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Genetically Modified Organisms and the Cartagena Protocol

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GENETICALLY MODIFIED ORGANISMS & THE CARTAGENA PROTOCOL

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INTRODUCTION

While many scientific breakthroughs have the potential to improve the quality of life, such breakthroughs are often accompanied by significant risk. For over three decades, scientists, politicians, and concerned citizens have attempted to reconcile the potential benefits and risks of genetic engineering in general, and the genetic manipulation of agriculture in particular. This paper begins by summarizing the main scientific issues and environmental concerns associated with biotechnology.[1] While the science behind biotechnology is highly technical, even a novice can quickly appreciate the lack of consensus on many of the most fundamental issues regarding genetically modified organisms (GMOs). This knowledge enhances understanding of what is at stake and how the people, organizations, and governments, which have accepted the responsibility for regulating GMOs, have dealt with these issues. The paper continues by presenting a detailed analysis of the Cartagena Protocol. It begins with a brief history of the 6-year

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1. Biotechnology refers to "The use of recombinant DNA or other specific molecular gene transfer or exchange techniques to add desirable traits to plants, animals, or other organisms, or to enhance biological processes. Organisms modified by genetic engineering are sometimes referred to as transgenic, bioengineered, or genetically modified." *See* THE U.S. HOUSE COMMITTEE ON AGRICULTURE GLOSSARY at http://agriculture.house.gov/-glossary/genetic_engineering.htm (last visited on June 14, 2000).

negotiation process that, ultimately led to the adoption of the treaty on January 29, 2000. Finally, this paper discusses three critical aspects of the treaty in greater detail.

I. WORLD OF GMOS

Part I of this paper begins with a basic introduction to genetic engineering and biotechnology. In Part II, this paper examines the potential benefits of biotechnology. Conversely, Part III discusses the risks associated with genetic engineering including major risks to human health and our natural environment. Finally, Part IV examines how a new multilateral environmental treaty called the Cartagena Protocol proposes to deal with these issues.

A. *Brief Introduction to Genetically Modified Organisms (GMOs)*

A basic understanding of the science and technology behind GMOs is necessary in order to fully appreciate and intelligently consider the international regulatory framework that will be imposed upon them by the Cartagena Protocol. As U.S. Agricultural Secretary Dan Glickman noted, "[w]e as a society must sort through some very complex issues to make informed decisions about policy, programs and initiatives that are in the best interest of all involved-consumers, farmers, processors, everyone in the food chain."[2] Part I of this paper is designed to introduce the science and technology behind genetic engineering and its application to agriculture. Of particular significance is the importance of genetically modified organisms to the world's food supply. Furthermore, Part I argues that because modern biotechnology differs from traditional cross breeding in several important ways, regulators were justified in establishing an international protocol to regulate the trade of GMOs.

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2. Secretary of Agriculture Dan Glickman, Remarks at the Advisory Committee on Biotechnology Opening Meeting, (Mar. 29, 2000), *at* http://www.usinfo.state.gov/topical/global/biotech/-00032901.htm (last visited Mar. 20, 2001).

1. Biotech Basics

For many years agronomists[3] have sought to improve the quality and yield of crops through selective breeding techniques.[4] These techniques have been used to enhance the desired characteristics of crops on a large-scale basis.[5] However, this process is both time consuming and imprecise (in so far as it is not effective in controlling individual traits).[6] Since the 1970's, agrobiologists have looked to biotechnology and genetic engineering to improve their ability to affect specific traits.[7] More specifically, "[b]iotech procedures allow scientists to move specific genes within an organism or from one organism to another, whether from an organism of the same species or from a different species."[8] The result of this process is a bioengineered or "transgenic" crop referred to as a "Genetically Modified Organism" (GMO) or a "Living Modified Organism" (LMO).[9]

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3. *See* WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 44 (3d ed.1995). (One who studies the science of farm management and the production of field crops).

4. *See generally*, RAOUL A. ROBINSON, RETURN TO RESISTANCE: BREEDING CROPS TO REDUCE PESTICIDE DEPENDENCE 3-18 (1996).

5. *See id.*

6. *Agricultural Biotechnology: Hearings on H.R. Before the Subcomm. on Risk Management, Research and Specialty Crops of the Comm. on Agriculture*, 106th Cong. 295-315 (1999).

7. "The use of recombinant DNA or other specific molecular gene transfer or exchange techniques to add desirable traits to plants, animals, or other organisms, or to enhance biological processes. Organisms modified by genetic engineering are sometimes referred to as transgenic, bioengineered, or genetically modified." *See* THE U.S. HOUSE COMM. ON AGRICULTURE GLOSSARY *available at* http://agriculture.house.gov/ glossary/genetic_engineering.htm (last visited on Feb 8, 2000).

8. *See* Holly Saigo, *Agricultural Biotechnology and the Negotiation of the Biosafety Protocol*, 12 GEO. INT'L ENVT'L. L. REV. 779, 783 (2000).

9. *See id.*

Thus, in the broadest sense, the term GMO is used to identify certain products produced through modern biotechnology.[10] The Cartagena Protocol itself defines LMO as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology."[11] This includes the use of in vitro nucleic acid techniques, including rDNA and "direct injection of nucleic acid into cells or organelles" or "fusion of cells beyond the taxonomic family" used to overcome natural physiological reproductive or recombination barriers.[12]

2. Use of Genetically Engineered Crops

Transgenic crops have been planted commercially in the United States since 1995.[13] Since then, their use has risen dramatically. In 1996, only 8 million acres of genetically engineered crops were grown in the U.S.[14] By 1998, 45 million acres of land were planted with a variety of genetically engineered crops.[15] In 1998, "[o]ver 25 percent of the U.S. corn acreage, 30 percent of soybean acreage and 45 percent of cotton acreage were planted with

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10. U.S. DEP'T OF STATE, FACT SHEET: BIOTECH BASICS (1999) *available at* http://www.state.gov/www/global/oes/fs-biotech_basics_991201.html (last visited Feb. 20, 2001) [hereinafter BIOTECH BASICS].

11. Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Jan. 29, 2000, art. 3(g), *available at* http://www.untreaty.un.org/English/notpubl/27-8a-eng.htm (last visited on July 30, 2000) [hereinafter Cartagena Protocol].

12. *See id* at art. 3(i).

13. *See* Press Release, National Academies, U.S. Regulatory Systems need Adjustment as Volume and Mix of Transgenic Plants Increase in Marketplace (April 5, 2000) *available at* http://usinfo.state.gov/topical/biotech/00040501.htm (last visited on May 12, 2000).

14. U.S. DEP'T OF AGRIC., Economic Research Service, *Impacts of Adopting Genetically Engineered Crops in the United States* (last updated on Dec. 15, 2000) *available at* http://www.ers.usda.gov/Emphases/issues/genengcrops.htm (last visited on Mar. 26, 2001).

15. *See id.*

biotech varieties."[16] The U.S. Department of State estimates that worldwide, almost 69 million acres of biotech crops were planted in 1998.[17] Last year more than 70 million acres of transgenic crops were planted in the U.S. alone.[18] "By 1999 nearly 60 percent of soybean-harvested acres in the U.S. was planted with herbicide-resistant soybeans, while nearly 40 percent of corn-harvested acreage and over 60 percent of cotton-harvested acreage was planted with biotech varieties."[19] While it appears that these numbers may have temporarily peaked,[20] the percentages of genetically engineered crops represent a substantial portion of the U.S. and worldwide food supply.

3. The Need for a New Multinational Environmental Agreement

Unfortunately, there is little consensus within the scientific community with regards to GMOs.[21] Even today, 30 years after the first genes were spliced and 10 years after GMO products first appeared on our supermarket shelves, scientists have yet to reach a

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16. *See* BIOTECH BASICS, *supra* note 10, *available at* http://www.state.gov/www/global/oes/fsbiotech_basics_991201.html

17. *See id.*

18. *See id.*

19. William W. Lin, William Chambers, & Joy Harwood, *Biotechnology: U.S. Grain Handlers Look Ahead,* AGRICULTURAL OUTLOOK, April 2000 *available at* http://usda.mannlib.cornell.edu-/reports/erssor/economics/ao-bb/2000/ao270.asc.

20. A nationwide market survey of GM seed sales conducted by Worldwatch, an environmental watchdog, suggests that global acreage of GM crops could fall as much as 25 percent compared to 1999. *See generally,* Julian Borger, *US farmers' desert GM crops,* THE GUARDIAN, February 17, 2000.

21. *See* ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT (OECD), THE OECD EDINBURGH CONFERENCE ON THE SCIENTIFIC AND HEALTH ASPECTS OF GENETICALLY MODIFIED FOODS, EDINBURGH, SCOTLAND, Feb. 18-Mar. 1 2000: GM Food Safety: Facts, Uncertainties, and Assessment, RAPPORTEUR'S SUMMARY (March 1, 2000) *available at* http://www.oecd.org/-subject/biotech/edinburgh.htm (last visited on Feb 8, 2001) [hereinafter OECD].

consensus on whether genetically engineered crops are fundamentally different from traditional cross-bred or selectively bred crops.[22] The vitality of this debate was reaffirmed at the recent OECD Edinburgh Conference on the Scientific and Health Aspects of Genetically Modified Foods.[23] According to the OECD Rapporteur's Summary, while some scientists see genetic modification merely as an extension of traditional breeding techniques, others see genetic modification as a drastic change in crop production.[24]

If genetic engineering is simply a variety of breeding then we may not be justified in treating genetically engineered foods differently then non-genetically engineered foods. Professor Chua Nam-Hai, Chairman of the Institute of Molecular Agrobiology, believes that genetic modification is simply a way to fast forward convention breeding.[25] Thus, it did not come as a great shock to many scientists when, in 1992 the FDA concluded that genetically engineered foods did not present any novel risks and that as a result, it was not necessary to implement more restrictive regulatory controls over them. More recently, over twenty four hundred prominent scientists, including two Nobel Prize laureates (James Watson and Norman Bourlaug),[26] signed a declaration in support of agricultural biotechnology which states that "[t]he addition of new or different genes into an organism by recombinant DNA techniques

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22. *Id.*

23. The OECD conference drew together 400 participants from 25 countries. John Krebs of Oxford University chaired the conference. *Id.*

24. *See generally, id.*

25. Lea Wee, *Get a vaccine from a banana?,* THE STRAIGHTS TIMES (Singapore), August 29, 1999, 1999 WL 8260913, at *1.

26. *See* Press Release, AgBio World, Noble Prize Winners Endorse Agricultural Biotechnology (Feb 7, 2000) *available at* http://www.agbioworld.com/pr/watson/html (last visited Feb 8, 2001) (Watson, along with colleague Crick, earned a Nobel Prize in Medicine in 1962 for his work in discovering of the structure of DNA; Borlaug was awarded a Nobel Peace Prize in 1970 for his work developing hybrid wheat to increase food production in Third World countries).

does not inherently pose new or heightened risks relative to the modification of organisms by more traditional methods. . . ."[27]

Yet, often time's GMO advocates, including the biotech industry and the U.S. government, downplay or altogether ignore what some consider to be fundamental differences between organic crops and GMOs.[28] According to Dr. Michael Antoniou, a senior lecturer in molecular pathology at Guy's Hospital in the U.K., "[f]rom the standpoint of the fundamental principles of genetics and the limitations in the technology, GE is neither more precise nor a natural extension of traditional cross breeding methods. If anything the opposite would appear to be true."[29] Philip Regal, a professor of ecology at the University of Minnesota-St. Paul, argues that the biotech industry and the U.S. government simply fails to take into consideration several fundamental differences between rDNA[30]

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27. *See* Petition from C.S. Prakash, Prof., Tuskegee University, to Scientific Comm., AgBio World, Scientists In Support of Agricultural Biotechnology *available at* http://www.agbioworld.com/petition/phtml (last visited on Feb 8, 2001) (emphasis added).

28. For instance, in response to a question about the difference between biotech and traditional plant breeding techniques, the U.S. Department of State simply noted the centuries long practice of intermingling genes through crossbreeding and then segued into biotech's ability to add speed and predictability to this process, thereby reinforcing the notion that biotech only differs from cross-breeding in its effectiveness. *See generally,* BIOTECH BASICS, *supra* note 9, at. http://www.state.gov/www/global/oes/fs-biotech_basics_991201.html.

29. Dr. Michael Antoniou, GENETIC ENGINEERING AND TRADITIONAL BREEDING METHODS: A TECHNICAL PROSPECTIVE (1995).

30. rDNA refers to recombinant deoxyribonucleic acid. Recombinant DNA techniques create DNA formed by combining segments of DNA from different organisms. *See generally,* Economic Research Service, U.S. DEP'T OF AGRIC., *Genetically Engineered Crops: Agricultural Biotechnical Concepts and Definitions available at* http://ers.usda.gov/Emphases/Harmony/issues/genencrops/terms.htm (last visited on Mar. 8, 2000).

techniques and conventional breeding.[31] For instance, using rDNA techniques can form radically new combinations of competitive features by "leap-frogging" adaptive traits over "vast phylogenetic distances."[32] Additionally, only with rDNA can exchange-based trade-offs associated with the exchange of alleles (variants of genes) be circumvented.[33] Furthermore, unlike traditional breeding practices, rDNA has the potential to "reprogram the large fraction of genomes that are functionally homozygous."[34] And finally, a host organism's failure to recognize transgenes can result in unusual genetic side effects.[35] While Professor Regal insists that experts in the field no longer use these "generic safety" arguments, they are still circulated by non-technical scientists and used by biotech public relations persons.[36]

The FDA has taken the position that GMOs are similar to traditionally cross bred crops, and as a result, do not need to be labeled or otherwise subject to stricter regulation.[37] Recently, U.S. public interest attorney Steven Drunker revealed that, as early as March 18, 1992, scientists at the FDA recognized major differences between genetic engineering and traditional crop breeding.[38] For instance, FDA microbiologist Dr. Louis Pribyl concluded that, "[t]here is a profound difference between the types of unexpected

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31. *See* Philip Regal, *A Brief History of Biotechnology Risk Debates and Policies in the United States, in* EDMONDS INSTITUTE OCCASIONAL PAPER *available at* http://www.edmonds-institute.org/regal.html (last visited on Feb. 20, 2001) [hereinafter Regal].

32. *Id.*

33. *See id.*

34. *Id.*

35. *See id.*

36. *See* Regal, *supra* note 30.

37. *See* Kristi Coale, *Mutant Food* (last visited on April 24, 2001) http://www.salon.com/news/feature/2000/01/12/food/index.-html.

38. *See* Press Release, Soil Association, US Public Interest Attorney Uncovers Suppressed Evidence of Potential GM Food Health Risks (Feb. 28, 2000) *available at* http://www.soilassociation.org/SA/SaWebDoc.nsf/($All)!)OpenView (last visited on Apr. 5, 2001).

effects from traditional breeding and genetic engineering."[39] Additionally, according to the Soil Association, in January of 1992, "[t]he head of the Biological and Organic Chemistry Section chided agency bureaucrats for turning prior policy 'on its head' in attempting to equate bioengineered foods with their conventional counterparts."[40] These opinions raise important questions about the credibility of the FDAs long standing position on GMOs.

The views of these scientists are meant to illustrate both the highly technical nature of the GMO debate and the intellectual vulnerability of non-experts attempting to regulate GMOs on an international basis. As U.S. Secretary of Agriculture Dan Glickman recently noted in a speech given at the 1st Meeting of the Standing Committee on Biotechnology Food and Fiber Production and the Environment at the National Academy of Sciences, "[i]t's clear from the intense public debate we've all seen over the last year or two, that there is no consensus on biotechnology."[41] While the verdict is still out on whether genetically engineered crops are fundamentally different from those harvested from traditional cross breeding techniques, it appears that a vocal minority of scientists have successfully raised enough credible evidence to justify a separate regulatory device to control the flow of GMO products in international trade.

II. THE BENEFITS OF GMOs

For years, scientists, governments, and private industry have touted the enormous benefits of GMOs. Such benefits include the potential to reduce pesticide and herbicide use, to reduce pressures on rain forests, to improve both the quantity and quality of the global food supply by reducing hunger and improving nutritional content, to distribute vaccines, to enhance agricultural productivity, and to

39. *Id.*

40. *Id.*

41. Secretary of Agriculture Dan Glickman, Remarks at the Agricultural Biotechnology Initiative, (May 4, 2000), *available at* http://usinfo.state.gov/topical/global/biotech/00050401.htm (last visited on Feb 12, 2001).

reduce prices for consumers.[42] However, as British Prime Minister Tony Blair recently emphasized, "[t]he key word here is *potential*, both in terms of harm and benefit. The potential for good highlights why we are right not to slam the door on GM food or crops without further research. The potential for harm shows why we are right to proceed very cautiously indeed."[43] This section will attempt to discuss some of the potential and proven benefits of GMOs. An understanding of these benefits is necessary to appreciate the positions taken by several of the negotiating groups, in particular the Miami group, at the First Extraordinary Meeting of the Conference of the Parties to the Convention on Biological Diversity and later at the Resumed Session for the Adoption of the Protocol on Biosafety. This part of the paper begins by examining the effects that biotechnology can have on environmental conservation. The paper continues by emphasizing the amazing degree to which scientists can enhance the nutritional quality of particular crops. Finally, this part of the paper deals with the delicate matter of feeding the worlds ever-growing population.

1. Environmental Conservation

GMO advocates argue that advances in modern biotechnology can be used to slow environmental degradation and foster sustainable development. The biggest improvement may come from a decrease in the need for pesticides and herbicides to control pests and weeds.[44] According to the National Academy of Sciences,

> [t]he attraction of herbicide-tolerant crops for farmers is that it lets them control weeds more efficiently and cheaply. Freed to use a single, effective spray without

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42. *See* Regal, *supra* note 30, *available at* http://www.edmonds-institute.org/regal.html.

43. *Tony Blair, The key to GM is its potential, both for harm and good, available* at http:///www.independent.co.uk/news/-UK/2000-02/blair270200.shtml (Feb. 27, 2000) (last visited on Feb. 8, 2001) (emphasis added).

44. *See* Eric S. Grace, BIOTECHNOLOGY UNZIPPED, PROMISES AND REALITIES 105-121 (1997). [hereinafter Grace].

> harming their crops, they need fewer application of herbicide. This saves time in the fields, lowers the costs of fuel and chemicals, and reduces the farmers' exposure to herbicides. In addition, less herbicide use means less environmental damage.[45]

Additionally, since the 1980's farmers have been using *Bacillus thuringiensis* (Bt), a bacterium that, when ingested by insects, germinates and produces toxins eventually killing the insects in their own life cycle.[46] Scientists have discovered the genetic code for over 50 Bt insecticides and the chemical is used against gypsy moth caterpillars, tobacco hornworms, Colorado potato beetles and cotton bollworms.[47] According to the National Agricultural Statistics Service, "two million fewer pounds of insecticide were used in 1998 to control bollworm and budworm than were used in 1995, before Bt insect protected cotton was introduced."[48] Similarly, scientists are working on ways to modify genes to boost bacterial efficiency, thereby decreasing the need for fertilizers.[49]

Additionally, "[b]iotechnology could provide enhanced resistance to natural climactic variation and lessen reliance on water source management. Plants could be made to withstand, for instance, a drop in temperature and frost by modifying their production of linoleic acid."[50] Canadian researchers "estimate that grape production in southern Ontario could double by developing grape varieties able to withstand freezing temperatures 2°C lower than the minimum endured by current vines."[51] Scientists are also working on new strains of crops that can thrive in marginal lands

45. *Id.* at 107.

46. *See id.* at 116.

47. *See id.* at 117.

48. *See Environmental Safety: Regulations and Benefits available at* http://www.whybiotech.com/9_2_c.html (last visited on May 15, 2000).

49. *See id.*

50. *See* BIOTECH BASICS, *supra* note 9, *available at* http://www.state.gov/www/global/oes/fsbiotech_basics_991201.html (last visited Feb. 20, 2001).

51. *See* Grace, *supra* note 43, at 122.

currently fallow due to iron, salt, or acid content.[52] These developments could decrease pressure on other natural resources such as tropical rainforests. Finally, biotechnology could reduce the need for tillage, "which causes both soil and water runoff and soil nutrient depletion" by increasing the lands ability to support continuous farming.[53]

2. Increasing Nutritional Content

Genetic engineering represents an incredible opportunity to alter the nutritional quality of plants.[54] One of the best examples comes from a study performed by Ingo Potrykus and published recently in the prestigious journal *Science*. According to demagogic studies, "one-quarter of the world's people are dependent on rice as a primary staple. Of those, 400 million are deficient in vitamin A."[55] The U.N. estimates that over 2 million children die each year from severe vitamin A deficiency.[56] Using genetic engineering, Ingo Potrykus has been able to create a variety of rice called "golden rice"

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52. *Id.* at 123; *see also See* BIOTECH BASICS, *supra* note 9, *available at* http://www.state.gov/www/global/oes/fs-biotech_basics_991201.html (last visited Feb. 20, 2001).

53. *See* BIOTECH BASICS, *supra* note 9, *available at* http://www.state.gov/www/global/oes/fsbiotech_basics_991201.html (last visited Feb. 20, 2001).

54. *See Genetically Modified Crops Benefit Agricultural Sector, Public, Sen. Lugar Says*, DAILY ENVIRONMENT, Jan. 25, 2000, at A-8. ISSN 1521-9402.

55. Chris Sumerville, *The Genetic Engineering of Plants*, in BIOTECHNOLOGY: THE SCIENCE AND THE IMPACT, at 12, (Conference held on Jan. 2000), *available at* http://www.usemb.nl/ bioproc; *see also* U.S. Ambassador Schneider, Remarks on Biotechnology and Europe: Promise and Paradox (Mar. 22, 2000), *available at* http://usinfo.state.gov/ topical/ global/biotech/00040301.htm (last visited on Feb. 8, 2001).

56. *See* Guy Gugliotta, *Gene-Altered Rice May Help Fight Vitamin A Deficiency Globally*, WASH. POST, January 14, 2000, at A7 [hereinafter Gugliotta]; People who suffer from vitamin A deficiency may suffer sever vision impairment, including blindness, and are more susceptible to other diseases. *See id.* at A6.

that will provide the necessary Beta Carotene to meet the people's daily requirements. The new "golden rice" contains three transplanted genes that allow plants to produce rice kernels carrying beta-carotene, a compound that is converted to vitamin-A within the human body.[57] Plans are already under way to distribute this new variety of rice to subsistence farmers within 3 years and at no cost.[58]

According to GMO proponents, "golden rice" is just the tip of the iceberg. The U.S. Department of State reports that crops can be modified to reduce saturated fat content in cooking oils (particularly those made form corn, soybean, and canola), and that potatoes are being modified to absorb less fat when frying.[59] "Nutriceuticals are being developed, including fruits and vegetables containing higher levels of certain nutrients such as Vitamins C and E, and beta-carotene, to help reduce the risk of chronic diseases such as some cancers and heart disease. Rice is being produced with an improved protein to include higher levels of the essential amino acid, lysine." [60] In Singapore, reports have circulated that scientists are modifying soybeans to contain more genistein, a compound that has anti-cancer effects.[61] Amazingly enough the lab that brought us golden rice is also working on another strain of rice with increased iron content.[62] While many of the advances in nutritional content are still in the research phase, the potential to improve the lives of billions of people through modern biotechnology is truly awesome.

3. Increasing Worldwide Food Supply

The human population on the Earth is growing at an astonishing rate. At the start of the last century, the Earth's

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57. *Id.*

58. *See id.*

59. *See* BIOTECH BASICS, *supra* note 9, *available at* http://www.state.gov/www/global/oes/fsbiotech_basics_991201.html (last visited Feb. 20, 2001).

60. *See id.*

61. *See* Lea Wee, *supra* note 24, at *1.

62. Iron deficiency-anemia is the world's worst nutritional disorder, affecting over 2 billion people worldwide. *See* Gugliotta, *supra* note 54, at A6.

population was a mere 1.65 billion.[63] Today, the population is estimated at over 6 billion.[64] At this rate, we can expect to add roughly 800 million new mouths to feed every ten years.[65] Some researchers estimate that the world population may reach 8 billion by 2025.[66] For example, the population in Sub-Sahara is expected to double by 2025, while "nothing in the regions agricultural history suggests it will increase food output to meet the demographically driven expansion of demand."[67]

The prospect of feeding an ever-growing population is often portrayed as an impossible task.[68] "Today roughly half the world's crop land is devoted to growing cereals. If we combine their direct intake (e.g. as cooked rice or bread) with their indirect consumption (about 40% of all grain is currently fed to livestock) then cereals account for approximately two-thirds of all human calorie intake."[69] World population growth has outpaced cereal production every year since 1984.[70] "Between 1950 and 1984, world grain output rose an astonishing 260 percent . . . ."[71] While we are responsible to feed approximately 90 million new mouths every year, "land degradation,

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63. *See* UNITED NATION, *The World at Six Billion*, Tbl.1 (World Population, year 0 to near stabilization) (ESW/P/WP.154), Oct. 12, 1999.

64. *See id.*

65. Tim Dyson, *World Food Trends and Prospects to 2025*, 96 PROC. NAT'L ACAD. SCI. 5929, 5932 (1999) [hereinafter Dyson].

66. *See id.* at 5933-34. *See also* BIOTECH BASICS, *supra* note 9, *available at* http://www.state. gov/www/global/oes/fs-biotech_basics_991201.html (stating he U.S. State Department estimates the world's population may reach 10 billion by 2030).

67. *See* Dyson , *supra* note 66, at 5934.

68. *See generally*, David Brower, *Forward* to PAUL EHRLICH, THE POPULATION BOMB, at xiii (1975).

69. *See* Dyson, *supra* note 66, at 5929.

70. *Id.* This may be a cause for some alarm considering that cereal production outpaced population growth almost every year from 1951-1984. *See id.* *See also* David Hoisington et al., *Plant Genetic Resources: What can they contribute towards increased crop productivity?*, 96 PROC. NAT'L ACAD. SCI. 5937, 5937 (May 1999) [hereinafter Hoisington].

71. *See* Grace, *supra* note 45, at 110

pest resistance, pollution, and climate change have slowed or leveled growth in crop production."[72]

While the results of the Green Revolution[73] were spectacular, the stark reality is that biotechnology *may* be the only way to increase crop yields to meet the world's ever growing population.[74] Due, in a large part, adoption of high yielding rice and wheat production technology, Asian cereal production has increased more than three times during the period between 1961 and 1998.[75] Nobel Laureate and father of the Green Revolution, Norman E. Borlaug, believes that from here on in "[i]t is access to new technology that will be the salvation of the poor . . . ."[76] "Production in Asia, where more than 90 percent of the world's rice is consumed grew by 116 percent between 1966 and 1997"[77] "Between 1950 and 1984, world grain output rose an astonishing 260 percent."[78]

Despite these advances, the U.S. Department of State estimates that biotechnology will "increase crop yields by 20% for smallholder farmers profitably without degrading natural resources."[79] According to Borlaug, the "IRRI remains optimistic that it will be successful in developing new 'super rice,' with fewer—but highly-productive—tillers. While still probably 10 years away from widespread impact on farmers' fields, IRRI claims that this new plant type, in association with direct seeding, could increase rice yield potential by 20-25 percent."[80]

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72. *Id.* at 110.

73. A movement to breed new, high yield stains of basic grains for individual habitats in developing worlds.

74. *See* Grace, *supra* note 45, at 110.

75. Norman E. Borlaug and Christopher Dowswell, *Global Food Security: Harnessing Science in the 21st Century* (March 7, 2000) *available at* http://www.useu.be/ISSUES/borlaug0807.html (last visited on Feb. 20, 2001).

76. *See id.*

77. See Gugliotta, *supra* note 57, at A-7.

78. *See* Grace, *supra* note 45, at 110.

79. *See* BIOTECH BASICS, *supra* note 9, *available at* http://www.state.gov/www/global/oes/fsbiotech_basics_991201.html (last visited Feb. 20, 2001).

80. *See* Borlaug, *supra* note 73, *available at* http://www.useu.be/ISSUES/borlaug0807.html.

III. THE RISKS OF GMOS

While the potential benefits of biotechnology appear staggering, a vocal minority of scientists,[81] consumer advocates,[82] and environmental groups[83] has raised serious questions concerning the potential risks associated with genetic engineering.[84] However, recent reports from the OECD Conference and the National Academy of Sciences suggest that more long-term studies must be conducted before we can be certain about the risks GMOs present to the natural environment.[85] The Cartagena Protocol reflects this concern in its adoption of the Precautionary Approach, which allows States to deny the importation of GMOs without conclusive scientific evidence that such products are actually harmful to humans or the environment.[86] This portion of the paper focuses on potential harms to human health and examines possible threats to biodiversity.

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81. *See e.g.* World Scientists' Statement, Institute of Science in Society, *Open Letter from World Scientists to All Governments concerning Genetically Modified Organisms (GMOs)* (Jan. 9, 2000) *available at* http://www.i-sis.org/list.shtml (last visited on Feb. 8, 2001) (calling for immediate suspension of a environmental releases of GM crops-signed by 386 scientists from 51 countries) [hereinafter World Scientists'].

82. *See, e.g.,* BioDemocracy and Organic Consumers Association *available at* http://www.purefood.org./ (last visited on Feb. 8, 2001).

83. *See, e.g.,* GREENPEACE *available at* http://www.-greenpeace.org/~geneng/ (last visited on Feb. 8, 2000).

84. *See, e.g.,* World Scientist, *supra* note 79, *available at* http://www.isis.org/lists.html.

85. *See* OECD, *supra* note 20, *available at* http://www.-oecd.org/subject/biotech/edinburgh.htm.

86. *See* United Nations, *Cartagena Protocol on Biosafety to the Convention on Biological Diversity* (2000), art. 10(6)-11(8), http://untreaty.un.org?English?notpubl/27-8a-eng.htm (supporting that the precautionary principle is used) [hereinafter Cartagena].

1. Harm to Human Health

While the Cartagena Protocol does not specifically cover threats to human health, a brief summary of these threats is necessary to fully appreciate the current policy debate. Potential threats to human health cover a wide range of topics including human allergens, antibiotic resistance, and the production of new toxins.[87] Many consumers fear that genetically engineered crops will introduce new food allergens that people would not know to avoid.[88] "A study by scientists at the University of Nebraska shows that soybeans genetically engineered to contain Brazil-nut proteins cause reaction in individuals allergic to Brazil nuts."[89] According to that study, "[a]n allergen from a food known to be allergenic can be transferred into another food by genetic engineering."[90] In the New England Journal of Medicine, Marion Nestle, Ph.D, M.P.H. at New York University argued that

> [m]ore information about incidence, prevalence, dietary exposure, antigeniticity, immune responses, diagnosis, and treatment would help researchers, regulators and biotechnology companies predict whether transgenic proteins are likely to cause harm. In the special case of transgenic soybeans, the donor

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87. U.S. STATE DEPARTMENT, FACT SHEET: THE CARTAGENA PROTOCOL BIOSAFETY (2000), *available at* http://www.state.gov/www/global/ors/fscart_prot_biosaf_000216.html (last visited on Mar. 1, 2000) [hereinafter CARTAGENA FACT SHEET].

88. UNION OF CONCERNED SCIENTISTS: FACT SHEET: RISKS OF GENETIC ENGINEERING (2000) *available at* http://www.ucsusa.org/agriculture/gen.risks.html (last visited on Mar. 6, 2001). [hereinafter RISKS OF GENETIC ENGINEERING 2].

89. *Id.*

90. Julie A. Nordlee et al., Abstract, *Identification of a Brazilian-Nut Allergen in Transgenic Soybeans, Article Abstract*, 334 NEW ENG. J. MED. 688, 688 (1996) *available at* http://www.nejm.org/content/1996/0334/0011/0688.asp (last visited on Feb 12, 2001).

> species was known to be allergenic. . .[t]he next case could be less ideal, and the public less fortunate.[91]

However, a new report transmitted to the Committee on Science for the 106th Congress found that risks of introducing new allergens into the food supply are the same for both biotech and traditionally breeding varieties.[92] Thus, while scientists remain uncertain about the affects of genetic engineering on the spread of allergens, it appears that some consumers (particularly those with known allergies) may have a legitimate cause for concern.

According to The Union of Concerned Scientists, "genetic engineering often uses genes for antibiotic resistance as 'selective markers.'"[93] While most of these genes have no additional use, some are still expressed in plant tissues.[94] The presence of antibiotic resistance genes poses two potential risks to human health. First, eating foods with such genes could "reduce the effectiveness of antibiotics to fight disease when these antibiotics are taken with meals."[95] For instance if a tomato containing antibiotic resistance genes was eaten at the same time as an antibiotic, it could potentially destroy the antibiotic in the stomach.[96] Second, antibiotic-resistance genes could be transferred to human or animal pathogens, thereby making them impervious to antibiotics.[97] While transference of genetic materials from plants to bacteria is extremely unlikely, the mere possibility may raise some cause for concern. The report to the

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91. Marion Nestle, *Allergies to Transgenic Foods—Questions of Policy*, 334 N. ENGL. J. MED. 726, 727 (1996).

92. CHAIRMAN NICK SMITH ON THE SUBCOMMITTEE ON BASIC RESEARCH, 106TH CONG., SEEDS OF OPPORTUNITY: AN ASSESSMENT OF THE BENEFITS, SAFETY, AND OVERSIGHT OF PLANT GENOMICS AND AGRICULTURAL BIOTECHNOLOGY 106-B, Appendix 1, page 79 (Comm. Print 2000) [hereinafter CHAIRMAN NICK SMITH].

93. NION OF CONCERNED SCIENTISTS: FACT SHEET: RISKS OF GENETIC ENGINEERING (2000) *available at* http://www.ucsusa.org/agriculture/gen.risks.html (last visited on Feb. 8, 2001) [hereinafter RISKS OF GENETIC ENGINEERING 1].

94. *See id.*

95. *Id.*

96. *See id.*

97. *See id.*

Committee on Science concluded that "[t]he risk that a health hazard will be created through the use of antibiotic resistance markers in the development of new plant varieties using agricultural biotechnology is insignificant."[98]

Other potential threats to human health include increasing toxicity within plants resulting from the reactivation of inactive pathways, contamination of food with high levels of toxic metals, such as mercury, from soil fertilized with municipal sludge, and an increase in fungal toxins, such as aflatoxin, resulting from the removal of genes necessary to protect plants against fungi.[99]

2. Harm to the Environment

One major ecological risk associated with transgenic crops is the flow of genes to non-target species through outcropping or cross-pollination. While outcropping occurs naturally, new evidence suggests that genes from transgenic plants may be as much as 20 times more likely to infect relative species than their natural counterparts.[100] According to Joy Bergelson, assistant professor of ecology and evolution at the University of Chicago, "genetic engineering can substantially increase the incidence of outcropping in selfing species."[101] One possibility is that the new traits might confer on wild or weedy relatives of crop plants the ability to thrive in unwanted places.[102] Similarly, evidence suggests that gene flow can occur from plant to plant, from plant to bacteria, and from plant

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98. *See* CHAIRMAN NICK SMITH, *supra* note 90, at 79.

99. *See id.* at 79-80

100. *See* J Bergelson et al., *Promiscuity in Transgenic Plants*, 395 NATURE 25, 25 (1998).

101. *See* UNIVERSITY OF CHICAGO MEDICAL CENTER, *Promiscuous Plants May Spread Genes to Weeds available at* http://www.sciencedaily.com/releases/1998/09/980903090806.htm (last visited on Mar. 6, 2001).

102. *See generally, id.*

to virus,[103] with the most significant threat coming from the flow of herbicide-tolerant genes from a plant to a close relative.[104]

"Recent reports indicate that the use of herbicide resistant products represents more than 50 percent of the GE crops today."[105] Some scientists and environmentalists are concerned that "[p]lants engineered to be herbicide resistant could become so evasive they are a weed problem themselves, or they could spread themselves to wild weeds making them more evasive."[106] These super-weeds have the potential of creating an imbalance in natural ecosystems resulting in the displacement of both native flora and fauna.[107] In 1998, scientists at Iowa State University reported that "velvetleaf, smartweed, and waterhemp species of weeds had developed tolerance or resistance to glyphosate (Roundup)."[108] Additionally,

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103. *See generally,* Thomas R. Mikkelsen et al., *The Risk of Transgene Spread,* 380 NATURE 31, 31 (1996).

104. *See, e.g.,* Rikke Jorgensen and Bente Anderson, *Spontaneous Hybridization Between Oilseed Rape (Brassica Napus) and Weedy B. campestris (Brassicaceae): A Risk of Growing Genetically Engineered Modified Oilseed Rape,* 81 AMER. J. BOTANY 1620, 1620-26 (1995).

105. PHYSICIANS AND SCIENTISTS FOR RESPONSIBLE APPLICATION OF SCIENCE AND TECHNOLOGY (PSRAST), *Traits Introduced in food by Genetic Engineering available at* http://www.psrast. org/geprodct.htm, at *1-2 (last visited on April 1, 2000). According to the Union of Concerned Scientists, "[i]n 1998 herbicide-resistant crops were planted on nearly 50 million acres, about 71 percent of the total while Bt insect resistant crops were planted on 19 million acres or 28 percent." *See* UNION OF CONCERNED SCIENTISTS, *A Surge in Commercial Transgenic Crops,* THE GENE EXCHANGE (1998) *available at* http://www.ucsusa.org/Gene/w98.world.html (last visited on Feb 8, 2001)

106. *See* GREENPEACE, *The End of the World as We Know It: The Environmental Costs of Genetic Engineering available at* http://www.greenpeace.org/~commss/cbio/brief2.html (last visited on Mar. 30, 2001).

107. *See id.*

108. *See* WORLD WILDLIFE FUND, *Do Genetically-Engineered (GE) crops reduce pesticides? The Emerging Evidence*

genetically engineered crops "will increase the resistance of pests to both pesticides and the novel gene in the crop itself, requiring additional, and potentially more toxic, sprays than the ones the technology is supposed to help reduce." [109]

Environmentalists fear that farmers will respond to super-weeds and super-pests by increasing their applications of pesticides and herbicides "which will lead to even greater resistance pressures or use of other, more toxic, herbicides."[110] Additionally, pest resistance to Bt due to the proliferation of Bt crops will eventually render the Bt spray useless. This in unfortunate considering that when used in moderation, Bt is relatively benign. The World Wildlife Fund ("WWF") predicts that "[e]ven with an effective refugia and high-dose Bt expression strategy, Bt crops may only be effective for 10 years maximum. If the refugia strategy fails, which

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says "Not Likely" available at http://www.global-reality.com/biotech/ ARTICLES/news132.htm, at *6 [hereinafter WORLD WILDLIFE FUND]; *see also* Bob Hartzeler, *Are Roundup Ready Weeds in Your Future*, IOWA STATE WEED SCI. REP. (1998) *available at* http://www.weeds.iastate.edu/mgmt/qtr98-4/roundupfuture.htm, at *1 (last visited on Mar 19, 2001).

109. *See* WORLD WILDLIFE FUND, supra note 106, *at* *6.

110. *Id.* The United States Department of Agriculture that indicated that "In 1997, increases in adoption of herbicide-tolerant cotton are estimated to have increased yields, leading to increased variable profits. However, no statistically significant change on herbicide use on cotton was observed in 1997." U.S. DEP'T OF AGRICULTURE, *Impacts of Adopting Genetically Engineered Crops in the U.S. available at* http://www.ers.usda.gov/emphases/harmony/issues/genengcrops/genengcrops.htm at *2. Independent research conducted by Dr. Charles Benbrook shows that based on soybean varietal trials, farmers use two to five times more herbicides than those planting conventional soybean varieties, and 10 times more herbicides than farmers who practice Integrated Weed Management. *See* Charles Benbrook, *Evidence of the Magnitude and Consequences of the Roundup Ready yield drag from University-based Varietal Trials in 1998*, AgBiotech InfoNet Technical Paper #1, at 2 (July 13, 1999).

is likely, the efficacy of Bt sprays could be lost in as little as five years."[111]

Finally, both environmentalists and scientists alike have expressed concern that transgenic crops may threaten beneficial insects resulting in an increase in the use of herbicides and an overall loss of biodiversity.[112] "Such beneficial insects include the lacewings and ladybird beetle."[113] Scientists from the Swiss Federal Research Station for Agroecology and Agriculture found that the mortality rate of lacewig larvae increased significantly after eating Bt-toxin similar to that found in GE corn produced by Novartis.[114] Researchers also revealed that "[m]ore than 60% of lacewings fed Bt-corn-reared-corn borers died compared to fewer than 40% of the control group."[115] Scientists at the Scottish Crop Research Institute found that "ladybird beetles (called ladybugs in the United States) fed aphids reared on transgenic potatoes experienced reproductive problems and failed to live as long as ladybirds fed on aphids from ordinary potatoes (the control group)."[116] Finally, last year researchers in the United States showed that monarch butterfly larvae are at risk of increased mortality from feeding off the pollen of Bt maize.[117] "The study published in *Nature* [the Losey Letter] found that exposure to pollen from transgenic corn plants expressing *Bacillus thuringiesis* endotoxin from a Bt-11 hybrid (N4640-Bt corn)

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111. *See* WORLD WILDLIFE FUND, *supra* note 106, at *5.

112. *See* PHYSICIANS AND SCIENTISTS FOR RESPONSIBLE APPLICATION OF SCIENCE AND TECHNOLOGY (PSRAST), *Genetically Engineered Crops May Threaten Beneficial Insects* (1998) *available at* http://www.prast.org/ (last visited on Mar. 8, 2001).

113. *Id.*

114. *See id.*

115. *Id.*

116. *Id.; see also* UNION OF CONCERNED SCIENTIST, *Risk Research: Transgenic Insect-Resistant Crops Harm Beneficial Insects* (1998) *available at* http://www.ucsusa.org/Gene/su.risk.html (last visited on Feb. 20, 2001) *(citing* A. Hilbeck et. al., *Effects of Trangenic Bacillus thuringiesis Corn-Fed Prey on Martality and Development Time of Immature Chrysoperla carnea (Neuroptera: Chrysopidae)*, ENVT'N ENTOMOLOGY 27 at 480-87 (1998).

117. *See* J.E. Losey, *Transgenic Pollen Harms Monarch Larvae*, 339 NATURE 214, 214 (1999).

resulted in increased mortality and delayed development compared with ingestion of non-Bt pollen"[118] However, Nick Smith, Chairman of the Subcommittee on Basic Research for the second session of the 106th Congress of the United States found that "[t]he threat posed by pest –resistant crop varieties developed using agricultural biotechnology to the Monarch butterfly and other non-target species has been vastly overblown and is probably insignificant."[119] The findings were buttressed by the fact that the Losey letter[120] was simply a preliminary study that "offered little new information and was likely to have little relevance to wild Monarch populations in the field."[121] Thus, while many environmentalist groups may have exaggerated the potential risks associated with agricultural biotechnology, more long-term studies should be done to establish with greater certainty what effects this new technology actually has on non-target and beneficial species.

IV. THE CARTAGENA PROTOCOL ON BIOSAFETY TO THE CONVENTION ON BIOLOGICAL DIVERSITY

A. *The Negotiation of the Cartagena Protocol*

1. The 1992 UN Convention on Biological Diversity

"The Convention on Biological Diversity (CBD), negotiated under the auspices of the United Nations Environment Programme (UNEP), was adopted on 22 May 1992 and entered into force on 29

118. CANADIAN FOOD INSPECTION AGENCY, *Preliminary Report on the Ecological Impact of BT Corn Pollen on the Monarch Butterfly in Ontario* (2000) *available at* http://www.cfia-acia.agr.ca/english/plaveg/pbo/btmone.shtml (last visited on Feb. 20, 2001).

119. *See* CHAIRMAN NICK SMITH, *supra* note 90, at 79.

120. T he study was rejected for publication as a research article in both *Nature* and *Science* before being published in the letters section of *Nature*. *See id.* at 44.

121. *Id.* at 45.

December 1993."[122] As of January 31, 2000, there were 176 parties to the convention.[123]

The CBD recognizes that genetically engineered organisms, referred to as LMOs may have adverse effects on the sustainability and conservation of natural resources.[124] Article 19 (3) of the CBD mandates:

> [t]he parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advanced informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.[125]

At the 2nd Conference of the Parties to the Convention on Biological Diversity, the participating governments decided that a negotiating process should begin in order to develop a Biosafety Protocol.[126] Between July 1996 and February 1999, experts met on six different occasions to in-order to prepare the protocol text to be adopted by the Parties to the CBD.[127] In August of 1998, the experts decided that an Extraordinary Conference of the Parties would be held to

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122. INTERNATIONAL INSTITUTE FOR SUSTAINABLE DEVELOPMENT (IISD), *A Brief History of the Biosafety Protocol,* 9 EARTH NEGOTIATIONS BULLETIN 1, 1 (2000).

123. *See id.*

124. *See generally,* Convention of Biological Diversity, June 5, 1992 [hereinafter Convention of Biological Diversity] .

125. *Id.* at art.19 (3).

126. UNITED NATIONS ENVIRONMENTAL PROGRAMME (UNEP), REPORT OF THE SECOND MEETING OF THE CONFERENCE OF PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY, Rules 3 & 4, UN Doc No. UNEP/CBD/COP/2/19 (1995).

127. *See* GREENPEACE, *The Negotiation of the Biosafety Protocol available at* http://www.greenpeace.org/~geneng/reports/bio/intrbio2.htm (last visited on Feb. 12, 2001).

adopt the Protocol.[128] At that meeting the representative from Columbia extended an invitation to host the Sixth Meeting of the Open-ended Ad Hoc Working Group on Biosafety and the Extraordinary session of the Conference of the Parties to adopt the Protocol in Columbia in February of 1999.[129]

2. The Extraordinary Conference of the Parties (ExCOP)

The sixth meeting was supposed to have concluded on February 19, 1999 with the final protocol to be voted for adoption by the Parties to the convention three days later.[130] Despite the best efforts of Mr. Veit Koester,[131] Juan Mayr Maldonado,[132] and over 600 participating representatives from 138 governments, the Parties could not reach a consensus on a number of important issues.[133] Areas of contention included trade issues, treatment of commodities and World Trade Order agreements.[134] Articles 4 and 5 of the Draft Protocol were particularly contentious. Article 4 was intended to deal with the scope of the protocol, while Article 5 dealt with the application of the advanced informed agreement (AIA) procedure.[135]

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128. *See* UNITED NATIONS ENVIRONMENTAL PROGRAMME (UNEP), REPORT OF THE FIFTH MEETING OF THE AD HOC OPEN-ENDED GROUP OF EXPERTS ON BIOSAFETY, Decision II/5, U.N.Doc.UNEP/CBD/BSWG/5/3 (1998).

129. *Id.* at 2.

130. *See generally,* UNITED NATIONS ENVIRONMENTAL PROGRAMME (UNEP), REPORT OF THE SIXTH MEETING OF THE AD HOC OPEN-ENDED GROUP OF EXPERTS ON BIOSAFETY, Decision II/5, UN Doc UNEP/CBD/ExCOP/1/2 (1999) [hereinafter SIXTH MEETING].

131. Mr. Veit Koester (Denmark) was the Chair of the Open-ended Ad Hoc Working Group. *Id.*

132. Mr. Maldonado (Colombian Environment Minister) chaired the ExCOP. *Id.*

133. *See* Belgian Biosafety Server, *Biosafety Under the Biodiversity Convention: A Brief History, Earth Negotiations Bulletin available at* http://biosafety.ihe.be/Biodiv/History.html (last visited on Feb. 12, 2001).

134. *See id.*

135. *See* SIXTH MEETING, *supra* note 128, at 20-21.

With respect to Article 4, several negotiating blocks were reluctant to exclude pharmaceuticals and LMOs destined for contained use; direct use as food or feed, or for processing (FFPs) from the protocol.[136] With respect to Article 5, many argued, "a seed is a seed" and were determined to see that all seeds were included in the AIA procedure.[137] While not a party to the CBD, the United States exerted considerable influence over the scope of the protocol.[138] Many viewed the United States' effort to limit the effect of the protocol as blatant protectionism for the U.S. biotechnology industry.[139] As a result of these and other problems, the Parties were unable to finalize the protocol in Cartagena and the Parties agreed to suspend negotiations.[140] As one delegate pointed out, "[i]t is better to have a stronger Protocol in the future than to settle for an unsatisfactory solution and a weak Protocol."[141]

3. The Negotiating Blocks

The 135 countries that participated in the negotiation of the Cartagena Protocol divided themselves into 5 different negotiating groups.[142] The countries in each group were generally aligned by the similar positions they had on the major issues being discussed hereunder.[143]

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136. *See id.*

137. *See* Chee Yoke Ling, *Delayed, but better, Biosafety Protocol available at* http://www.twnside.org.sg/title/delay.htm at *1 (last visited on Feb. 12, 2001).

138. *See* Andrew Pollack, *With U.S. Under Pressure, Biotechnology Talks Resume*, THE N.Y. TIMES, January 23, 2000.

139. *See* id. (discussing the resentment toward the U.S.).

140. *See* id.

141. *See* Ling, *supra* note 135, at *1.

142. *See* GREENPEACE, *Country Positions in the Biosafety Protocol Negotiations available at* http://www.greenpeace.org/~geneng/reports/bio/intrbio8.htm at *1 (last visited on Feb 12, 2001).

143. *See id.*

a. The "Like Minded Group"

The Like Minded Group (the "LMG") consisted of "all developing countries (known as the Group of 77 plus China), but with exception of Argentina, Chile, and Uruguay."[144] This block represented the largest number of countries at 75 (or 100 if you count the members of the Central and Eastern European block) and almost 80% of the world's population.[145] In the broadest sense, this group was in favor of a strong Biosafety Protocol.[146] Their proposal required countries exporting commodities, including bulk commodities such as corn and cotton, to notify importing countries and seek consent before any shipment was allowed into the importing countries.[147] The LMG was also particularly concerned about the capacity of developing nations to adequately regulate and handle GMOs.[148] Additionally, the LMG was in favor of comprehensive identification and documentation requirements, a strong statement of the precautionary principle, and tough liability and redress provisions.[149]

b. The "Miami Group"

The Miami Group was comprised of 6 counties (the smallest number) including Canada, Australia, Argentina, Uruguay, Chile and the US.[150] This group consisted of the largest grain commodity and

144. *Id.*

145. *See id.*

146. *See id.*

147. *See* U.S. DEP'T OF STATE, Foreign Press Center Briefing Transcript, *Upcoming Biosafety Protocol Negotiations, Montreal Canada* (2000) *available at* http://www.fpc.gov/00_trans/sand0100.htm (last visited at Feb. 20, 2001).

148. *See id.*

149. *See* Aaron Cosbey & Stas Burgiel, *The Cartagena Protocol on Biosafety: An Analysis of Results*, INT'L INSTITUTE FOR SUSTAINABLE DEV., (2000) [hereinafter Cosbey].

150. *See Cartagena Biosafety Protocol: New International Agreement Regulating GMOs available at* http://www.harmonizationalert.org/January00/protocol.htm, at *1 (last visited on July 20, 2000).

GMO exporting countries.[151] Generally speaking the Miami group was in favor of a less restrictive Protocol (i.e. one that would not disrupt international trade in GMOs).[152] The main goal of the Miami Group was to negotiate a treaty that would protect the Earth's biological resources without disrupting worldwide trade.[153] The Miami Group argued that commodities, which total 90% of all GMOs, and pharmaceuticals, should be entirely excluded from the Protocol or at least from the AIA procedures.[154] The group also argued for a "savings clause" that could ensure that the Protocol would not displace or trump any other international agreements (i.e. the WTO).[155]

c. The European Union

The European Union (EU) negotiating block included all 15 members of the EU.[156] The EU attempted to take the middle ground during the negotiating session.[157] Due in part to the incredible public outrage over food safety, the EU sought a comprehensive treaty that would include threats to human health.[158] The EU argued that FFPs should be included in the treaty even if they were not subject to the

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151. *See generally, id.*

152. *See generally, Summary of the Cartagena Protocol on Biosafety (2000) available at* http://www.greenpeacecanada.org/e/feature_geconsumer/archives/bp summary.html (last visited on July 20, 2000).

153. *See* Press Statement from Frank E. Loy, Under Secretary of State and Global Affairs and Head of the US Delegation, Upon Adoption of the Biosafety Protocol (Jan. 29, 2000) *available at* http://www.state.gov/www/policy_remarks/-2000/000129_loy_biosafety.html (last visited on Feb. 20, 2001).

154. *See Who Wants What at the International Biosafety Protocol Negotiations? available at* http://www.foe.org/safefood/biosafetyneeds.html (last visited on March 8, 2001) [hereinafter Who Wants What].

155. *See id.*

156. *See* Greenpeace, *supra* note 155.

157. *See id.*

158. *See id.*

AIA procedures.[159] However, the most important issue for the EU was the inclusion of the precautionary principle into the AIA procedures.[160] Finally, the EU objected to the inclusion of a savings clause arguing that it could create problems for importing Parties that denied importation based on the precautionary principle.[161]

d. The "Compromise Group" and the "Central and Eastern European Group"

Two smaller negotiating groups helped round out the negotiating sessions. The Compromise Group included Switzerland, Korea, Mexico, Norway, New Zealand, and possibly Japan.[162] This group claimed to be acting as a facilitator or mediator and attempted to broker a compromise in Vienna for a weaker AIA procedure (which was rejected by the Miami Group).[163] The Central and Eastern European Group "essentially acted with the Like Minded Group."[164]

4. A Compromise is Reached

After a break of nearly 11 months from the February meeting in 1999, the Parties reconvened in Montreal, Canada at the Resumed Session of the First Extraordinary Meeting of the Conference of the Parties to the Convention on Biological Diversity.[165] Over 700 delegates attended the meeting from governments, intergovernmental organizations and NGOs, including over 40

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159. *See generally* Who Wants What, *supra* note 167.

160. *See generally* GREENPEACE, *The Precautionary Principle and the Biosafety Protocol* available at http://www.greenpeace.org/~geneng/reports/bio/intrbio5.htm (last visited on May 25, 2001).

161. *See generally* Who Wants What, *supra* note 167, *available at* http://www.foe.org/safefood/ biosafetyneeds.html.

162. *See id.*

163. *See id.*

164. *See id.*

165. *See Cartagena Protocol on Biosafety: Background* available at http://www.biodiv. org/biosafety (last visited on May 25, 2001).

ministers.[166] After a last minute compromise on the provision regarding documentation, the Parties to the CBD reached an agreement in the early hours of Saturday, January 29, 2000.[167] The Protocol was opened for signature from May 15-26, 2000 at the Fifth Conference of the Parties to the CBD in Nairobi and from June 5, 2000 to June 4, 2001 in New York.[168] Sixty-four governments plus the European Community signed the Protocol in Nairobi.[169] As of May 25, 2001 there were ninety six signatories and three parties to the Cartagena Protocol.[170]

The Protocol was immediately hailed as a success. Margrot Wallstrom, the European Commissioner for the Environment said, "[t]his is a historical moment and a breakthrough for international agreements on trade . . . ."[171] Wallstrom added that the protocol "reflects the common will to protect the world's environment and confirms the importance of the Convention on Biodiversity."[172] David Sandalow, Assistant U.S. Secretary of State for Oceans, Environment and Science commented that "[o]n balance, we think this is an agreement that protects the environment."[173] "Frank E. Loy, an undersecretary of state and head of the U.S. team in

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166. *See id.*

167. *See* Andrew Pollack, *130 Nations Agree on Safety Rules for Biotech Food*, N.Y. TIMES, January 30, 2000.

168. *See Decision EM-I/3: Adoption of the Cartagena Protocol and Interim Agreements* available at http://www.biodiv.org/decisions/default.asp?lg=0&m=excop01&d=03 (last visited on May 25, 2001).

169. *See Parties to the Convention on Biological Diversity/ Cartagena Protocol on Biosafety* available at http://www.biodiv.org/world/parties.asp (last visited on May 25, 2001).

170. *See id.*

171. *See EU welcomes international bio-safety trade pact*, REUTERS (Jan 29, 2000) *available at* http://home.intekom.com/tm_info/rw00130.htm, at *17-18.

172. *See id.*

173. *Id.*

174. *See* Doug Palmer, *Countries Reach Landmark GMO Food Agreement*, REUTERS (January 29, 2000) *available at* http://home.intekom.com/tm_info/rw00130.htm, at *17-18.

Montreal, described the agreement as 'not perfect'. . .however, that laying out rules will 'make it easier for all of us to harness the promise of this technology to feed the world's growing population....'"[174] Notwithstanding Under Secretary Loy's remarks, both environmental groups and biotech industrialists applauded the Protocol.[175] Michael Khoo a Greenpeace organizer who rallied at the Montreal Convention said that "[w]e (Greenpeace) won almost all the points we were pushing for."[176] The L.A. Times reported that "[t]he Global Industry Coalition, representing 2,200 biotech companies, said it too was encouraged by the outcome."[177] If nothing else, the protocol may be remembered as the first major international treaty of 21st century that treated an environmental issue as important as a trade issue. From this standpoint, it is easy to appreciate why environmental ministers from each of the negotiating blocks and the environmental NGOs, despite their often intense differences during the past 5 years, were equally quick to embrace the new treaty as a success.

B. The Cartagena Protocol

This portion of the paper sets forth the major issues reflected in the Protocol. It examines the scope of the Protocol, discusses the Precautionary Principle, and considers the relationship between the Protocol and other international agreements, particularly the World Trade Organization (WTO).

1. Scope

As adopted, the Protocol is limited in scope to the to the transboundary movement of all LMOs that may adversely affect

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175. John Burgess, *Trade Rules Set on Food Genetics, Compromise Gained On Labeling Issue*, WASH. POST, January 30, 2000, at A20.

176. *See* Maggie Farley, *Deal Struck to Regulate Genetically Altered Food*, L. A. TIMES, January 30, 2000 (last visited on February 1, 2000) at http://www.latimes.com /news/ nation/20000130/t000009630.html.

176. *Id.*

177. *Id.*

biological diversity.[178] The Protocol does not address food safety issues or pharmaceuticals.[179] By the time the Parties arrived at Montreal, the last major issue under contention was whether to include LMOs intended for direct use as food, feed, or processing under the Protocol's Advanced Informed Agreement procedure.[180] The Miami Group, and the U.S. in particular, argued that FFPs should not be included because the costs of regulating such widely traded commodities, such as corn, wheat, and canola, would be overly burdensome.[181] Furthermore, they argued that because FFPs are not intended for introduction in the environment, they do not possess a real threat to biodiversity.[182] In the end, while FFPs are covered under the Protocol, they are not subject to the AIA procedures.

2. The Advance Informed Agreement (AIA) Procedure

The AIA procedures are set forth in Articles 8-10.[183] Article 7 of the Protocol requires the Party of export to comply with Articles 8-10 *prior to the first transboundary movement of LMOs intended for introduction into the environment* of the Party of import.[184] LMOs intended for direct use as food or feed, or for processing (FFPs) are specifically excluded from compliance with Articles 8-10.[185] Additionally, Article 7 does not cover the intentional transboundary

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178. *See* Cartagena Protocol, *supra* note 11, at art. 4.

179. *See id.* at art. 5.

180. *See* U.S. DEP'T OF STATE , *David B. Sandalow: Press Briefing at Biosafety Protocol Negotiations, Montreal, Canada* (Jan. 25, 2000) *available at* http://www.state.gov/www/ policy_re...000/000125_sandalow_biosafety.html, (last visited on Feb 20, 2001).

181. *See* Cosbey, *supra* note 162, at 3 (2000).

182. *See* U.S. DEP'T OF STATE, *David B. Sandlow: Press Briefing at U.S. Mission to the European Union, Brussels, Belgium* (January 12, 2000).

183. *See* Cartagena Protocol, *supra* note 11, at art. 8-10.

184. *See* id. at art. 7. Note that article 7 does not apply to the domestic transit of LMOs.

185. *Id.*

movements of LMOs that are unlikely to have an adverse affect on the conservation or sustainable use of biological diversity (as determined by the Conference of the Parties).[186] Consequently, while the AIA represents the main regulatory provision contained in the Protocol it only applies to a small percentage of traded LMOs.[187]

Article 8 requires the Party of export to notify, in writing, the Party of import prior to the first intentional transboundary movement of all LMOs intended for introduction into the environment.[188] The notification must include the information contained in Annex 1, including, *inter alia*, taxonomic status of both the recipient and donor organisms, centers of origin and centers of genetic diversity of the recipient organism, a description of the nucleic acid and the technique used for the modification introduced, a previous and existing risk assessment report, and the regulatory status of the LMO in the State of export.[189] Additionally, the Protocol requires the Party of export to regulate the accuracy of any disclosures made in accordance with Annex 1.[190]

Article 9 requires the Party of import to acknowledge receipt of the exporting Parties notification within 90 days.[191] The acknowledgement sent by the importing Party must state whether to proceed under the domestic regulatory framework of the importing party or, according to the procedure set froth in Article 10.[192] The Protocol specifically states that a failure of the Party of import to acknowledge receipt within 90 days does not imply their consent to an intentional transboundary movement.[193] The importing Party also has 90 days after receipt of the Article 8 to inform the exporting Party whether the shipments can proceed only after the Party of import has given their consent or after no less than 90 days without a

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186. *Id.*

187. *See* CARTAGENA FACT SHEET, *supra* note 85, *available at* http://www.state.gov/www/global/ors/fscart_prot_biosaf_-000216.html.

188. *See* Cartagena Protocol, *supra* note 11, at art. 8(1).

189. *Id.* at annex 1.

190. *Id.* at art. 8(2).

191. *Id.* at art. 9(1).

192. *Id.* at art. 9(2)(c).

193. *See* Cartagena Protocol, *supra* note 11, at art. 9(4).

subsequent written consent.[194] If the Party of import chooses to require the exporting Party to wait for written notification, then the Party of import has 270 days in which to decide and notify the Biosafety Clearing-House of its decision.[195] The Protocol states that a failure to make a decision within 270 does not constitute its consent to an intentional transboundary movement.[196] The Party of import can decide to (1) approve the import adding certain conditions (2) prohibit the import (3) request additional information or (4) extend the deadline by a definite period of time.[197] Finally, Article 12 allows the Party of import to review its decision at any time if new scientific information becomes available.[198] Additionally, the Party of export may request that the Party of import review a decision it has made under Article 10.[199] In such cases, the Party of import has 90 days to make a decision and set forth its reasons.[200]

LMOs intended for food, feed, or for processing (FFPs) are covered by Article 11.[201] Article 11 places the onus on each Party to enact legislation that restricts the domestic use of FFPs.[202] Parties have 15 days after making their decisions to inform the other parties through the Biosafety Clearing-House.[203] Any Party enacting such legislation must, at a minimum, include the information specified in Annex II to the Clearing-House.[204] "Thus, while the AIA procedure lays first responsibility on the Party of export to notify its intent to export, the procedure for [FFPs] lays first responsibility on potential importers to develop and announce regulations proactively."[205] Developing countries in transition that lack a domestic regulatory framework can take up to 270 days to make a decision regarding the

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194. *Id.* at art. 10(2)(a)-(b).
195. *Id.* at art. 10(3).
196. *Id.* at art. 10(7).
197. *Id.* at art. 10(3)(a)-(d).
198. *See* Cartagena Protocol, *supra* note 11, at art. 12(1)
199. *Id.* at art. 12(2).
200. *Id.* at art. 12(3).
201. *See id.* at art 11(1)
202. *See id.*
203. *See* Cartagena Protocol, *supra* note 11, at art. 11(1).
204. *See id.*
205. *See* COSBEY, *supra* note 162, at 8.

first importation of FFPs so long as it undertakes a risk assessment in accordance with Annex III.[206]

3. The Precautionary Principle

Throughout the negotiations, the EU remained steadfast in its insistence that the precautionary principle be incorporated into the Protocol. Consequently, the Cartagena Protocol contains the strongest and most sophisticated expression of the precautionary principle to date[207] Both articles 10 (which applies to the direct release of GMOs into the environment) and 11 (FFPs) state that:

> a lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regards to the import of the living modified organism in question, as appropriate, with regard to the import of that living modified organism. . . in order to avoid or minimize such potential adverse effects.[208]

Additionally, both the Preamble and Article 1 state that the main objective of the Protocol is to ensure protection against GMOs in accordance with the "precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development . . . ."[209] The final reference to the Precautionary Principle can be found in Annex III (Risk Assessment), which states that "[l]ack of scientific

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206. *See* Cartagena Protocol, *supra* note 11, at art. 11(1).

207. *See generally* Kristen Dawkins, *Battle Royale of the 21st Century*, SEEDLING, March 2000, *available at* http://www.grain.org/publications/mar00/mar001.htm (last visited on May 25, 2001).

208. Cartagena Protocol, *supra* note 11, at art. 10(6), art. 11(8).

209. *Id.* at art. 1.

knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk."[210] Clearly, the Cartagena Protocol has succeeded in propelling the Precautionary Principle to the forefront of international environmental law.

While a detailed analysis of the Precautionary Principle is beyond the scope of this paper, the underlying principle behind the Precautionary Principle can be easily summarized. At the heart of the Precautionary Principle is the idea that sometimes action must be taken to prevent human harm or harm to the environment, even in the face of scientific uncertainty.[211] According to Frank E. Loy, the head of the U.S. delegation, the Precautionary Principle stands for the proposition that "lack of full scientific certainty should not be used to postpone cost-effective measures to protect the environment against serious or irreversible threats."[212] According to the European Commission such action should:

> be based on an examination of the potential benefits and costs of action or lack of action and subject to review in the light of new scientific data and should thus be maintained as long as the scientific data remain incomplete, imprecise or inconclusive and as long as the risk is considered to high to be imposed on society.[213]

Furthermore, any action taken should be proportionate to the chosen level of protection, non-discriminatory in its application and consistent with prior measures.[214] While some Parties were concerned that the Precautionary Principle would be used as a

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210. *Id.* at annex III(4).

211. *See* Nancy Myers, *Debating the Precautionary Principle*, *available at* http://www.sehn.org/ppdebate.html (last visited on Mar. 20, 2001).

212. *Press Briefing by Frank E. Loy and David B. Sandlow*, U.S. Embassy, January 24, 2000.

213. *Commission Adopts Communication on Precautionary Principle*, THE EUROPEAN COMMISSION (Feb. 2, 2000), *available at* http://europa.eu.int/comm/trade/ whats_new/ dpp_en.htm.

214. *Id.*

pretense for protectionism (e.g. WTO Beef-Harmones Appellate Body), the general consensus is that precaution should be part of a scientific approach, not a substitute for one. However, the Protocol also contains a provision that allows Parties to take into account socio-economic considerations in reaching a decision on the import of GMOs under the Protocol.[215] As will be discussed below, it remains unclear to what extent Parties can base their decisions on the Precautionary Principle and socio-economic considerations without violating the provisions of prior international agreements.

4. The Cartagena Protocol and International Law (WTO)

One of the most controversial aspects of the Protocol is the relationship between the Protocol and other international agreements (i.e. the WTO). As was discussed earlier, the Miami Group advocated the inclusion of a "savings clause," while the EU objected to a savings clause.[216] After lengthy informal negotiations throughout the Montreal session, the Parties agreed to include three preambular clauses;

> [t]he mutual supportiveness of trade and environment agreements with a view to achieving sustainable development; the statement that the Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under existing international agreements and the explanatory statement that the above clause is not intended to subordinate the Protocol to other international agreements.[217]

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215. *See* Cartagena Protocol, *supra* note 11, at art. 26.

216. *See infra* Part IV(3)(a)-(b).

217. The Miami Group favored language implying a change in obligation. The EU argued that the language was not intended to subordinate Protocol. *Report of the Resumed Session of the Extraordinary Meeting of the Parties for the Adoption of: The Protocol on Biosafety to the Convention on Biological Diversity*, Colaboraciones, (last visited on July 30, 2000) at http://www.bioplanet.net/2000febrero/colaboraciones/o22feb2000(1).htm.

Ultimately, the final text does not resolve the question of how the Protocol related to other international agreements. It appears that statement that the Protocol will not change any Parties existing obligations under the WTO and the statement that Protocol will not be subordinate to those same obligations may come into conflict. For example, a Party may attempt to implement the Protocol by banning certain GMOs under Article 11's precautionary principle.[218] However, the exporter may still argue that the ban violates the provisions of the WTOs Agreement on Sanitary and Phytosanitary Measures (SPS), which requires Parties to establish a scientific basis for regulation. The wording of the two passages suggests that the Protocol and the WTO must be read as mutually supportive and not conflicting. Thus, while the issue remains unresolved, it appears that the WTO rules would apply to any disputes brought before the Dispute Settlement Body (DSB). Nonetheless, if the Protocol is interpreted as creating customary international law, then the DSB or other international tribunals might rely on the Protocol as a reflection of the current status of international law (at least with respect to GMOs).

CONCLUSION

In light of the lack of consensus with respect to the risks posed by GMOs, the Cartagena Protocol represents a well-balanced and rational approach to international regulation of genetically modified organisms. While the Precautionary Principle is not appropriate for all environmental issues, it is appropriate in this context. As was discussed in this paper, the potential harm to biodiversity is staggering. Yet the Protocol does not ban the trade GMOs. In fact, the Protocol fails to cover 90 percent of GMO goods (i.e. commodities). Nonetheless, the Protocol has succeeded in establishing a system to facilitate the sharing of information and requires the approval of importing Parties for the most dangerous (potentially) GMOs (i.e. those intended for direct introduction into the environment). While the Protocol took 6 years to finalize, it represents only the foundation for greater control over GMO trade in the future. The Parties have yet to agree on issues of liability,

218. *See* Cartagena Protocol, *supra note 11*, at art. 11

documentation, and identification. For the Protocol to be truly effective, these controversial issues must be resolved. Yet, as it stands now, the Protocol is a monument to international negotiation and a beacon for environmental law. In the end, the greatest contribution of the Cartagena Protocol will surely be its progeny.