutant in the US others with potentially similar effects could be as well. There is definitive proof that bioengineered corn has been discovered hundreds of miles from its US source in Oaxaca, Mexico. The cultivation of GMO's has been illegal in Mexico since 1998.⁷² A claim regarding transboundary pollution akin to *Trail Smelter* would be strengthened if such a connection could be made.

Without affirmative labeling and traceability requirements and lax safety protocols relating to production the American consumer is for the most part uninformed.

⁷¹ *United States Pub. Interest Research Group v. Atl. Salmon of Me., LLC*, 2003 U.S. App. LEXIS 16055 (1st Cir. 2003)

⁷² Stewart, Jr. C. Neal, Genetically Modified Planet Oxford University Press, 2004 Pgs. 73-75

Access to information and public input is a hallmark of American democracy. The National Environmental Policy Act of 1969 (NEPA) requires that an Environmental Impact Statement (EIS) be completed before certain federally authorized projects can commence.⁷³ This is similar to the mandates set forth by the Aarhus Convention. The unique aspect of an EIS is that while it may affect the agency's decision it does not require any specific actions. The EIS is a self-described "action forcing" mechanism requiring that a "hard look" be taken at potential environmental consequences before the project can begin. More importantly it provides that relevant information will be disseminated to the public who will in turn become part of the decision making process. While there is no requirement that a "worst case scenario" be planned for the goal is to assess "reasonably foreseeable environmental consequences" based on "credible scientific evidence."⁷⁴ Although *Shalala* barred this claim against the FDA further investigation on the environmental impact of GMO's may help to establish such a procedure. In fact, the terms used in the EIS nearly mirror those used in certain EC GMO regulations.

Public awareness, especially public consumer awareness is a powerful motive for both public agencies and private corporations to consider environmental concerns. In the context of GMO's, absence of information is akin to the absence of choice. To further the point, there are standards relating to what can be labeled organic whereas there are none relating to GMO's. In 1969 the Congress decided that the public should be made aware of decisions affecting the environment. In 2006 it is helping to maintain worldwide ignorance as to the food we eat. If anything is to change the public must be involved. In

⁷³ <http://www.epa.gov/compliance/nepa/index.html>

⁷⁴ *Robertson, Chief of the Forest Service, Et Al. v. Methow Valley Citizens Council Et. Al.* 490 U.S. 332 (U.S. 1989)

2000, a private consumer group determined that Cry9C, a pesticide not approved for human consumption was present in taco shells made from modified corn. While the FDA and EPA reacted it was the producer, Kraft Foods that voluntarily initiated a total recall.⁷⁵

In 2001 the FDA issued a draft guidance for voluntary labeling for bioengineered food. While the publication was made available for comment only and has no binding legal authority it suggest that the FDA has recognized a need or desire on the part of the public or specialized industry concerns in the matter.⁷⁶ Some companies have already began advertising their products as “GMO Free” but without a definitive ruling on what constitutes a GMO food and an absence of tracking and labeling requirements concerned have been raised over how accurate these statements are furthering the sentiment that GMO specific legislation will become necessary even if GMO’s are deemed to be safe.⁷⁷ This is analogous to the growing popularity of organic food. While a minority of US citizens purchase such food exclusively the government has taken action to ensure that certain standards are met by producers that label their products as organic. There is no reason to not provide the same protections to those persons who wish to purchase GMO free food.

The previous examples have shown how general environmental policy may conflict with the current US policy on GMO’s. While food and food additives are loosely regulated by The Act in comparison to drugs there is one clause which is strictly interpreted and causes an immediate ban to be issued if there is any evidence that the additive may be a cancer causing agent. §721(b)(5)(B) is the “Delaney Clause” and can

⁷⁵ www.cfsan.fda.gov/~dms/fdbioen2.html

⁷⁶ <http://www.cfsan.fda.gov/~dms/biolabgu.html>

⁷⁷ Patricia Callahan and Scott Kilman, “Seeds of Doubt: Some Ingredients Are Genetically Modified, Despite Labels' Claims --- Lab Test Finds Altered DNA In Soy O's, Veggie Bacon, Belying Marketing Pitch --- No Proven Dangers to Health” in The Wall Street Journal, April 5, 2001

be found under the food additives portion of The Act.⁷⁸ The Delaney Clause was interpreted in *Public Citizen v. Young* which held that there is no de minimis exception under the Clause for cancer causing agents. The statute is rigid and any evidence, however slight, is grounds for a ban on the product. Under this law if any causal connection could be scientifically proven between a given GMO and cancer the law would require that the product be removed from the market. Color additives are “batch traced” whereas with GMO’s there is no traceability, no labeling requirements and the danger that the modified organisms have escaped into the native population.

The FDA is an administrative agency. Its power is a result of a Congressional delegation. When the FDA attempted to regulate cigarette sales as a restricted device under §520(e) of The Act the Supreme Court affirmed the decision in *FDA v. Brown and Williamson Tobacco Co.* which held that Congress specifically withheld tobacco regulation from the FDA. While tobacco is not necessarily a drug as it does not pertain to the “diagnosis, mitigation cure or treatment of a disease” it does affect the “structure or function of the body.”⁷⁹ Food however is a much clearer topic; after all it is the *Food and Drug Administration*. Administrative agencies can only act within the realm of their delegated power. Cigarettes are known to be injurious to health yet they are one of the few products that Congress has withheld from FDA regulation. GMO’s are now afforded this same leeway. The key difference is that, second hand smoke aside, an individual can choose not to smoke or try and quit if they do. An individual cannot live without food. Congress has the power to compel enhanced regulation of GMO’s. This is not to suggest that they should immediately impose a moratorium. The absence of regulation is to the

⁷⁸ FDLI Pg. 223

⁷⁹ *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (U.S. 2000)

possible detriment of public health and environmental safety both domestically and abroad. That alone should suffice to compel enhanced regulation of GMO's.

Ethical/Religious

Many religions place restrictions on the foods that their followers can eat. Two of the more common are the laws of Kashrus and Halal as followed by observers of the Jewish and Hindu faiths respectively.⁸⁰ Other religions utilize food in observance; Holy Communion is one example. Many feel that genetic engineering is unethical for a variety of other reasons such as cruelty to animals.

In 2002 McDonalds settled a pending case involving the use of a beef flavoring agent in its French-fries. Members of the Hindu faith are prohibited from eating products containing beef. The settlement provided that McDonalds would issue a formal letter of apology, make better disclosure of its ingredients and pay \$10 million to be divided amongst several organizations. McDonalds had disclosed that the French-fries contained "natural flavoring" which was accepted under the FDA rules.⁸¹ While there is no legal authority behind this decision it indicates the power of the American consumer. If the Catholic Church moved against GMO's or the Jewish Americans refused to label foods containing GMO's as Kosher would the GMO industry sit by idly? Of course not. Even if GMO's are perfectly safe people have a right to know what it is they are eating for a variety of other reasons.⁸²

The EU

⁸⁰ See Wexler, Jeremy "Kilayim Pie" at: http://www.socialaction.com/education_resources/weekly_torah/vayikra_leviticus/kedoshim/kilayim_pie.shtml stating that: "The Torah proscribes the interbreeding of animals and plants. "You will keep my laws; you will not breed your animals as *kilayim* [the junction of two inappropriate things], you shall not seed your fields as *kilayim* (Leviticus 19:19)."

⁸¹ http://www.hinduismtoday.com/press_releases/mcdonalds/

⁸² Gutman, Benjamin N. "Ethical Eating: Applying the Kosher Food Regulatory Regime to Organic Food" 108 Yale L.J. 2351

The European Union has existed for a far shorter duration than the United States. Nevertheless certain legislation and decisions in the ECJ (CELEX, European Court of Justice) suggest that the EC and its individual members disagree amongst themselves as to the standards imposed by EC regulations. Furthermore, while the current debate over safety and health casts GMO's in a less than positive light there remains a corresponding obligation to investigate the use of GMO's for their potentially beneficial purposes. As the EC has legislated beyond the scope of BCD and CP for the purposes of this paper it will be accepted that they are not in violation of those agreements.

While the more recent legislation promulgated by the EU severely restricts the use of GMO's the EU has recognized, at least to some degree, the need for legal protection of biotechnology. In 1998 The European Directive on the Legal Protection of Biotechnology Inventions was passed despite dissent amongst several member states. The directive provides that an invention is patentable *even if* it concerns biological material or processes (Italics added). The "even if" language is indicative of the political stance on biotechnology in Europe. The directive is highly protective of research on human functions and contains a "ordre public" or morality clause precluding patents from being awarded for nearly any human genetic research as well as modifying the genetic identity of any animal likely to cause suffering absent a substantial medical benefit to man or animal.⁸³ From this language one can assume the threshold for biotechnology relating to crops is less stringent. A challenge brought by the Kingdom of the Netherlands seeking to annul the directive was dismissed in 2001 and it remains a valid law.⁸⁴ While safety

⁸³ Wei, Pgs. 290-292

⁸⁴ 2001 ECJ CELEX LEXIS 6015

concerns may prevent the current utilization of GMO crops, this Directive can be interpreted as encouraging research and development of GMO's.

The arguments surrounding labeling are amongst the most contentious in the US/EC dispute. In a decision interpreting Council Directive 90/313/EEC regarding the freedom of access to information on the environment the ECJ held that it was “not intended to give a general unlimited right of access to all information held by public authorities which has a connection, however minimal with one of the environmental factors.” The court dismissed a private action by an Austrian citizen seeking specific information regarding a particular import of maize under the compulsory label law, EC No 1139/98.⁸⁵ The merits of this decision are debatable as its long term effects may be harmful. It is presented to show that while the EC values public access it also recognizes a need to set a stopping point. Whether this case was decided correctly is immaterial. The fact that the ECJ is willing to enforce a restriction however is not.

While this isolated decision most likely does not set a binding precedent it suggests that the transparency and freedom to information might not be as open as once thought; and that might be a good thing. Consider the following, Monsanto’s Italian subsidiary brought suit in the ECJ for violation of an Italian directive banning certain products derived from GM corn despite a finding of “substantial equivalence” under Reg. 258/97. The court held that presence of transgenic protein in products produced from genetically modified organisms does not preclude substantial equivalence and that Food that is substantially equivalent may be placed on the market under a simplified procedure when those foods and food ingredients still contain residues of transgenic protein but it has been demonstrated that those materials do not present a danger for the consumer. A

⁸⁵ 2003 ECJ CELEX LEXIS 224

member state can still adopt temporary measures if it comes into possession of new information that indicates a product is unsafe.⁸⁶ Here the restrictions were not valid. This decision was made in 2003, the same year as the WTO Request. While it is mere speculation, perhaps the judicial tides changed as a result.

The EC is a collective of 15 nations. While the purpose of the EC is to encourage cooperation amongst members several nations have disagreed over certain policies as indicated in the examples above. The EC has warned member nations, most recently France and Germany, to implement EC directives into their domestic legislation following the 2003 WTO Request.⁸⁷ The proximity and interdependence of the EC member states each with their own legal agenda has led to a delicate political balance. While the EC can place pressure on a member nation the presence of the regional authority adds a layer to the GMO problem. When a nation seeks redress from a collective authority rather than an individual member it may indeed cause the “undue delay” asserted by the WTO. The nation committing the violation may seek to use the regional authority as a shield.

Lastly, how legitimate is the public advisory process. While it is assumed that NGO’s and public interest groups assist policymakers in a positive way whose interests are they representing? The prevailing view on GMO’s in Europe is one of distrust. Speculation alone cannot deter progress, even in the face of risks. Rio made clear that procedural safeguards against political influence were necessary to “ensure integrity” and instill “public confidence” in the proceedings.⁸⁸ The US cannot be condemned for assisting cutting-edge biotech firms if the EC or its member states become subject to the

⁸⁶ 2003 ECJ CELEX LEXIS 359

⁸⁷ http://archives.foodsafetynetwork.ca/agnet/2005/12-2005/Agnet%20Dec.%2021_05.eml.html#story1

⁸⁸ Kimball, Pg. 146

will of propaganda machines. This is not to say that either side is right, it is merely offered to show a distinction.

So Who Is Right? The Middle View?

New Zealand (and Australia)

As the GMO phenomenon began Australia and New Zealand took a proactive approach and crafted legislation that centered on risk management. Neither is a party to the 2003 WTO action however the results of their efforts seem to have produced a medium between the US and EC views. New Zealand was the more zealous of the two nations in crafting legislation. The Biosecurity Act of 1993 and the Hazardous Substances and New Organisms Act (HSNO) set forth the regulatory framework.⁸⁹

The New Zealand approach is novel on several levels. It regulates GMO's in both food and drugs making it GMO specific legislation rather than attempting to adapt old legislation to the issues surrounding GMO's. The HSNO makes accommodations for what called a "conditional release." Through such methods as developing special security fencing for animals or planting GM crops timed to flower at a different time than conventional crops New Zealand has been able to investigate the potential uses of GM technology in a controlled setting.

The HSNO established the Environmental Risk Management Authority (ERMA) which regulates the research, development and importation of GMO's. Public hearings are required prior to any approval, introduction, and field testing or conditional release of a GMO. ERMA has delegated authority for low-risk experiments in contained laboratories to Institutional Biological Safety Committees (ISBC's) many of which are

⁸⁹ <http://www.mfe.govt.nz/issues/organisms/regulation/gm-regulation.html>

located at universities. This facilitates research while retaining oversight and mandating certain safety protocols.

New Zealand's existing Food Safety Authority (NZFSA) administers safety as well as labeling standards. If a product contains a GMO it must be labeled as such.

In addition to its domestic legislation New Zealand joined Australia in forming Food Standards Australia New Zealand (FSANZ).⁹⁰ It is a cooperative body headed by the Ministers of Health of both Australia and New Zealand charged with the task of developing food standards applicable to both nations. This type of local agreement creates a uniform standard rather than setting a floor and allowing member states to enact stricter regulations and thus causing the need for protracted international dispute resolutions.

Nigeria

Hunger is a pressing issue in Africa and therefore it is important to recognize the issue from the perspective of at least one African nation's unique GMO policy. While Nigeria is a more developed nation than Zambia it still recognizes both the need for effective control as well as the potential benefits of GMO's. In accordance they have created a regime which utilizes a "diluted precautionary approach." The standard imposed in Nigeria's 1994 Guidelines on Biosafety require "familiarity" with a GMO rather than proof of safety. This requires that information suitable for reasonable assurances that similar products are safe be available along with heightened regulations for new introductions.⁹¹

⁹⁰ <http://www.foodstandards.gov.au/>

⁹¹ Reconciling Environment and Trade Pgs. 646-647

On March 16, 2005, World Consumer Rights Day, the All- Nigerian Consumer Movements Union issued the following statement. "Whereas it is true that GM technology may have the potential to increase food production and improve the nutritional quality of food, it is not being used by its dominant practitioners, the private corporation to produce either more of better food."⁹² That's it in a nutshell. A more concise statement of the problem cannot be found. The tension is mounting in WTO states, in CBD/CP states and other states across the world. Before there is to be a solution there must be recognition. If there is one constant to be drawn from this issue it is that denial and forced ignorance will not be tolerated in perpetuity.

Several other nations have taken a unique approach towards GMO regulation. While it is not suggested that these are the perfect solutions the respective frameworks are in some ways far superior to their US and EU counterparts. In summation, the New Zealand regulations place heightened regulations on GMO's but facilitates research and development and allows the importation of approved products subject to simple labeling requirements. It also permits the public, including NGO's to have their opinions heard and provides for cooperation with neighboring states rather than a forum in which disputes can be litigated for years with no foreseeable resolution.

A Proposed Solution

The goal of any viable solution will be to produce sufficient food for the world's population through safe, sustainable and environmentally conscious methods. If methods could be proven safe to the satisfaction of the parties to the WTO presumably there would be no need to resort to economic law to resolve an environmental conflict. Several steps must be taken, here are a few suggestions:

⁹² <http://www.angolapress-angop.ao/noticia-e.asp?ID=326883>

Creation of GM Specific Safety Legislation Common to all WTO Parties

It is clear that the EC will not accept GMO's absent proof of safety, labeling and tracking requirements. Many US consumers are incensed over the high prices of prescription drugs. While at first glance the two issues may not seem related the reasoning behind them is quite similar. High prescription drug prices can be found in §505 of the Food Drug and Cosmetic Act which requires that any new drug introduced into the US market requires a New Drug Application (NDA).⁹³ To receive FDA approval the drug must be proven to be "safe and efficacious" after Phase III in vivo (human) trials. §801(a)(3)⁹⁴ requires that in the case of imports, an NDA must be completed even if the imported product is identical to the one produced in the United States by the same producer. Each approved NDA must list the plants at which the drug is manufactured. Conveniently for the drug companies (which lobbied heavily for the passage of these provisions) §801(d)(1)⁹⁵ adds that any importation of a drug manufactured in the US and re-imported must be done by the drug company so they may keep prices at a set level. Many nations have price controls on medication.⁹⁶ For the most part, the US does not. The result is that the American consumer bears the research and development cost for the entire world.

The regulation of drugs in the US is far stricter than that of food and proves that we are capable of managing a reliable and effective scientifically based risk assessment

⁹³ <http://www.fda.gov/cder/regulatory/applications/default.htm>

⁹⁴ FDLI Pg. 248 - 249

⁹⁵ Id.

⁹⁶ See the United States Department of Commerce International Trade Administration's "Pharmaceutical Price Controls in OECD Countries Implications for U.S. Consumers, Pricing, Research and Development, and Innovation" December 2004, indicating that that aggregate pharmaceutical prices were 18 to 67 percent less than U.S. prices, in Organization for Economic Cooperation and Development (OECD) Countries at Pg. ix

<http://www.ita.doc.gov/td/chemicals/drugpricingstudy.pdf>

mechanism. If GM food products were regulated in the same or similar manner as drugs the requisite evidence would be available to those European nations currently unwilling to accept imports. In exchange for an agreement that would allow for a more even distribution of research and development costs the US could offer to impose standards consistent with those in the Cartagena Protocol in relation to food. This would reduce costs for EC members trying to satisfy their WTO obligations. It would also provide the US with a valuable incentive to alter its policy.

Farm Subsidies

Farm subsidies have been a contentious subject for years. The US government allocated billions to profitable industrial farms each year.⁹⁷ The US should strongly consider withholding subsidies to industrial farms in future legislation. One of the major issues surrounding the use of GMO's has been the adverse affects on individual farmers across the world. The CBD and other agreements have addressed the need for transparency and shared technologies. Subsidies are incredibly hard to revoke given the political pressure placed on members of the government⁹⁸. That said the EC, by not condoning GMO research and development and the US by protecting the interests of the Big Five have failed in their shared obligation to assist less developed nations which could benefit from GMO technology. The United States, if possible, should reallocate those resources to fulfill their obligations as should the EC by promoting research or

⁹⁷ \$12.5 billion in 2004 alone, see <http://www.ewg.org/farm/findings.php>

⁹⁸ <http://www.thematrix.com/learnmore/legislation.html>

providing products. Interestingly enough, the WTO has its own rules relating to government subsidies to which the US rigorously adheres.⁹⁹

The EC Directives on Import Restrictions Must be Altered to Establish a Standard Rather than a Floor

By allowing member nations to regulate in excess of the existing legislation it enabled the “de facto” moratoriums. The absence of a dispute resolution system within the CBD and Cartagena Protocol only exacerbated matters. The European directives are based on those in the Cartagena Protocol. The U.N. needs to create a binding dispute resolution body, perhaps under the auspices of the FAO to determine what procedures are acceptable. The Clearinghouse envisioned by Cartagena would be a useful part of this solution and should be adopted on a world wide basis. As an initial matter, the U.N. and WTO alike should abolish any legislation or action designed to function as a disincentive for developing nations to utilize GM crops. While these goals are more than ambitious given the snails pace at which such compromises are typically made GMO’s are a hot topic and the WTO dispute may provide the necessary impetus for action to be taken,

As a sub issue, any new GMO specific legislation must be deemed superior to any other existing legislation. There are many conflicting international, regional and sub-regional agreements. The UN’s FAO and a given regional group may have the same goals but without common means there can be no common end. The issues surrounding GMO’s are specific and therefore warrant specific rather than regional agreements.

Uniform Labeling Standards Must be Adopted in the US and the Obligation to Feed the Worlds Hungry Must Be Enforced

These two seemingly unrelated solutions are placed together because they are both designed to show good faith on behalf of the US. As previously mentioned the

⁹⁹ World Trade Organization (WTO) Agreement on Subsidies and Countervailing Measures (Subsidies Agreement) at http://www.wto.org/english/tratop_e/scm_e/scm_e.htm discussed in <http://ia.ita.doc.gov/esel/reports/seo2002/2002.html>

general sentiment is that GM food is not trustworthy and is not labeled because manufacturers have something to hide. The US justification in 1992 for the preferential treatment afforded to GMO's centered on the need to feed the worlds hungry, most notably in Africa. Since that time no discernable effort has been made to meet that goal. If GMO producers are to be afforded such benefits as direct farm subsidies and the aid of governmental representation in forums like the WTO the primary obligation to assist the worlds hunger problem must be undertaken. Concrete steps towards developing viable and sustainable crops in or for Africa and other impoverished nations is the first step in attempting to distance the government from appearing as though they are serving the interests of large biotech firms. It is also imperative that the US adopt a uniform labeling system consistent with the requirements in place in the EC. These actions would ease any transition in the EC by showing good faith on the part of the US at a time when distrust, especially in the context of GMO's is rampant in parts of Europe.¹⁰⁰

Shareholder Action

Many large bio-tech corporations are shareholder owned. Today a large percentage of publicly traded and privately placed shares are owned by institutional investors.¹⁰¹ By means of voting rights, shareholder proposals and other proactive shareholder activity perhaps GMO producers would come to the conclusion that it is in their best business interest to voluntarily conform to EC labeling requirements.¹⁰²

The Future of GMO's

¹⁰⁰ Tracy, Lisa A. "Does a Genetically Modified Rose Still Smell as Sweet? - Labeling of Genetically Modified Organisms Under the Biosafety Protocol" 6 Buff. Env'tl. L.J. 129, 168

¹⁰¹ <http://www.organicconsumers.org/corp/geshares.cfm>

¹⁰² In 2006, 7.3 percent of DuPont shareholders voted in favor of a resolution urging the company to disclose any potentially material risk or "off-balance sheet liability" that could be posed by its manufacturing and distribution of food-related genetically modified organisms (GMOs) <http://www.seedquest.com/News/releases/2006/april/15625.htm>

A stable food supply is necessary for the survival of every living thing on the planet. It follows then that the law of food should transcend both the laws of trade and the law of the environment. GMO's are not going away, nor should they. Under the current state of the law the major producers of GMO's seek to state a claim under the international law of trade whereas the major opponents seek what amounts to a moratorium based on speculation and ignore a mounting crisis facing a growing number of people each day. In the middle are marginalized producers and beneath them are those who stand to benefit the most from GMO's, those who suffer from hunger. Unfortunately it is those people who have the least input in terms of both governmental and economic representation. Until international uniform policies regarding GMO's are established to the satisfaction of both sides the humanitarian goals will remain on the back burner. An optimist would believe that the 2006 WTO decision will help to facilitate an agreement whereas the pessimist will presume that the two sides are diametrically opposed and this problem, which for the most part has been confined to the realm of economics will cross into the realm of environmental catastrophe. While no measure taken can be fool proof to take no measures at all is simply foolish.