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Samuel Blaustein

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Author's Note: This paper refers to a preliminary ruling issued on February 7, 2006 in response to a May 13, 2003, complaint brought by the United States alleging that the European Communities (EC) were purposely delaying approval of genetically modified (GM) food in violation of World Trade Organization (WTO) rules. A final decision was issued on September 29, 2006, and on November 21, 2006, the European Union (EU) decided not to appeal the decision.[1]

Part I. Introduction, Basics, Right to food, Need for Genetically Modified Food—Part I provides the reader with a background to the current dispute and sets forth the primary parties and agreements. A brief discussion of the relevant law, science, and history is included. Lastly, the ethical and legal rights to food are addressed as is the need for genetically modified food to satisfy any such obligations.

Part II. WTO verse Cartagena: Contrasting Schemes U.S./EC—Part II contrasts and compares the World Trade Organization schema, under which the United States brought the underlying claim, and the Cartagena Protocol on Biosafety. Whereas the former is more concerned with addressing impermissible barriers to trade, the latter is more concerned with safety and other factors such as labeling and transboundary movement. The EC is a party to both while the United States is only a party to the WTO, resulting in several points of conflict

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1. *See* WTO, Reports Out on Biotech Disputes, http://www.wto.org/english/news_e/news06_e/291r_e.htm. *See also* America.gov, WTO Upholds U.S. Challenge to European Ban on Biotech Food, http://www.america.gov/st/washfile-english/2006/February/20060208110902AKllennoCcM1.772708e-02.html

exacerbated by the United States' dominant role as an economic superpower and the interplay between the individual nations that comprise the EC. The regulatory schemes of both the United States and EC are discussed. While the FDA, the United States' primary regulatory body, has not proscribed GMO-specific regulations, the EC has developed numerous directives in addition to country specific regulations.

Part III. Contradiction: Australia/New Zealand + Nigeria—Part III looks to other sources of law including, international law as adopted by both primary parties, and country specific law that conflicts with the WTO and Cartagena Protocol. Public policy and social concerns are touched upon as well. The paper suggests that these contradictions may in fact help to resolve the current debate as they indicate a mutual willingness to compromise. Lastly, the regulatory schemes of certain non-parties, namely Australia/New Zealand (FSANZ) and Nigeria, are discussed in order to showcase alternative solutions.

Part IV. Proposed Solution: Future—Part IV offers suggestions for solving the problem, mainly the creation of GMO specific legislation that applies to both parties, and through what mechanisms this goal can be accomplished. The article concludes with a brief look into the future of GMOs.

I. Introduction

On February 7, 2006, the World Trade Organization (WTO)[2] issued a preliminary ruling indicating that the European Communities (EC)[3] had violated their WTO obligations by permitting several member states to erect "de facto" barriers to trade against certain genetically modified (GM) products previously approved by the umbrella organization, and by failing to enforce its own mandates.[4] This decision amounted to the

2. "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." World Trade Organization, What is the WTO?, http://www.wto.org/english/thewto_e/whatis_e/whatis_e.htm (last visited Apr. 24, 2008).

3. *See* EC Member Countries, http://www.mywebcalls.com/pop_up_ec.php (last visited April 24, 2008). 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. *See generally* Wikipedia, European Community, http://en.wikipedia.org/wiki/European_Community (last visited April 24, 2008).

4. *See* The World Conservation Union, WTO Panel Provisionally Rules Against EU Moratorium Biotech Approvals, http://www.ictsd.org/biores/06-02-17/story1.htm

realization of fears long held by environmentalists around the globe including members of The United Nations (UN), national governments, and private advocacy groups.[5] This paper will address whether this decision can be reconciled with the Cartagena Protocol (CP) on Biosafety[6] and other genetically modified organism (GMO) specific legislation.[7] The respective views of both parties to the WTO dispute, the United States (U.S.) (joined by Canada and Argentina, 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.[9] The U.S. 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 of a similar nature.[10]

International law is complex, especially when the laws of an individual state conflict with laws or norms of the international community. Under U.S. law, treaty formation and adoption are within the purview of Article II of the U.S. Constitution. Relevant here, Article

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(last visited April 23, 2008).

5. *See* Dorothy Nelkin et. al., *Genetically Modified Organisms: Foreword the International Challenge of Genetically Modified Organism Regulation*, 8 N.Y.U. ENVTL. L.J. 523 (2000).

6. *See* Convention on Biological Diversity, Cartagena Protocol on Biosafety, http://www.biodiv.org/biosafety/default.aspx (last visited April 24, 2008).

7. The United States has not adopted GMO specific legislation. *See generally* SHELDON RAMPTON & JOHN STAUBER, TRUST US WE'RE EXPERTS: HOW INDUSTRY MANIPULATES SCIENCE AND GAMBLES WITH YOUR FUTURE (Tarcher 2002) (explaining why the U.S. has not done so). EC members began to adopt GMO specific legislation in the early 1990's. Amongst the most important are Directive 2001/18/EC (repealing Council Directive 90/220/EEC) regarding the deliberate release of GMOs into the environment, Regulation (EC) 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, Regulation (EC) 1830/2003 (amending Directive 2001/18/EC) concerning traceability and labeling, Commission Regulation (EC) 65/2004 establishing unique identifiers for GMOs and finally Commission Regulation (EC) 641/2004 which provides detailed rules regarding the implementation of Regulation (EC) 1829/2003. This is not an all inclusive list but showcases the major issues surrounding the GMO debate.

8. *See* GreenPeace, The Miami Group—The Bad Guys, http://www.greenpeace.org/international/campaigns/genetic-engineering/biosafety-protocol/the-miami-group-the-bad-guys (last visited April 24, 2008).

9. *See* Commission Regulation 1946/2003, Regulation of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms, 2003 O.J. (L 287) 48.

10. "Signing a treaty has consequences under international law. Specifically, a state (country) that has signed, but not ratified, a treaty is to refrain from acts that would defeat the object and purpose of a treaty until it shall have made its intention clear not to become a party to the treaty." Republican Policy Committee, *Unratified and Unsigned Treaties Still Constrain U.S. Action*, May 16, 2006, *available at* http://rpc.senate.gov/_files/May1605UnsignedTreatiesMS.pdf. *See also id.* (detailing a recent and informative overview of the ramifications of signing but not ratifying international treaties).

II states that the President "shall have Power, by and with the Advice and Consent of the Senate, to make Treaties." The Vienna Convention on the Law of Treaties[11] mandates that any treaty signed by a recognized representative of a state is binding on that state.[12] It further states that a signatory is "obligated to refrain from acts which would defeat the object and purpose of the treaty" and cannot "invoke the provisions of its internal law as justification for its failure to perform a treaty."[13] The United States Senate has never ratified the Vienna Convention which was signed by President Richard Nixon in 1970.[14] Furthermore, certain bodies of international law can, over time, become components of "customary international law" or "CIL."[15] Under international law, both written agreements, (i.e. treaties and CIL) are afforded equal weight.[16] Accordingly, the United States should recognize both.[17] The result is that other signatories are likely to see the U.S. signature as a binding commitment to honor the 1992 Rio Convention. This sentiment will only grow stronger as the mandates of Rio and its progeny gain further acceptance around the world.[18] Lastly, failure to honor international

11. Vienna Convention on the Law of Treaties Between States and International Organizations, Mar. 21, 1986, *available at* http://untreaty.un.org/ilc/texts/instruments/english/conventions/1_2_1986.pdf.

12. *See id.* at Article 7(2). *See also* Malcolm N. Shaw, INT'L LAW 125 (1977) (discussing a 1972 International Court case holding that "heads of state belonged to the group of persons who in virtue of their functions and without having to produce full powers are considered as representing their state.").

13. Vienna Convention, *supra* note 11, at Article 18, 27.

14. *See* Andreas Paulus, *The Influence of the United States of the Concept of the "International Community," in* UNITED STATES HEGEMONY AND THE FOUNDATIONS OF INTERNATIONAL LAW 57, 83 (Michael Byers & George Nolte eds., 2003). *See also* Michael Byers & Simon Chesterman, *Changing the Rules About Rules? Unilateral Humanitarian Intervention and the Future of International Law, in* HUMANITARIAN INTERVENTION: ETHICAL, LEGAL AND POLITICAL DILEMMAS 177, 180 (J.L. Holzgrefe & Robert O. Keohane eds., 2003).

15. "The Court, whose function is to decide in accordance with international law such disputes as are submitted to it, shall apply . . . international custom, as evidence of a general practice accepted as law." U.N. Charter art. 92.

16. *See* Curtis A. Bradley & Jack L. Goldsmith, *Customary International Law as Federal Common Law: A Critique of the Modern Position*, 110 HARV L. REV. 815, 843 (1997). *See also* RESTATEMENT (THIRD) OF FOREIGN RELATIONS LAW OF THE UNITED STATES §§ 102-103.

17. *See* Jean-Marie Henckaerts, *Study on Customary International Humanitarian Law: A Contribution to the Understanding and Respect for the Rule of Law in Armed Conflict*, 87 INT'L REV. OF THE RED CROSS 175 (2005).

18. *See* Vienna Convention, *supra* note 11 (stating that no treaty may disaffirm a preemptory norm (*jus cogens*) and must yield to emerging preemptory norms). At present it is highly unlikely that any body of GMO specific law could be considered a preemptory norm however there may be other maxims that hold true in relation to GMOs. *See also infra* p. 27. *But see* Sean D. Murphy, *Environmental Torts Do Not Violate Customary International Law*, 98 AM. J. INT'L L. 175, 175-77 (2004).

agreements can have ramifications in other respects.[19]

A. The Basics

Genetically modified organisms, or GMOs, 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.[20] GMOs are sometimes known as "genetically engineered" (GE) "living modified organism" (LMO), and "transgenic."

There are several major benefits, as well as potential detriments, regarding the production and use of GMOs. The benefits include increased and faster food production as well as resistance to certain pests, degeneration, and diseases.[21] Certain health benefits such as higher vitamin content can be achieved, as can the removal of less desirable traits.[22]

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 "[f]rankenfood,"[23] as it has been referred to by its detractors, and the potential for adverse economic consequences to local farmers and industries in both modern and developing nations in favor of large multinational biotech corporations.[24] The primary disagreements among the parties center on safety, health concerns, labeling, traceability, and production methods.[25]

Another factor that cannot be ignored is public opinion. Public access to environmental information is vital towards both the initial acceptance and continued reliance on new technologies and projects.[26]

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19. *See infra* p. 41 (discussing how the U.S. was unable to sponsor a resolution after being voted off the UN Commission on Human Rights (UNCHR) in 2001 in part because of a disassociated failure to pay certain arrears on political grounds).

20. *See generally* George Wei, *An Introduction to Genetic Engineering*, LIFE SCIENCES AND THE LAW 32 (2002); Sophia Kolehmainen, *In Depth: Genetically Engineered Agriculture: Precaution Before Profits: An Overview of Issues in Genetically Engineered Food and Crops*, 20 VA. ENVTL. L.J. 267 (2001).

21. *See* BILL LAMBRECHT, DINNER AT THE NEW GENE CAFÉ: HOW GENETIC ENGINEERING IS CHANGING WHAT WE EAT, HOW WE LIVE, AND THE GLOBAL POLITICS OF FOOD 67 (Thomas Dunne Books 2002).

22. *See* http://www.ifap.org/about/wfcbiotech.html (presenting a comprehensive list of the basic benefits and detriments) (last visited Apr. 24, 2008).

23. *See* HENRY I. MILLER & GREGORY CONKO, THE FRANKENFOOD MYTH: HOW PROTEST AND POLITICS THREATEN THE BIOTECH REVOLUTION 29 (Praeger Publishing 2004).

24. *See* PETER PRINGLE, FOOD, INC.: MENDEL TO MONSANTO—THE PROMISES AND PERILS OF THE BIOTECH HARVEST 54 (Simon & Schuster 2005).

25. *See* GMO Food for Thought, http://www.gmofoodforthought.com/2005/11/ (last visited Apr. 24, 2008).

26. At present, Al Gore is gaining popularity for his film "An Inconvenient Truth" and his environmental policy. *See* William Booth, *Al Gore, Rock Star Oscar Hopeful*

The absence of public participation can lead to widespread skepticism.[27] Certain governments and private businesses alike have used a "clean green" marketing image in order to garner public support for their policies on GMOs.[28] Greenpeace, while potentially biased, has conducted surveys throughout Canada and the U.S. 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.[29] Additionally, certain areas in the United States, often considered to be more environmentally aware such as Vermont and California, were considering the establishment of localized GMO-free zones in 2005.[30] Whether this view is shortsighted is not the ultimate point. If GMOs are going to gain widespread acceptance, people must perceive them as safe and nutritious rather than artificial and dangerous.[31] The best way to accomplish such a goal would be to prove that GMOs can be produced and consumed safely, without causing an adverse effect to human health or the environment.[32]

B. Is There a Right to Food?

1. Is There a Naturally Inherent Right?

Though in the abstract one might say there is a right to food, this is contradicted by the very laws of nature. Darwinian terms like "natural

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May Be America's Coolest Ex-Vice President Ever, WASHINGTON POST, Feb. 25, 2007, at A1.

27. *See* Lambrecht, *supra* note 21, at 233 (discussing recent incidents in both the United Kingdom and United States, the former having to do with Novartis contributing funds to British Prime Minister Tony Blair's Labor Party and the latter having to do with Monsanto's "wining and dining" of American politicians).

28. *See* C. NEAL STEWART JR., GENETICALLY MODIFIED PLANET 40 (Oxford University Press 2004).

29. *See Greenpeace Canada attacks health minister over GMO labeling*, http://www.foodnavigator.com/news/ng.asp?id=42135-greenpeace-canada-attacks (last visited Apr. 24, 2008).

30. *See generally* Institute of Island Studies, The Economic, Social and Environmental Implications of Genetically Modified Crops (GMOs) on Islands, http://www.upei.ca/islandstudies/rep_gmo_1.htm (last visited Apr. 24, 2008).

31. A 1999 quantitative analysis study conducted in the UK regarding BSE (Bovine spongiform encephalopathy aka "Mad Cow Disease") indicated that there was an impact on the public's perception of GMOs and that it fueled the rise of anti-GMO interest groups, such as the "Friends of the Earth." *See* ERICA MEINS, POLITICS AND PUBLIC OUTRAGE: EXPLAINING TRANSATLANTIC AND INTRA-EUROPEAN DIVERSITY OF REGULATIONS ON FOOD IRRADIATION AND GENETICALLY MODIFIED FOOD 132 (Lit Verlag, 2003).

32. *See* David Byne, EU Health and Consumer Prot. Comm'r, Transatlantic Food for Thought, Speech at the Annual Meeting of the Transatlantic Consumer Dialogue (Feb. 3, 2004), *available at* http://www.eurunion.org/News/press/2004/20040013.htm.

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 upon us by morality and compassion towards fellow human beings.[33]

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."[34] 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."[35] From this broad language it is nearly impossible to identify what, if any, affirmative obligations governments have to combat world hunger[36] and it leaves open the question of through what means may these goals be accomplished.[37] A strict interpretation of the language 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.

C. Is There a Need for GM Food?

Americans and Europeans alike are fortunate in that they have not experienced wide scale hunger in several generations.[38] But the reality is that, despite improved production and the process of globalization, a large number of people throughout the world go hungry each day.[39] In

33. *See* Wikipedia, Survival of the Fittest, http://en.wikipedia.org/wiki/Survival_of_the_fittest (last visited Aug. 2, 2008) .

34. International Covenant of Social, Economic and Cultural Rights, art. 11, U.N. Doc. A/6316, (Dec. 16, 1966), *available at* http://www.unhchr.ch/html/menu3/b/a_cescr.htm.

35. *Id.*

36. *See generally* Hugh Lacey, *Assessing the Value of Transgenic Crops*, 8 SCI. & ENGINEERING ETHICS 497 (2002) (discussing research ethics in the context of GMOs).

37. *See generally id.*

38. The last wide-scale famine affecting those of European decent was the Irish potato famine which ranged from 1845-1851. *See* William A. Spray, *Irish Famine Emigrants and the Passage Trade to North America*, *in* FLEEING THE FAMINE: NORTH AMERICA AND IRISH REFUGEES, 1845-1851, 3, 18 (Margaret M. Mulrooney ed., 2003). *See generally* FLEEING THE FAMINE: NORTH AMERICA AND IRISH REFUGEES, 1845-1851 (Margaret M. Mulrooney ed., 2003) (discussing the politics of the Irish potato famine).

39. *See* USAID Africa, Initiative to End Hunger in Africa (Aug. 22, 2007), http://www.usaid.gov/locations/sub-saharan_africa/initiatives/ieha.html.

2002, the African nations of Zambia and Uganda, amongst others, initially rejected an offer of food aid from the U.S. because it contained GM maize.[40] Some countries, most notably Zimbabwe, relented only when the maize was milled prior to importation.[41] The reasons behind this go straight to the heart of the debate surrounding genetically modified food. Aside from immediate health consequences to their respective people, the nations feared that acceptance of GMOs might taint their future potential crops for export to the EU and other GM wary nations. In 2003, the Southern African Development Community (SADC)[42] 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."[43] That said, Egypt, a country which has long accepted aid from the U.S. and is a regional political power has cooperated with the United States Agency for International Development (USAID) to develop its own GM crops.[44] With the possibility of cross-contamination as well as the marginalization or elimination of non-GM producers, along with the backing of the U.S., it seems inevitable that GMOs will become widespread in the African environment.[45]

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.[46] The presumption is that the U.S. 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.[47] 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

40. *See* Debbie Collier, *Access to and Control over Plant Genetic Resources for Food and Agriculture in South and Southern Africa: How Many Wrongs Before a Right?*, 7 MINN. J.L. SCI. & TECH. 529, 530 n.8 (2006).

41. *See id.*

42. *See generally* SADC, Southern African Development Community (Mar. 4, 2008) http://www.sadc.int/.

43. *See* SIMONETTA ZARRILLI, INTERNATIONAL TRADE IN GMOS AND GM PRODUCTS: NATIONAL AND MULTILATERAL LEGAL FRAMEWORKS 8, 24, 27 n.52 (United Nations 2005), *available at* http://www.unctad.org/en/docs/itcdtab30_en.pdf.

44. *See* AHMED GALAL & ROBERT Z. LAWRENCE, ANCHORING REFORM WITH A U.S.-EGYPT FREE TRADE AGREEMENT 22 (2005); Joseph Krauss, *Egypt to develop biotech crops*, BUSINESS TODAY, July 2005, http://www.gmoafrica.org/2005/07/egypt-to-develop-biotech-crops.html.

45. *See* C.D. Vilijoen et. al., *Detection of GMO in food products in South Africa: Implications of GMO labeling*, 5 AFR. J. BIOTECH. 2, 73-82, (2006).

46. *See generally* GMO-free Europe, www.gmofree-europe.org/ (last visited Apr. 22, 2008).

47. *See* Stewart, *supra* note 28, at 214.

presidents seeks to gain worldwide dominance in the agricultural market before nations have time to adopt substantive regulations. Tactics include getting "a foot in the door" by selling to GM-friendly countries such as Poland who are trying to gain favor with the U.S.[48]

While definitive proof to the contrary is not available, there are certainly viable justifications for exploring the potential uses of GMOs as a solution for both short term hunger issues and long term environmental concerns.[49] 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.[50] 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.[51] 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.[52] 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.[53] 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 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

48. *See* PAUL SMITH, SEEDS OF DESTRUCTION, chapter 3 (Publish America 2006).

49. *See generally* CONSUMER ACCEPTANCE OF GENETICALLY MODIFIED FOODS (Robert E. Evanson & Vittorio Santaniello, CABI Publishing 2004) (containing a collection of interesting studies and article).

50. *See* Bryan G. Norton, WHY PRESERVE NATURAL VARIETY? 260 (Princeton University Press 1987).

51. *See* Stewart, *supra* note 28, at 40-41.

52. *See generally* M. Cafaro, et. al., *The Fat of the Land: Linking American Food Overconsumption, Obesity, and Biodiversity Loss*, 19 JOURNAL OF AGRICULTURAL AND ENVIRONMENTAL ETHICS, 541 (2006) (giving an example in the context of food).

53. *See generally* SCIENCE MAGAZINE'S STATE OF THE PLANET 2006-2007 (Donald Kennedy ed., Island Press 2006). *See also* World Wildlife Federation, www.panda.org (last visited Apr. 24, 2008).

footprint" is an unfathomable 9.6 hectares per person.[54] When one considers the UN'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.[55]

To compound the problem, desertification as a result of human activities is becoming an even greater problem.[56] The 1996 Convention to Combat Desertification (UNCCD)[57] 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[58]) 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.[59] Although the Montreal Protocol[60] 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 irreversible damage."[61] If GMOs 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

54. *See* World Wildlife Federation, WWF Living Planet Report, http://www.panda.org/news_facts/publications/key_publications/living_planet_report/about_lpr/index.cfm (last visited Apr. 24, 2008).

55. *See* U.N. POPULATION DIVISION, WORLD POPULATION PROSPECTS: THE 2000 REVISION, VOL. III ANALYTICAL REPORT, at 5, U.N. Doc. ST/ESA/SER.A/200, Sales No. E.01.XIII.20 (2002).

56. Desertification is "land degradation in arid, semi-arid and dry sub-humid areas resulting from various factors including climatic variations and human activities". Jonathan Handley, *Environmental and Policy issues of Land degradation; UNSD/UNEP Questionnaire 2004*, *available at* http://unstats.un.org/unsd/ENVIRONMENT/envpdf/sess08land_deg_intro.pdf. *See generally* David Freeston, *The Road From Rio: International Environmental Law After the Earth* Summit, 6 J. ENVTL. L. 193, 193-218 (1994).

57. *See* United Nations Convention to Combat Desertification, http://www.unccd.int/convention/menu.php (last visited Apr. 24, 2008).

58. *See* E.O. Wilson, *Hotspots: Preserving Pieces of a Fragile Biosphere*, NAT'L GEOGRAPHIC, Jan. 2002, at 86.

59. *See* WORLD RESOURCES 2000-2001: PEOPLE AND ECOSYSTEMS 30 (United Nations et. al. eds., World Resources Institute 2001).

60. *See* Ozone Secretariat United Nations Environment Programme, The Montreal Protocol on Substances That Deplete the Ozone Layer (2000), *available at* ozone.unep.org/pdfs/Montreal-Protocol2000.pdf.

61. LEE A. KIMBALL, TREATY IMPLEMENTATION: SCIENTIFIC AND TECHNICAL ADVICE ENTERS A NEW STAGE 127 (American Society of International Law 1996).

presented in the U.S./EC WTO debate.

II. The Issue Presents Itself: The WTO vs. the Cartagena Protocol

The WTO was established in 1995 following the Uruguay Round, a seven-and-a-half year series of trade negotiations culminating in Marrakesh in 1994.[62] Its principle rules are found in the General Agreement on Tariffs and Trade (GATT) which was established in 1948.[63] The WTO's purpose is to facilitate free trade among the nations of the world. Through such practices as "most favored nation status"[64] the WTO seeks to assist producers and consumers by way of internationally agreed-upon standards to eliminate barriers to trade and to establish new markets. The WTO claims to be sensitive to governments' social and environmental objectives as set forth in the preamble to the agreement establishing the WTO.[65] Nevertheless it has been constantly chastised as environmentally insensitive and solely reliant on the principles of a free market, rather than an expression of genuine concern for the people and environment that the agreements affect.[66] Whether or not this sentiment is true is of little consequence. The WTO rules are focused on trade concerns with certain environmental safeguards. It is therefore important to recognize from the outset that any WTO violation is strictly a violation of trade and not one of environmental policy.[67]

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 GMOs enacted by the European Communities.[68] 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

62. *See* Understanding the WTO—The Uruguay Round, http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact5_e.htm (last visited Apr. 24, 2008).

63. *See* World Trade Organization, The GATT years: from Havana to Marrakesh, http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact4_e.htm (last visited Apr. 19, 2008).

64. General Agreement on Tariffs and Trade pt. I, art. 1, Oct. 30, 1947, *available at* http://www.worldtradelaw.net/uragreements/gatt.pdf.

65. *See generally* World Trade Organization, WTO Legal Texts, http://www.wto.org/english/docs_e/legal_e/legal_e.htm (last visited Apr. 24, 2008).

66. *See* Paulette L. Stenzel, *Why and How the World Trade Organization Must Promote Environmental Protection*, 13 DUKE ENVTL. L. & POL'Y 1, 1 (2002).

67. *See generally* GARY P. SAMPSON, THE WTO AND SUSTAINABLE DEVELOPMENT (United Nations University Press 2005); BRADLEY J. CONDON, ENVIRONMENTAL SOVEREIGNTY AND THE WTO: TRADE SANCTIONS AND INTERNATIONAL LAW 1 (Hotei Publishing 2006).

68. *See* GATT Secretariat, European Communities—Measures Affecting the Approval and Marketing of Biotech Products, (Sept. 29, 2006), http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds291_e.htm (last visited Apr. 24, 2008).

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).[69]

The SPS Agreement seeks to prevent baseless restrictions 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.[70] 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 GMOs approved prior to 1998 have adversely affected imports from the U.S., 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.[71]

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.[72] The final text of the decision has not been disseminated as of the time of this writing, 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

69. *See id.*

70. *See* World Trade Organization, Agreement on Technical Barriers to Trade, Technical Regulations and Standards art. 2(2.2), *available at* http://www.wto.org/english/docs_e/legal_e/17-tbt.doc (last visited Aug. 2, 2008).

71. *See* Press Release, European Union, Europe's Rules on GMOs and the WTO (July 2, 2006), *available at* http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/06/61&format=HTML&aged=0&language=EN&guiLanguage=en.

72. *See* Trade Observatory, http://www.tradeobservatory.org/library.cfm?refid=78475 (last visited Apr. 24, 2008).

violating Article 8 and Annex C of the SPS Agreement. Additionally, failure to consider for final approval 24 of 27 GMOs constituted a violation. Furthermore, allowing individual member nations the right to implement SPS measures is not itself a violation. However failure to conduct a risk assessment when reliable scientific data was available constituted a violation.

While the preliminary ruling sides with the U.S. 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 provided that they do not cause undue delay and/or act as "de facto" moratoriums. The WTO explicitly chose not to investigate whether GMOs are safe, whether they are "equivalent" to non GMOs, or whether certain EC regulations violate the WTO rules. Nevertheless many EC members and interested independent groups have expressed dismay and continue to protest further imports of GMOs.[73] 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 U.S. has not yet ratified Rio raises questions relating to true motive, however in the end the WTO may be more closely aligned with general principles of humanitarianism as they are perceived.

Historically, taxation of agriculture has been a "brutal mechanism" through which resources were allocated unfairly and inefficiently.[74] 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 U.S. failure to ratify Rio is a product of lack of accommodation.[75] This is not meant to serve as a justification; it is simply a theory in regard to why a controversial decision was made.

A. The Cartagena Protocol

The timing of the WTO Request was obviously an attempt to

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

74. *Rural Organizations and Associations*, *in* THE RIGHT TO FOOD, 179 (K. Tomasevki ed., Stitchting Studie, 1984).

75. This is a stance the U.S. has taken in regards to other international agreements, such as the more widely known Kyoto Protocol, relating to greenhouse gas reduction which has allegedly not been presented to Congress because of disparate treatment afforded to developing nations, most notably China, rather than disagreement with the Protocol's goals. *See* Helen Dewar & Kevin Sullivan, *Senate Republicans Call Kyoto Pact Dead*, THE WASHINGTON POST, December 11, 1997, at A37.

mitigate the effects of the Cartagena Protocol on Biosafety.[76] The Protocol was designed specifically to address the transboundary movement of GMOs. 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 GMOs.[77]

Three primary affirmative duties are required under the Protocol. The first centers around the Advanced Informed Agreement (AIA) in Articles 7-10 and 12 which provides that countries exporting GMOs 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 duty requires parties to the Protocol to access and utilize the Biosafety Clearinghouse (BCH).[78] 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 must 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."[79]

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 GMOs. 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 are to conduct a scientific risk assessment when determining whether to ban a GMO. The absence of such techniques, then, would leave the potential importer free to deny the import without any factually based reason.

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76. *See* EuropaWorld, US Decision to file WTO case on GMOs misguided and unnecessary (May 16, 2003), http://www.europaworld.org/week129/usdecision16503.

77. *See* Convention on Biological Diversity, Cartagena Protocal Background, http://www.biodiv.org/biosafety/background.shmtl (last visited Apr. 22, 2008).

78. *See* Convention on Biological Diversity, Biosafety Clearing House, http://bch.biodiv.org/default.asp (last visited Apr. 24, 2008).

79. Convention on Biological Diversity, Cartagena Protocol on Biosafety to the Convention of Biological Diversity art. III, ¶ 3 (Jan. 29, 2000) *available at* 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."[80] Neither the CBD nor the Protocol provide for a dispute resolution procedure regarding the use of GMOs.

B. Contrast and Comparison: Regulatory Schemes in The U.S. and The EC

1. 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.[81] 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"[82]
2. § 409—Defines "food additive"[83]

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 intervention.[84] 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. The courts have been deferential to the FDA's decision to pursue actions

80. Convention on Biological Diversity, June 5, 1992, No. 30619, *available at* http://www.biodiv.org/doc/legal/cbd-un-en.pdf.

81. *See* Mystery Bridgers, *Genetically Modified Organisms and the Precautionary Principle: How the GMO Dispute Before the World Trade Organization Could Decide the Fate of International GMO Regulation*, 22 TEMP. ENVTL. L. & TECH. J. 171, 176 (2004).

82. STATUTORY SUPPLEMENT: FEDERAL FOOD, DRUG, AND COSMETIC ACT AND RELATED SECTIONS OF ADDITIONAL STATUTES, 27 (Food and Drug Law Institute 2005).

83. *Id.* at 58.

84. *See* United States v. Anderson Seafoods, Inc., 622 F.2d 157, 162 (Former 5th Cir. 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). *See also* 21 C.F.R. § 110.110 (1990).

based on what the agency feels is "necessary for the protection of public health."[85] In the context of GMOs however, the FDA, subject to political pressure, has chosen not to act.[86]

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."[87] Essentially the FDA relies on a presumption that GMOs are safe or GRAS (generally recognized as safe).[88] 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 without 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 its position by way of an appearance by James H. Maryanski, Ph.D. before the House Committee on Science Subcommittee on Basic Research. In short, The FDA retains the authority to effectuate proceedings 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 GMOs to the market.[89]

In 2001, the FDA proposed new rules regarding GMOs, 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."[90] Apparently a lack of evidence

85. Young v. Cmty. Nutrition Inst., 476 U.S. 974, 974 (1986).

86. *See generally* Smith, *supra* note 48.

87. *Statement of Policy: Foods Derived From New Plant Varieties*, 57 FEDERAL REGISTER, May 29, 1992, at 22991.

88. *See* 21 C.F.R. § 170.36(c)(1) (proposed).

89. James H. Maryanski, Ph.D., Biotechnology Coordinator of the Center for Food Safety and Applied Nutrition on behalf of Food and Drug Administration, Speech before the Committee on Science Subcommittee on Basic Research of the United States House of Representatives, Oct. 19, 1999, *available at* http://www.fda.gov/ola/1999/ plant2.html.

90. Raymond Formanek Jr., *Proposed Rules for Bioengineered Foods*, FDA

having nothing to do with production methods or biodiversity was insufficient to win over the skeptics. That said, the U.S. has no affirmative labeling requirements for GMOs, however there are guidelines that must be met before an article can be certified organic.[91]

The issue came to a head in *Alliance for Bio-Integrity v. Donna Shalala* 116 F.Supp.2d 166 (D. D.C. 2000) 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 Statement[92] in violation of the National Environmental Protection Act, the FDA's GRAS[93] standard and labeling requirements were "arbitrary and capricious" (the standard for administrative agency review)[94], and was in violation of the Religious Freedom Restoration Act. The DC Circuit held that the Agency's statement merely set forth a "rebuttable presumption" and was not a final agency determination, and as such was not arbitrary and capricious.[95]

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.[96] The courts in several other cases have upheld the FDA's GRAS standard but at the same time have enforced copyright violations regarding GMOs.[97] It seems contradictory to hold that on the one hand an agency policy stating that the final products are no different is valid, while the seeds are subject to copyright laws. These decisions are from 2004 and 2005 respectively. These and other cases illustrate domestic dissention,

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CONSUMER, Mar.-Apr. 2001, *available at* www.cfsan.fda.gov/~dms/fdbioen2.html.

91. *See* NATIONAL ORGANIC STANDARDS BOARD, POLICY AND PROCEDURES MANUAL, 29, (2002), *available at* http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELDEV3013893.

92. *See* 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. *See* U.S. Environmental Protection Agency, National Environmental Policy Act, http://www.epa.gov/compliance/nepa/index.html (last visited Apr. 27, 2008).

93. *See* U.S. Food and Drug Administration, Guidance for Industry: Frequently Asked Questions about GRAS, http://www.cfsan.fda.gov/~dms/grasguid.html#Q1 (last visited Apr. 28, 2008) (explaining §§ 201(s) & 409 of the Food Drug and Cosmetic Act).

94. *See* 5 U.S.C. § 706(2)(A) (1966). *See also* Natural Res. Defense Council v. EPA, 966 F.2d 1292, 1297 (9th Cir. 1992).

95. *See* Alliance for Bio-Integrity v. Donna Shalala 116 F.Supp.2d 166, 173 (D. D.C. 2000).

96. *See* Showmaker v. Advanta *U.S.A, Inc.*, 2004 U.S. Dist. LEXIS 28066, at *1-2 (S.D. Ill. Jan. 14, 2004).

97. *See, e.g.*, Syngenta Seeds Inc. v. Monsanto Co. 409 F.Supp.2d 536 (D. Del. 2005).

suggesting that the current regulatory scheme is insufficient to deal with the issues surrounding GMOs.

Before continuing, it is important to note that the U.S. is not a party to either the CBD or CP, and therefore its administrative agencies cannot be admonished for failure to comply from a legal perspective.[98] The conflicts between U.S. policy and failure to ratify CBD and CP are addressed later in the article.

2. The European Communities

Unlike the U.S., 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 the "deliberate release" of GMOs. Its 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 GMOs from entering the EC market according to the U.S. 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.[99]

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.[100] 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 GMOs. 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 the

98. *See* Republican Policy Committee, *supra* note 10. *See also* Shaw, *supra* note 13; Vienna Convention on the Law of Treaties, *supra* note 11.

99. *See* GEORGETOWN LAW CTR., RECONCILING ENVIRONMENT AND TRADE 633 (Edith Brown Weiss & John H. Jackson eds., Transnational Publishers Inc. 2001).

100. *See id.* at 635.

mandates of Cartagena is a valid attempt toward 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 1830/2003 (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.[101] 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 Unites States' assumed position is that such requirements act as technical barriers to trade in violation of the TBT Agreement.[102] Plausible arguments exist on both sides. On the one hand, labeling may add expenses, however they may also satisfy the concerns of an increasingly wary public 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, while a long winded dispute over the length 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, nutritional value, metabolism, intended use, and the level of undesirable substances contained therein."[103] Monsanto and other GMO producers have sought to use this provision to their advantage.[104]

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101. *See* Commission Regulation 1830/2003, Concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, 2003 O.J. (L 268/24), *available at* http://www.biosafety.be/GB/Dir.Eur.GB/Del.Rel./1830_2003/1830_2003_TC.html.

102. *See* World Trade Organization, Technical Barriers to Trade, http://www.wto.org/English/tratop_e/tbt_e/tbt_e.htm (last visited Apr. 20, 2008).

103. Advisory Committee For Novel Foods and Processes, Astaxanthin Extract from Haematococcus pluvialis, www.food.gov.uk/multimedia/pdfs/ACNFP_65_2.PDF (last visited Apr. 20, 2008).

104. *See* Bundesgerichtshof [BGH] [Federal Court of Justice] March 8, 1995, 159/94 UNCITRAL (F.R.G.) (holding that the sale of New Zealand mussels by a Swiss seller to a German concern was a valid transaction despite the fact that the oysters contained more cadmium than recommended by the German health authority. The court ruled that the mussels were still edible and that the seller need not provide goods that conform to all

The EC's GMO policy on the transboundary movement of GMOs is codified in Regulation (EC) 1946/2003.[105] 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 believes that 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 to date, no such charge has been brought, 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 trans-boundary movement—remain constant.

III. Contradiction

A. Conflicts of Law

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.

1. International Law as Applied to Both WTO Parties

Several additional UN sponsored agreements may be applicable to

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statutory or public provisions in the import State unless the same rules existed in the seller's State or the seller was informed by the buyer or should have known due to special circumstances. Does this case, which took place at very beginning of the GMO debate, offer an applicable rule of law?).

105. *See* Commission Regulation 1946/2003, Transboundary movement of genetically modified organisms, 2003 O.J. (L 287), *available at* http://64.233.169.104/search?q=cache:zmib8-eK5QEJ:europa.eu/scadplus/leg/en/lvb/l28119.htm+Commission+Regulation+1946/2003,&hl=en&ct=clnk&cd=1&gl=us&client=safari.

the current GMO dispute. In order for a nation to be bound they need to be a party absent an overriding international custom.[106] 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."[107] As GMOs had not yet been introduced in 1972, there are no specific references to GMOs in the Stockholm Declaration. However the principle dealing with science and technology is still valid. The U.S. presumption that GMOs are safe appears to run afoul of this principle, as it fails to establish any control over what is a 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.[108] The United States is not a party, while the European Community is. A special Working Group on Genetically Modified Organisms was established. Article 6 of the Aarhus Convention references GMOs and states that there is a need for "transparency" and public participation as well as oversight by a competent state authority.[109] The UN has identified such a need and

106. *See* United Nations Charter, *supra* note 15. *See also* RESTATEMENT (THIRD) OF U.S. FOREIGN RELATIONS LAW § 102(2) (1987) (stating that "[c]ustomary international law results from a general and consistent practice of states followed by them from a sense of legal obligation"). The comment states that no definition has gained universal acceptance. *See id.*

107. LAKSHMAN D. GURUSWAMY, ET. AL., INTERNATIONAL ENVIRONMENTAL LAW AND WORLD ORDER 103-07 (West Publishing Company 2nd ed. 1999).

108. *See* Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, European community- member states, June 25, 1998, *available at* www.unece.org/env/pp/documents/cep43e.pdf.

109. *See* Article 6.11 specifically excludes GMOs from the public participation provisions of the Aarhus Convention. An Ecoforum (under the Economic Commission for Europe) Position Paper dated May 2003 presents and informative argument as to why this position is incorrect. *See* Legally Binding Provisions on Public Participation and the Need to Amend the Convention, Ecoforum Position Paper, 2003, *available at* http://www.unece.org/env/pp/gmo/lbecoforum.doc.

placed affirmative burdens on member states to regulate GMOs.

While the United States has refused to join these conventions, they remain a party to the Stockholm and a signer of the Rio Conventions. Simply because they do not cover GMOs specifically does not (or should not) absolve parties of their general obligations and responsibilities.[110] 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 U.S. and EC are both powerful political forces. While it is unlikely to occur, it would be interesting to see either party attempt to enforce these obligations.

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 U.S. 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 among the parties regarding the potential transboundary impact of a proposed activity.[111] Whether this convention applies here, in light of the more recent Protocol, is debatable. While the activity of producing GMOs 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. Also, while the applicability of the EIA is debatable, neither side stands to lose much by engaging in consultations.

GMOs are a cutting edge topic, yet many nations—including those with far fewer resources than the U.S.—have enacted at least some form of GMO specific regulation.[112] Although it is early in the process, an argument can be made, now or in the future, that the unrestricted use of GMOs is a violation of international custom (CIL). *United States v. Canada Trail Smelter Arbitration,* 3 R.I.A.A. (1938) 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.[113] While that case dealt with air pollution, it set forth a standard of liability for transboundary pollution disputes. Oddly enough the U.S. was the

110. *See* Republican Policy Committee, *supra* note 10. *See also* Vienna Convention, *supra* notes 11-13.

111. *See* Convention on Environmental Impact Assessment in a Transboundary Context (Espoo, 1991)—the "Espoo (EIA) Convention," United Nations Economic for Europe, *available at* http://www.unece.org/env/eia/eia.htm#article5 (last visited April 17, 2008).

112. *See generally* Food Safety Network, http://www.foodsafetynetwork.ca/en/ (last visited Aug. 2, 2008).

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

complaining party. If GMOs ever gain status as pollutants, the U.S. may come to regret that victory.[114]

2. Domestic Law and Customs of the United States Contradicting the Current Policy on GMOs

An analysis of domestic statutory and case law reveals that the United States' policy relating to GMOs 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 GMOs 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.[115] Aquaculture or fish farming is accomplished by holding a large number of fish in an enclosed pen within a natural body of water.[116] 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.[117] 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 U.S., others with potentially similar effects could be as well. There is proof that bioengineered corn has been discovered hundreds of miles from its U.S. source in Oaxaca, Mexico. The cultivation of GMOs has been illegal in Mexico since 1998.[118] 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. Access to information and public input is a

114. *See* Weis, *supra* note 99, at 635.

115. *See* United States Pub. Interest Research Group v. Atl. Salmon of Me., LLC, 2003 U.S. App. LEXIS 16055, 28-29 (1st Cir. 2003).

116. *See* T.V.R. PILLAY & M.N. KUTTY, AQUACULTURE: PRINCIPLES AND PRACTICES 5 (Blackwell Publishing Limited, 2nd ed. 2005).

117. *See id. See also Aquaculture: An International Journal*, SCIENCEDIRECT, May 12, 2008, http://www.sciencedirect.com/science/journal/00448486 (listing a wide variety of articles on the subject) (last visited May 10, 2008).

118. *See* C. NEAL STEWART, JR., GENETICALLY MODIFIED PLANET: ENVIRONMENTAL IMPACTS OF GENETICALLY ENGINEERED PLANTS 73-75 (Oxford University Press 2004).

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.[119] 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.[120] 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."[121] Although *Shalala* barred this claim against the FDA, further investigation on the environmental impact of GMOs 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.[122] In the context of GMOs, absence of information is akin to the absence of choice.[123] To further the point, there are standards relating to what can be labeled organic whereas there are none relating to GMOs.[124] In 1969 the Congress decided that the public should be made aware of decisions affecting the environment. In 2006, the last time federal standards of labeling or traceability were enacted, it was helping to maintain worldwide ignorance as to the food we eat. If anything is to change, the public must be involved. In 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,

119. *See* United States Environmental Protection Agency, National Environmental Policy Act, http://www.epa.gov/compliance/nepa/index.html (last visited May 10, 2008).

120. *See* Defenders of Wildlife v. Babbitt, 130 F.Supp.2d 121, 136 (D.D.C. 2001).

121. Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 354 (1989).

122. *See* Nathan Young & Ralph Matthews, *Experts' Understanding of the Public: Knowledge Control in a Risk Controversy,* 16(2) PUBLIC UNDERSTANDING OF SCIENCE 123-144 (2007) (discussing Aquaculture).

123. *See* Joseph Henry Vogel, *From the "Tragedy of the Commons" to "The Tragedy of the Commonplace": Analysis and Synthesis through the Lens of Economic Theory, in* BIODIVERSITY AND THE LAW: INTELLECTUAL PROPERTY, BIOTECHNOLOGY & TRADITIONAL KNOWLEDGE 115 (Charles McManis ed., Earthscan Publications Ltd. 2007).

124. In 2002 the USDA created the National Organic Program. *See* HOW TO GO FURTHER: A GUIDE TO SIMPLE ORGANIC LIVING 69 (Frank Condron ed.,Warwick Publishing 2005) (summarizing the requirements to use the "organic" label).

that voluntarily initiated a total recall.[125]

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 suggested that the FDA has recognized a need or desire on the part of the public or specialized industry concerns in the matter.[126] Some companies have already begun advertising their products as "GMO Free." Based on a lack of a definitive ruling on what constitutes a GMO food, coupled with an absence of tracking and labeling requirements, concerns have been raised over how accurate these statements are. This trend is furthering the sentiment that GMO specific legislation will become necessary even if GMOs are deemed to be safe.[127] This is analogous to the growing popularity of organic food.[128] While a minority of U.S. 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 U.S. policy on GMOs. While food and food additives are loosely regulated by The Act relative 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. The "Delaney Clause" can be found under the food additives portion of The Act.[129] The Delaney Clause was interpreted in *Public Citizen v. Young*, 831 F.2d 1198 (D.C. Cir. 1987), 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 product must be removed from the market.[130] While color

125. *See* United States Food and Drug Administration, FDA Consumer, www.cfsan.fda.gov/~dms/fdbioen2.html (last visited May 10, 2008).

126. *See* Food and Drug Administration: Center for Food Safety and Applied Nutrition, Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering (2001), *available at* http://www.cfsan.fda.gov/~dms/biolabgu.html.

127. *See* Patricia Callahan & 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*, WALL STREET JOURNAL, April 5, 2004.

128. *See generally* LESLIE A. DURAM, GOOD GROWING: WHY ORGANIC FARMING WORKS: OUR SUSTAINABLE FUTURE (Bison Books 2005).

129. *See* The Food Quality and Protection Act of 1996, 1627 Pub. L. No. 104-170 (1996).

130. Epidemiological studies are difficult, time consuming and expensive. *See*

additives are "batch traced," GMO's are not traceable as of yet. They are also not subject to labeling requirements, thus enhancing the potential threat to 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, in *FDA v. Brown and Williamson Tobacco Co.*, 539 U.S. 120 (2000), 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."[131] Food, however, is a much clearer topic. Administrative agencies can only act within the realm of their delegated power. Cigarettes are presumed by many to be injurious to health, yet they are one of the few products that Congress has withheld from FDA regulation.[132] GMOs are now afforded this same leeway. The key difference it that, second hand smoke aside, an individual can choose not to smoke. An individual cannot live without food. Congress has the power to compel enhanced regulation of GMOs. This is not to suggest that they should immediately impose a moratorium. The absence of regulation is to the possible detriment of public health and environmental safety both domestically and abroad. That alone should suffice to compel enhanced regulation of GMOs.

3. Ethical/Religious Perspectives

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.[133] 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.[134]

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generally CALUM STEWART MUIR ET AL., HUMAN CANCER: EPIDEMIOLOGY AND ENVIRONMENTAL CAUSES, (Cambridge University Press 1992).

131. FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 130 (2000).

132. *See generally* RICHARD KLUGER, ASHES TO ASHES: AMERICA'S HUNDRED-YEAR CIGARETTE WAR, THE PUBLIC HEALTH, AND THE UNABASHED TRIUMPH OF PHILIP MORRIS (Alfred Knopf, Vintage Books 1997) (1996).

133. 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)." Jeremy Wexlar, Kilayim Pie, http://www.socialaction.com/education_resources/weekly_torah/vayikra_leviticus/kedoshim/kilayim_pie.shtml (last visited May 10, 2008).

134. *See* AgoBioWorld, Playing God or Improving Human Lives? Religious, Moral and Ethical Perspectives on Food Biotechnology, http://www.agbioworld.org/biotech-info/religion/index.html (last visited Apr. 21, 2008) (providing numerous articles

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.[135] While there is no legal authority behind this decision, it indicates the power of the American consumer. If the Catholic Church moved against GMOs, or Jewish and Muslim Americans refused to label foods containing GMOs as Kosher and Halal respectively, would the GMO industry sit by idly? One would think not. Even if GMOs are perfectly safe, people have a right to know what it is they are eating for a variety of other reasons.[136]

4. The EU

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 as to the standards imposed by EC regulations. Furthermore, while the current debate over safety and health casts GMOs in a less than positive light, there remains a corresponding obligation to investigate the use of GMOs for their potentially beneficial purposes. As the EC has legislated beyond the scope of BCD and CP for the purposes of this article, 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 GMOs, 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 dissention among 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

extolling the merits of biotechnology from a religious perspective).

135. *See* Hinduism Today, McDonald's Supersizes Hindu Endowment, http://www.hinduismtoday.com/press_releases/mcdonalds/ (last visited Aug. 2, 2008).

136. *See generally* Benjamin N. Gutman, *Ethical Eating: Applying the Kosher Food Regulatory Regime to Organic Food*, 108 YALE L.J. 2351 (1999).

modifying the genetic identity of any animal likely to cause suffering absent a substantial medical benefit to man or animal.[137] 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.[138] While safety concerns may prevent the current utilization of GMO crops, this directive can be interpreted as encouraging research and development of GMOs.

The arguments surrounding labeling are among the most contentious in the U.S./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 access was not intended to be without limits, dismissing 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.[139] 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 will not likely set a binding precedent, it suggests that the transparency and right 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 member state can still adopt temporary measures if it comes into possession of new information that indicates a product is unsafe.[140] 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

137. *See* Wei, *supra* note 20, at 290-92.

138. *See* Case C-377/98, Kingdom of the Netherlands v. European Parliament, 2001 E.C.R. I-7079.

139. *See* Case C-106/01, The Queen v. Licensing Authority, 2004 E.C.R. I-4403.

140. *See* Commission Regulation 258/97, Concerning Novel Foods and Novel Food Ingredients, 1997 O.J. (L 043) 1, 1-6.

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.[141] 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 NGOs and public interest groups assist policymakers in a positive way, whose interests are they representing? The prevailing view on GMOs 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.[142] The U.S. cannot be condemned for assisting cutting-edge biotech firms if the EC or its member states become subject to the will of propaganda machines. This is not to say that either side is right, it is merely offered to show a distinction.

B. So Who Is Right? The Middle View?

1. 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 middle ground between the U.S. 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.[143]

The New Zealand approach is novel on several levels. It regulates

141. *See* Food Safety Network, http://archives.foodsafetynetwork.ca/agnet/2005/12-2005/Agnet%20Dec.%2021_05.eml.html#story1 (last visited May 10, 2008).

142. *See* Kimball, *supra* note 61, at 146.

143. *See* Ministry for the Environment, How Genetic Modification is Regulated in New Zealand, http://www.mfe.govt.nz/issues/organisms/regulation/gm-regulation.html (last visited May 10, 2008).

GMOs in both food and drugs, making it GMO specific legislation, rather than attempting to adapt old legislation to the issues surrounding GMOs. The HSNO makes accommodations for what is 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 GMOs. Public hearings are required prior to any approval, introduction, and field testing or conditional release of a GMO. ERMA has authorized low-risk experiments in contained laboratories to Institutional Biological Safety Committees (ISBC's), many of which are located at universities. This facilitates research while retaining oversight and mandating certain safety protocols.

New Zealand's Food Safety Authority (NZFSA) administers both safety and 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).[144] 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, thus causing the need for protracted international dispute resolutions.

2. Nigeria

Hunger is a pressing issue in Africa. It is therefore important to recognize the issue from the perspective of at least one African nation's unique GMO policy. While Nigeria is admittedly more developed than other African nations, it recognizes both the need for effective control as well as the potential benefits of GMOs. Accordingly, they have created a regime which utilizes a "diluted precautionary approach." The standard, imposed in Nigeria's 1994 Guidelines on Biosafety, requires 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.[145]

On March 16, 2005, World Consumer Rights Day, the All-Nigerian Consumer Movements Union issued the following statement: "Whereas

144. *See* Welcome to Food Standards Australia New Zealand, http://www.foodstandards.gov.au/ (last visited May 10, 2008).

145. *See* Weiss, *supra* note 99, at 646-47.

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."[146] 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 also 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 U.S. and EU counterparts. In summation, the New Zealand regulations place heightened regulations on GMOs while facilitating research and development and allowing the importation of approved products subject to simple labeling requirements. It also permits the public, including NGOs, 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.

IV. A Proposed Solution & The Future of GMOs

A. Proposed Solutions

The goal of any viable solution should 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; The following are a few suggestions.

1. Creation of GM-Specific Safety Legislation Common to all WTO Parties

It is clear that the EC will not accept GMOs absent proof of safety, labeling, and tracking requirements. Many U.S. 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

146. *Nigerian consumer body rejects GMOs*, ANGOLA PRESS, March 16, 2005, *available at* http://www.gmfoodnews.com/an160305.txt (last visited Apr. 19, 2008).

U.S. market requires a New Drug Application (NDA).[147] To receive FDA approval, the drug must be proven to be "safe and efficacious" after Phase III in vivo (human) trials. Section 801(a)(3)[148] 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)[149] adds that any importation of a drug manufactured in the U.S. 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.[150] For the most part, the U.S. 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 U.S. is far stricter than that of food and proves that we are capable of managing a reliable and effective, scientifically-based risk assessment 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 U.S. 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 U.S. with a valuable incentive to alter its policy.

2. Farm Subsidies

Farm subsidies have been a contentious subject for years. The U.S. government allocated billions of dollars to profitable industrial farms each year.[151] The U.S. should strongly consider withholding subsidies to industrial farms in future legislation. One of the major issues

147. *See* Food and Drug Administration, Drug Approval Application Process, http://www.fda.gov/cder/regulatory/applications/default.htm (last visited Apr. 19, 2008).

148. *See* Federal Food, Drug, and Cosmetic Act, *supra* note 82, at 248-49.

149. *See id.*

150. *See* UNITED STATES DEPARTMENT OF COMMERCE INTERNATIONAL TRADE ADMINISTRATION, PHARMACEUTICAL PRICE CONTROLS IN OECD COUNTRIES IMPLICATIONS FOR U.S. CONSUMERS, PRICING, RESEARCH AND DEVELOPMENT, AND INNOVATION, ix (2004), *available at* http://www.ita.doc.gov/td/chemicals/drugpricingstudy.pdf (indicating that aggregate pharmaceutical prices were eighteen to sixty-seven percent less than U.S. prices, in Organization for Economic Cooperation and Development (OECD) countries).

151. *See* Environmental Working Group, http://www.mulchblog.com/2007/06/full_disclosure_who_really_ben.php (last visited Apr. 19, 2008) (indicating that $34.75 billion was spent from 2003-2005).

surrounding the use of GMOs 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 government.[152] That said, the EC, by not condoning GMO research and development, and the U.S. 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 providing products. Interestingly enough, the WTO has its own rules relating to government subsidies to which the U.S. rigorously adheres.[153]

3. 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, the EC 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 UN 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 UN 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, GMOs 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 or state-specific legislation.[154] 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 GMOs are specific and therefore warrant specific rather than regional agreements.

152. *See* Sustainable Table, http://www.sustainabletable.org/issues/policy/ (last visited Apr. 19, 2008).

153. *See* World Trade Organization, Subsidies and Countervailing Measures, http://www.wto.org/english/tratop_e/scm_e/scm_e.htm (last visited May 10, 2008).

154. *See* Vienna Convention, *supra* note 11, at art. 7, 18, 27.

4. Uniform Labeling Standards Must be Adopted in the U.S. 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 U.S. As previously mentioned, the general sentiment is that GM food is not trustworthy and is not labeled because manufacturers have something to hide. The U.S. justification in 1992 for the preferential treatment afforded to GMOs centered on the need to feed the worlds hungry, most notably in Africa.[155] Since that time, no credible effort has been made to meet that goal.[156] 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 it is serving the interests of large biotech firms. It is also imperative that the U.S. 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 U.S. at a time when distrust, especially in the context of GMOs is rampant in parts of Europe.[157]

5. 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.[158] By means of voting rights, shareholder proposals, and other proactive shareholder activity, perhaps GMO

155. The need to combat world hunger was again mentioned by President George W. Bush in an address to the United Nations General Assembly. *See* President George W. Bush, Address to the United Nations General Assembly (Sept. 25, 2007), *available at* http://www.whitehouse.gov/news/releases/2007/09/20070925-4.html.

156. In August of 2007, CARE, a worldwide charity, declined $45 million in U.S. food aid, citing inefficiencies. Mr. Odo of CARE stated that "agribusiness and shipping interest groups have tremendous political influence" and that domestic policy influences how the United States provides aid, and that "[w]hat's happened to humanitarian organizations over the years is that a lot of us have become contractors on behalf of the government." Celia W. Dugger, *Care Turns Down Federal Funds for Food Aid*, N.Y. TIMES, Aug. 16, 2007.

157. *See* Lisa A. Tracy, *Does a Genetically Modified Rose Still Smell as Sweet? - Labeling of Genetically Modified Organisms Under the Biosafety Protocol*, 6 BUF. ENVT'L. L.J. 129, 168 (1999).

158. *See* Organic Consumers Association, Shareholder Pressure on GE Issue Worries Major Food & Biotech Companies, http://www.organicconsumers.org/corp/geshares.cfm (last visited May 10, 2008).

producers would come to the conclusion that it is in their best business interest to voluntarily conform to EC labeling requirements.[159]

B. The Future of GMO— Conclusion

A stable food supply is necessary for the survival of every living organism on the planet. It follows then that the law of food should transcend both the laws of trade and the law of the environment. GMOs are not going away, nor should they. Under the current state of the law, the major producers of GMOs 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 GMOs, those who suffer from hunger. Unfortunately, it is those people who have the least input in terms of both governmental and economic representation. Until internationally recognized uniform policies regarding GMOs are established to the satisfaction of both sides, the humanitarian objectives 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 these issues, 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.

159. 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). *See 7.3 percent of DuPont shareholders vote in favor of a GMO disclosure resolution*, SEEDQUEST, Apr. 26, 2006, http://www.seedquest.com/News/releases/2006/april/15625.htm (last visited May 10, 2008). "Any Whole Foods Market branded products created with only non-genetically engineered ingredients will be labeled as such so customers can make an informed choice. As organic products must, by law, be created only with non-genetically engineered ingredients, all organic Whole Foods Market branded products will be labeled as not grown from genetically engineered seed." http://www.wholefoodsmarket.com/issues/list_biotech.html