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ARTICLE

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I. INTRODUCTION

The Convention on Biological Diversity (CBD) defines biodiversity as "the variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems."[1] Thus, the CBD, which is the primary international instrument for addressing biological diversity issues, provides a terse definition for a concept that still has different meanings for different audiences. For some, the term "biodiversity" is merely a newer, emotive variant of older concepts such as life, wilderness, or conservation.[2] Others recognize the term as a descriptor of variability at several different scales: genetic variation within species, the variety of species in a habitat, the variety of habitat types within a landscape, as well as landscape variability on a global scale. But even this latter definition is often approached from different perspectives in which some are primarily

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1. Convention on Biological Diversity, June 5, 1992, 1760 U.N.T.S. 79 [hereinafter CBD].

2. *See* John Lloyd, *Biodiversity*, ENCYCLOPEDIA OF EARTH, http://www.eoearth.org/article/Biodiversity?topic=49480 (last updated May 7, 2012).

concerned with ecosystem and evolutionary processes, while others focus on compositional attributes such as populations, communities, or other organizational categories.[3] With such a variety of ways to approach the concept of biodiversity, Sarkar argues that, operationally, biodiversity is simply a measure of whatever is the valued target of conservation priority setting for different localities.[4]

Pragmatically, the CBD requires States to promote the protection of ecosystems and natural habitats and to maintain viable populations of species in natural surroundings.[5] The CBD also specifically requires States to prevent the introduction of alien species that threaten ecosystems, habitats or other species, and to control or eradicate those alien species if they are introduced.[6] Parties to the CBD identified invasive alien species prevention and management as a cross-cutting theme which cuts across various work programs including inland water systems, forests, and coastal and marine management. Invasive alien species are those plants, animals, and microbes that are introduced and spread outside of their natural range, and whose establishment and spread adversely impact other species, habitats and ecosystems.[7]

Despite differences in how biodiversity is perceived, there is general agreement that across the planet it is endangered from a number of inter-related factors including climate change, overpopulation of the human species, industrial and agricultural pollution, and unsustainable exploitation of natural resources. The relative importance of different issues rises and falls in the public's mind over time. Sometimes, these differences in emphasis give rise to inconsistent regulatory philosophies and policies, both domestically and as reflected in international law.

3. *See* J. Baird Callicott et al., *Current Normative Concepts in Conservation*, 13 CONSERVATION BIOLOGY 22, 25 (1999).

4. *See generally* SAHOTRA SARKAR, BIODIVERSITY AND ENVIRONMENTAL PHILOSOPHY: AN INTRODUCTION (2005).

5. CBD, *supra* note 1, art. 8(d).

6. *Id*. art. 8(h).

7. STAS BURGIEL ET AL., CTR. FOR INT'L ENVTL. LAW, INVASIVE ALIEN SPECIES AND TRADE: INTEGRATING PREVENTION MEASURES AND INTERNATIONAL TRADE RULES 5 (2006), *available at* http://cleantrade.typepad.com/clean_trade/files/iastraderpt0106.pdf.

This paper considers one such tangled web of conflicting developments. It involves the popular desire to replace chemical pesticides with more "natural" biological control strategies, plus a slowly emerging awareness of a less benign side to microbial pest control agents, based on their potential invasiveness and sometimes striking similarities to agents of bioterrorism and biological warfare. This desire, however, is overshadowed by concerns about the environmental release of genetically engineered organisms. I argue that as some of the concerns about ecological diversity, as captured by the Convention on Biodiversity, were channeled into the subsequent Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Cartagena Protocol)[8] with its emphasis entirely on products of biotechnology, microbial pest control agents have "fallen through the cracks" of international environmental law.

II. BIOLOGICAL CONTROL OF PLANT PESTS: A "BIODIVERSITY-FRIENDLY" TECHNOLOGY?

The term biological control, or biocontrol, encompasses those strategies that employ living agents for suppression of insect pests, weeds, and plant diseases.[9] Biological control presents an alternative to chemical control methods. Although the practice of biocontrol predated the 1962 publication of Rachel Carson's seminal book *Silent Spring*[10] by many years, and some would claim that it dates almost from the dawn of agriculture, Carson's book generated a storm of controversy over the use of chemical pesticides, which gave a major boost to biocontrol research and application. Broad-spectrum chemical pesticides have become ecologically and socially unacceptable to many people. Rachel Carson's contention, which has acquired the status of dogma in some academic and environmental circles, is that using biological

8. Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Jan. 29, 2000, 2226 U.N.T.S. 208; *see also* CBD, *Report of Extraordinary Meeting of the Conference of the Parties for the Adoption of the Protocol on Biosafety to the Convention on Biological Diversity*, at 42, U.N. Doc. UNEP/CBD/ExCOP/1/3 (Feb. 20, 2000).

9. *See Biological Control*, CORNELL UNIV., http://www.biocontrol.entomology.cornell.edu/what.html (last visited Nov. 7, 2012).

10. RACHEL CARSON, SILENT SPRING (1962).

organisms to control undesirable pests or diseases is a much better alternative than conventional chemical pesticides, because such non-chemical methods do not leave toxic residues that can contaminate and harm the environment.[11] Those biological control agents that possess a narrow host-range are usually considered to be the most environmentally friendly.

Some biological control agents are arthropods, such as ladybird beetles that prey on aphid populations, or herbaceous insects that feed selectively on certain weed species. For those agents that are microbes (bacteria, fungi, viruses, or nematodes), the term "microbial pest control agent" (MPCA) is often used. The U.S. Environmental Protection Agency (EPA) defines a microbial pest control agent as ". . . any of those microorganisms including (but not limited to) bacteria, fungi, viruses, and protozoa . . . that are used to control pests."[12] Some MPCAs are applied inundatively and kill the target host either shortly after application or following ingestion. This is the case with the bacterium *Bacillus thuringiensis* (Bt), which produces an insecticidal toxin that is applied over vast acreages to control spruce budworm, gypsy moth, and other forest or agricultural pests.[13] MPCAs that are used in this manner are often called microbial pesticides, or more specifically, depending on the type of target host, microbial insecticides or microbial herbicides. Other MPCAs are released to proliferate in the environment, resulting in a sustained suppression of the host population. The latter approach is appealing because, under ideal conditions, these natural enemies of pests can become established and provide a self-perpetuating form of control. An example would be the use, still in the exploratory stage, of the rust fungus *Puccinia cardorum* to control invasive musk thistle.[14]

11. *Id.*

12. U.S. EPA, EPA 712-C-96-280, MICROBIAL PESTICIDE TEST GUIDELINES: OPPTS 885.0001 OVERVIEW FOR MICROBIAL PEST CONTROL AGENTS 7 (1996) [hereinafter MICROBIAL PESTICIDE TEST GUIDELINES].

13. *Biological Control*: *Bacteria*, CORNELL UNIV., http://www.biocontrol.entomology.cornell.edu/pathogens/bacteria.html (last visited Nov. 7, 2012).

14. William Bruckart et al., *Susceptibility of Musk Thistle and Related Composites to* Puccinia carduorum, 74 PHYTOPATHOLY 687 (1984).

The first organism registered as a microbial pesticide in the United States (U.S.) was the naturally occurring soil bacterium *Bacillus popilliae*. This agent has been in use since 1948 and has been applied to countless lawns and golf courses to control the soil-inhabiting larval stage of the invasive Japanese beetle.[15] Currently, a number of other MPCAs also are registered in the U.S. for use in agriculture, forestry, home and urban landscapes, and aquatic systems (in the latter case, for example, to control mosquitoes). A number of plant pathogenic fungi are registered as mycoherbicides, and are used to kill invasive weeds including Northern jointvetch and dandelion.[16] Some MPCAs are in extensive use worldwide, including microbial insecticides such as Bt and the fungi *Beauveria basssiana* and *Metarhizium anisopliae*.[17] In China, spores of *B. bassiana* have been applied to large forest acreages by aerial spraying and even by packing them into artillery shells and bombarding the forest hillsides.[18]

MPCAs are by definition aimed at killing target pest populations. Yet, relatively few concerns have been raised about their potential negative effects on biodiversity, at least for those which are naturally occurring organisms. Possibly, enthusiasm for "environmentally benign" biological control methods would have been somewhat dampened if the general public had been aware that the U.S. Army, as part of its biological weapons program centered at Fort Detrick, Maryland, was for several years evaluating the potential for large-scale deployment of spores of the wheat stem rust fungus as a mycoherbicide.[19] The program, conducted during the 1950's, was presumably focused on one of the United States' two major cold war enemies: the Soviet Union. Not surprisingly, parallel research was allegedly

15. EPA, *BACILLUS POPILLIAE* SPORES (054502) FACT SHEET (2004), *available at* http://www.epa.gov/pesticides/biopesticides/ingredients/factsheets/factsheet_054502.htm.

16. SUSHIL K. KHETAN, MICROBIAL PEST CONTROL 200-01 (2001).

17. *Id.* at 84, 212.

18. M. G. Feng et al., *Production, Formulation, and Application of the Entomopathogenic Fungus* Beauveria bassiana *for Insect Control: Current Status*, 4 BIOCONTROL SCI. & TECH. 3, 19 (1994).

19. James Martin et al., *History of Biological Weapons: From Poisoned Darts to Intentional Epidemics*, *in* MEDICAL ASPECTS OF BIOLOGICAL WARFARE 5 (Zygmunt F. Dembek ed., 2007).

being conducted at Fort Detrick using the fungal pathogen that causes rice blast disease, a potentially devastating weapon against the People's Republic of China.[20] It would be hard to argue that a mycoherbicide that was successfully deployed to destroy major croplands of an unfriendly country would not have substantial impacts on biodiversity and the environment. However, partly due to the secrecy that surrounded offensive mycoherbicide research prior to international adoption of the Biological Weapons Convention of 1975,[21] and perhaps in part because of the environmentally benign patina that biological control had acquired, relatively few concerns were raised.

However, in 1987, the use of a microbial pest control agent did capture the public imagination, in a very negative way, when Montana State University professor Gary Strobel injected genetically modified cells of the bacterium *Pseudomonas fluorescens* into a number of elm trees on the university campus, in an attempt to control the fungal Dutch elm disease pathogen.[22] Strobel conducted the experiment as a self-styled exercise in "civil disobedience" in defiance of existing regulations concerning release of recombinant organisms. During the uproar that followed his experiment, Strobel was obliged to cut down his experimental trees with a chain saw, and was both sanctioned by the EPA as well as formally reprimanded by the university.[23]

Public concerns about the new technology of genetic engineering were at a high point in the mid- to late-1980s. The Montana State University fiasco shared the news with protests and lawsuits attempting to halt experiments by scientists at the University of California, who had applied to conduct the first approved environmental release of a genetically modified

20. *See id*.

21. Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, Apr. 10, 1972, 1015 U.N.T.S. 163 (entered into force 26 March 1975).

22. Ian Anderson, *Rumpus Over Rogue Release of Microbes*, 27 NEW SCIENTIST 15 (1987); Keith Schneider, *Tearful Scientist Halts Gene Test*, N.Y. TIMES, Sept. 4, 1987, at A11.

23. *Id*.

organism (GMO), the so-called "ice-minus" bacteria.[24] The bacteria, which had been engineered by deleting a gene involved in ice crystal formation, were intended to out-compete native bacteria on strawberry leaves, thereby protecting the plant from frost injury.[25] In 1985, the D.C. Circuit Court of Appeals affirmed an injunction against the experiment, expressing its concern that governmental agencies had not yet given "adequate consideration to broad and important issues relating to its role in approving deliberate release experiments."[26] The appellate court also noted:

> Should organisms containing recombined DNA be dispersed into the environment, they might, depending on their fitness relative to naturally occurring organisms, find a suitable ecological niche for their own reproduction. A potentially dangerous organism might then multiply and spread. Subsequent cessation of experiments would not stop the diffusion of the hazardous agent.[27]

In recent years, recombinant microbes (as opposed to crop plants) have largely moved out of the public spotlight and to the sidelines of the debate over recombinant DNA technology. However, reports and experimental trial results for a number of genetically engineered MPCAs appear increasingly in the literature. Genetically modified microbial pesticides are bacteria, fungi, viruses, protozoa, or algae, whose DNA has been modified to express pesticidal properties, enhance pathogenicity to target organisms, or to improve survival in the environment. Although MPCAs typically are less effective and more costly than chemical pesticides, thus limiting their widespread use,[28] genetic engineering may provide one means to boost their efficacy or enhance their specificity. For example, Fan et al. engineered the

24. *See* Guy R. Knudsen et al., *Aerial Dispersal and Epiphytic Survival of* Pseudomonas syringae *During a Pretest for the Release of Genetically Engineered Strains into the Environment*, 54 APPLIED & ENVTL. MICROBIOLOGY 1557 (1988).

25. *Id.*

26. Found. on Econ. Trends v. Heckler, 756 F.2d 143, 160 (D.C. Cir. 1985).

27. *Id.* at 148-49.

28. *See* Matthew Thomas & Andrew Read, *Fungal Bioinsecticide with a Sting*, 25 NATURE BIOTECH. 1367, 1367 (2007).

fungal entomopathogen *Beauveria bassiana* to overexpress the enzyme chitinase, enhancing its ability to penetrate the cuticle of host insects.[29] Wang and St. Leger engineered the fungus *Metarhizium anisopliae* to express an insect-specific scorpion neurotoxin, making it more deadly to specific insect pests.[30] To date, however, no genetically engineered MPCAs are close to EPA registration, and in the U.S. at least, biotech crops continue to receive the lion's share of public attention.

III. THE CARTAGENA BIOSAFETY PROTOCOL: THE WORLD FOCUSES ON BIOTECHNOLOGY

Predicted doomsday scenarios surrounding the environmental release of genetically modified organisms (GMOs) have for the most part not materialized. Genetically engineered organisms, especially genetically modified (GM) crops, continue to transform our world. However, concerns about the products of biotechnology persist in the general public and among many members of the scientific community, both in the United States and internationally. Perceived risks of GMOs include the possibility of adverse effects on human health, environmental harms including damage to non-GM crops, and ecological impacts such as loss of biodiversity or other nontarget effects.[31] International concerns about the transnational movement of the products of biotechnology, and possible adverse effects on biodiversity, were briefly addressed in the Convention of Biological Diversity. The CBD requires Parties to establish or maintain means to regulate, manage, or control the risks associated with the use and release of living modified organisms (LMOs) resulting from biotechnology which threaten adverse biological diversity and human health.[32] The CBD also requires

29. Y. Fan et al., *Increased Insect Virulence in* Beauveria bassiana *Strains Overexpressing an Engineered Chitinase*, 73 APPLIED ENVTL. MICROBIOLOGY 295, 295 (2007).

30. See C. Wang & Raymond St Leger, *A Scorpion Neurotoxin Increases the Potency of a Fungal Insecticide*, 25 NATURE BIOTECH. 1455, 1456 (2007).

31. *See* P. WHITACRE, GENETICALLY ENGINEERED ORGANISMS, WILDLIFE, AND HABITAT: A WORKSHOP SUMMARY (2008).

32. *See* CBD, *supra* note 1, art. 8. The term "LMO" is essentially synonymous with "GMO," except that GMO is sometimes used to refer to

that parties consider the need and appropriate form of protocol setting out appropriate procedures, including advanced informed agreements for the safe transfer, handling, and use of any LMO resulting from biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity.[33]

Thus, the CBD placed LMOs in a context, with regards to biodiversity protection, that distinguishes them from other organisms on the basis of their origin in recombinant DNA technology, rather than on any potentially invasive or otherwise harmful characteristics of the organisms themselves. This focus on the recombinant nature of organisms was carried forward into the Cartagena Protocol, which entered into force on September 11, 2003.[34] To date, the U.S. has signed but not ratified the CBD, and thus is not a party to the Cartagena Protocol. Nonetheless, the U.S. played a significant role as an initial advocate of the latter instrument. The Cartagena Protocol's objective is to facilitate the safe importation and use of LMOs. Organisms covered by the Cartagena Protocol include genetically engineered plants, animals, and microorganisms that cross international borders.[35]

The stated primary goal of the Cartagena Protocol is to minimize adverse effects on biodiversity, including possible risks to human health, without unnecessarily disrupting the world food trade. The Protocol imposes different levels of stringency depending on the intended use of a particular LMO. For those that will be directly used as food or feed, or for processing, only a relatively simple information procedure is required.[36] For LMOs intended for introduction into the environment of the importing state, the Protocol requires an Advanced Informed Agreement (AIA) prior to the first transboundary movement of the organism.

nonliving bulk commodities of recombinant origin. Here, the two terms will be used interchangeably and restricted to living organisms that are released into the environment and which are potentially capable of growth and reproduction.

33. *See id.* art. 19.

34. *See* Cartagena Protocol on Biosafety to the Convention on Biological Diversity, *supra* note 8.

35. *See id.* art. 4.

36. *See id.* art. 11.

Components of the AIA include notification and an exchange of information between the exporting and importing countries.[37]

Although the Cartagena Protocol does not dwell on the question of invasiveness of engineered organisms, it adheres to the "precautionary principle" or "precautionary approach" first delineated in the Rio Declaration on Environment and Development.[38] The most commonly expressed version of the precautionary principle states "[w]here there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."[39] As applicable to the Cartagena Protocol, the precautionary principle provides that lack of scientific certainty about the extent of potential adverse effects shall not prevent a party, typically the importing State, from making a decision not to allow importation of a LMO. Proponents of this approach included a number of developing nations who expressed fears that a major loss of biodiversity could result from a replacement of traditional farming methods by genetically engineered crops. Their views were echoed by environmental non-governmental organizations present at Cartagena including Greenpeace and the Worldwide Fund for Nature.[40]

IV. U.S. REJECTION OF THE PRECAUTIONARY APPROACH AND THE "PROCESS VS. PRODUCT" DEBATE

The decision to follow the precautionary approach was contentious, and did not sit well with the United States.[41]

37. *See id.* art. 7-10, 12.

38. *See* United Nations Conference Environment and Development (UNCED), Rio de Janiero, Braz., June 3-14, 1992, *Rio Declaration on Environment and Development,* U.N. Doc. A/CONF.151/26 (Vol. I), Principle 2, 22, Agenda 21, Ch. 26.4.

39. *See id.* Principle 15.

40. *See* Lavanya Rajamani, *The Cartagena Protocol - a Battle Over Trade or Biosafety?*, THIRD WORLD NETWORK, http://www.twnside.org.sg/title/lavanya-cn.htm (last visited Nov. 28, 2012).

41. *See* ROSIE COONEY, THE PRECAUTIONARY PRINCIPLE IN BIODIVERSITY CONSERVATION AND NATURAL RESOURCE MANAGEMENT: AN ISSUES PAPER FOR POLICY-MAKERS, RESEARCHERS AND PRACTITIONERS 13 (2004); Thomas P. Redick,

During the development of the Cartagena Protocol, the U.S., although initially a State sponsor of the process, lobbied unsuccessfully for the adoption of a less restrictive "scientific evidence standard," alternatively known as the "sound scientific knowledge" basis. The scientific evidence standard conforms to the criterion found in the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures; the latter is relevant to alien species characterized as pests or pathogens, to the extent that measures for their management affect international trade.[42] WTO member States may adopt national measures to protect human, animal, or plant health/life from risks arising from the entry, establishment, or spread of pests, diseases, or disease-causing organisms and to prevent or limit other damage within their territory from these causes.[43]

Following the WTO language,[44] the scientific evidence standard would essentially require that confirmed scientific evidence of harm be present prior to banning the import of a LMO. In this effort, the U.S. was joined by a number of other countries (the so-called "Miami Group," whose other members were Argentina, Australia, Canada, Chile, China, and Uruguay), and was bolstered by support from the U.S. biotech industry. The motivation for the U.S. to first champion but then abandon the Cartagena Protocol has been debated. Keleman and Vogel contend that governments are more likely to support international environmental agreements when those agreements provide advantages to domestic producers in international competition, and tend to oppose such agreements when the costs of compliance put domestic firms at a competitive disadvantage.[45] From this perspective, early U.S. enthusiasm for a biotechnology

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Stewardship for Biotech Crops: Strategies for Improving Global Consumer Confidence, 44 JURIMETRICS J. 5, 39 (2003).

42. *See* WTO Agreement on the Application of Sanitary and Phytosanitary Measures, art 2(2); annex A, Apr. 15, 1994, 1867 U.N.T.S. 493, *available at* http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm.

43. *Id.*

44. *Id.*

45. R. Daniel Kelemen & David Vogel, *Trading Places: The Role of the United States and the European Union in International Environmental Politics*, 43 COMP. POL. STUD. 427, 444 (2010).

protocol might be viewed as a preemptive attempt to occupy the regulatory field, in which a weaker protocol would effectively codify a more laissez-faire approach to international regulation of biotechnology, to the advantage of U.S. producers. However, as a major biotech exporting country, and with anti-biotech litigation an ongoing feature in the domestic courts,[46] the U.S. apparently was concerned that inclusion of the precautionary approach as a fundamental tenet of the Cartagena Protocol could have a chilling effect on exports. Some observers believed that the Miami Group's strategy was to maintain exports of GMO commodities without the hindrance of information, documentation, or a chance for informed decision-making by importing countries.[47] Allegedly, frustrated delegates from the developing world were heard to complain that the negotiations at Cartagena were on "Biotrade," rather than Biosafety.[48]

Biotechnology is big business in the United States, but it has been contentious and litigious, especially with regards to the approval and release of GMO crops.[49] Globally, the area planted with GM crops increases annually; it was more than 90 million hectares in 2005, with five countries (U.S., Argentina, Brazil, Canada, and China) accounting for approximately 95% of the total area devoted to GM crops.[50] Globally, soybean is the GM crop occupying the greatest acreage, followed by corn, cotton, and oilseed rape.[51] For each of these crops, the most common engineered trait is herbicide tolerance (e.g., "Roundup-Ready,"™ referring to tolerance to Monsanto Corporation's glyphosate herbicide).[52] Corn and cotton have also been engineered to express the insecticidal endotoxin derived from the bacterium

46. *See* Guy Knudsen, *Biotech Crop Litigation Update*, 13 ABA AGRIC. MGMT. COMM. NEWSL. (Am. Bar Ass'n, Chicago, Ill.), Aug. 2009, at 5.

47. *See* Rajamani, *supra* note 40, at 1.

48. *See id.* at 2.

49. *See* Knudsen, *supra* note 46, at 5.

50. *See* O. Sanvido et al., *Ecological Impacts of Genetically Engineered Crops: Ten Years of Field Research and Commercial Cultivation*, INFO. SYS. FOR BIOTECH.: AGRIC. & ENVTL. BIOTECH., Dec. 2006, at 6, *available at* http://www.isb.vt.edu/news/2006 /dec06.pdf.

51. *Id.*

52. *Id.*

Bacillus thuringiensis (Bt).[53] Other types of engineered traits in commercialized GM crops include resistance to various plant pathogens including fungi, bacteria, viruses, and nematodes. "Golden rice,"™ a variety engineered to biosynthesize ß-carotene (provitamin A), was developed as a fortified food to be used in regions of the world where there is a shortage of dietary vitamin A.[54] A number of companies also are working to engineer plants that produce pharmaceuticals.

To date, the bulk of domestic anti-GMO litigation has focused on adverse effects on organic and conventional crops and their marketability, because of the potential for contamination with GM plant material. For example, product liability formed the basis of the seminal *StarLink Corn* case, when traces of the genetically engineered Bt corn variety "StarLink,"™ which was intended for animal feed, were found in taco shells at Taco Bell™ restaurants.[55] Suits based on administrative and environmental law have been used to enjoin, at least temporarily, the planting of several types of genetically engineered Roundup-Ready™ crops.[56] However, potential harms may be more subtle, and their demonstration more difficult, when wildlands and natural aquatic systems are involved. Evaluation of damage is especially difficult when non-commercial interests are implicated, such as the preservation of biodiversity, protection of endangered species, or prevention of invasive organisms in natural ecosystems.[57] There are several ways in which genetically modified plants, animals, or microbes might negatively impact the environment, including potential invasiveness of the GMO or organisms with which it hybridizes, and direct effects on nontarget organisms. Novel genetic material engineered into crops may move into

53. *Id.*

54. *See* Jacqueline A. Paine et al., *Improving the Nutritional Value of Golden Rice Through Increased Pro-vitamin A Content*, 23 NATURE BIOTECH. 482 (2005).

55. *See* StarLink Corn Prod. Liab. Litig. v. Adventis CropScience USA Holding, Inc., 212 F. Supp. 2d 828 (N.D. Ill. 2002); Andrew Pollack, *Kraft Recalls Taco Shells With Bioengineered Corn*, N.Y TIMES, Sept. 23, 2000, http://www.nytimes.com/2000/09/23/business/kraft-recalls-taco-shells-with-bioengineered-corn.html.

56. *See, e.g.*, Geertson Seed Farms v. Monsanto, 541 F.3d 938 (9th Cir. 2009), *rev'd*, 130 S. Ct. 2743 (2010).

57. *See* Sanvido et al., *supra* note 50, at 235.

environments or organisms beyond the intended host, for example, via dispersal of seeds or pollen of a genetically modified plant by wind, animals, or insects.[58]

To compare the United States' perspective on biotechnology with that embodied by the Cartagena Protocol, it may be informative to look at how the U.S. regulates biotechnology within its own borders. In the United States, the Coordinated Framework for the Regulation of Biotechnology was established in 1986 for federal oversight of GMOs.[59] In order to address uncertainties about these issues and other emerging products of biotechnology, the White House Office of Science and Technology Policy and the Council for Environmental Quality undertook a review of the relevant agencies and statutes for regulating biotechnology products in May 2000. This review, along with a number of federal and state laws, covers oversight of GMOs today.[60]

Regulatory policies are intended to be based on scientific understanding of the nature of biotechnology products, and optimal practices for their safe use. In its opposition to enshrining the precautionary principle as a fundamental component of the Cartagena Protocol, the United States' position was consistent with its domestic stance: biotechnology products in the U.S. are not "special," but are, in principle at least, regulated under the same laws that govern the safety, efficacy, and environmental impacts of comparable products derived by conventional methods. The Coordinated Framework is in part based on the assumption that the "process" of genetic engineering itself poses no unique risks;[61] rather, the regulatory emphasis is on the "product" that results.[62] Thus, for example, FDA regulates

58. *See* Norman Ellstrand, *When Transgenes Wander, Should We Worry?*, 125 PLANT PHYSIOLOGY 1543 (2001).

59. *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986).

60. *See* COUNCIL ON ENVTL. QUALITY & OFFICE OF SCI. & TECH. POL'Y, CEQ AND OSTP ASSESSMENT: CASE STUDIES OF ENVIRONMENTAL REGULATIONS FOR BIOTECHNOLOGY (2001), *available at* http://www.whitehouse.gov/files/documents/ostp/Issues/ceq_ostp_study1.pdf.

61. *Id.* at 4.

62. The process/product dichotomy addressed by the Coordinated Framework is similar to one that continues to be a major topic of debate in international

biotechnology food products with the same requirements that are used to safeguard all foods in the marketplace, such as safety and nutritional characteristics.[63] Similarly, EPA's guidelines for registration of microbial pesticides include ". . . both those that are naturally occurring, and those that are strain-improved, either by natural selection or by deliberate genetic manipulation."[64]

V. CARTAGENA PROTOCOL: FOCUS ON BIOTECHNOLOGY AT THE EXPENSE OF BIODIVERSITY?

In contrast to the U.S. domestic regulatory approach, the Cartagena Protocol came down squarely on the "process" side of the "process vs. product" debate, in that the Protocol is solely focused on engineered organisms, with the goal of minimizing their potential adverse effects on biodiversity. The concept of

trade, that of Processes and Production Methods (PPMs). *See* Steve Charnovitz, *The Law of Environmental "PPMs" in the WTO: Debunking the Myth of Illegality*, 27 YALE J. INT'L L. 59, 60 (2002). At issue in the international trade debate is the appropriateness of imposing trade measures that are contingent on the production process. *See id*. The argument has been advanced that refusal to import products made with disfavored processes, e.g., genetic engineering, amounts to an effort by an importing country to impose its own environmental or moral standards on exporting countries. *See* Robert Howse & Donald Regan, *The Product/Process Distinction - An Illusory Basis for Disciplining "Unilateralism" in Trade Policy*, 11 EUR. J. INT'L L. 249 (2011). The motivation for imposing such trade restrictions has been described as consumer-driven, representing the growing concern of consumers in industrialized countries about health and environmental issues. *See* Robert Read, *Like Products, Health & Environmental Exceptions: The Interpretation of PPMs in Recent WTO Trade Dispute Cases*, 5 ESTEY CTR. J. OF INT'L L. & TRADE POL'Y 123 (2004). With the Coordinated Framework, however, the product/process distinction is motivated primarily by risk analysis, with any identifiable risks being attributed to the characteristics of the product itself, rather than the process of genetic manipulation *per se*. One exception should be noted: USDA certification of organic agricultural products includes a set of production standards that are process-based, such as avoidance of chemical pesticides, genetic modification, or irradiation. *See National Organic Program*, USDA AGRIC. MKTG. SERV. (Mar. 15, 2011), http://www.ams.usda.gov/AMSv1.0/nop.

63. *See* Lauren Zeichner, *Product vs. Process: Two Labeling Regimes for Genetically Engineered Foods and How They Relate to Consumer Preference*, 27 ENVIRONS ENVTL. L. & POL'Y J. 468, 481-82 (2004).

64. MICROBIAL PESTICIDE TEST GUIDELINES, *supra* note 12, at 1.

invasiveness, which had been so clearly a focus of the CBD, was thus relegated to the status of, at best, a secondary theme in the Cartagena Protocol. After the U.S. and other members of the Miami Group essentially turned their backs on the Protocol, the document that emerged was viewed widely as a victory for supporters of the precautionary principle.[65] At first glance, it does appear to further the biodiversity goals envisioned in the CBD, since it recognizes that uncontrolled introductions of LMOs could have serious and perhaps irreversible impacts on ecosystems. Somewhat ironically, however, the Cartagena Protocol simultaneously jettisoned an important component of the regulatory philosophy favored by the United States: organisms should be judged by their attributes, and not just on the basis of their family tree. With respect to biodiversity protection, the critical ecological attribute of invasiveness is not (and probably should not be) necessarily linked to an organism's status as "LMO" or "non-LMO." Therefore, by focusing on a criterion (genetic modification), which is arguably of secondary importance for biodiversity, the drafters of the Cartagena Protocol missed an opportunity to create an international instrument that comprehensively addresses the threat of transboundary movement of invasive organisms.

VI. WHAT ARE INVASIVE SPECIES AND CAN MPCAS BECOME INVASIVE?

Invasive species are those non-indigenous plants, animals, or microbes that adversely affect the habitats and ecosystems they invade, whether economically or ecologically.[66] They present a serious threat to all types of ecosystems, especially considering that the severity of their impacts may be exacerbated by climate change and the ongoing destruction of habitats.[67] There are many examples of exotic organisms causing great harm in their

65. *See* COONEY, *supra* note 41, at 13.

66. *See What is an Invasive Species?*, U.S. DEP'T OF AGRIC. (July 18, 2012), http://www.invasivespeciesinfo.gov/whatis.shtml#.UKK5YmnuVQY.

67. *See* WORLD RES. INST., MILLENNIUM ECOSYSTEM ASSESSMENT, ECOSYSTEMS AND HUMAN WELL-BEING: BIODIVERSITY SYNTHESIS 10 (2005), *available at* http://www.maweb.org/documents/document.354.aspx.pdf.

newfound homes, including animal species[68] (gypsy moth, red imported fire ant, Africanized honey bees, and the Asian carp), plants (kudzu and Eurasian watermilfoil), and plant pathogens[69] (e.g., the causal agents of chestnut blight, Dutch elm disease, and white pine blister rust). Some of these were accidental introductions, while others were intentionally released or escaped. Several have essentially replaced or destroyed indigenous species through competition, predation, or disease.

The three plant pathogens listed above are of course similar to mycoherbicides used as MPCAs, in that they are pathogenic fungi which kill particular species of plants.[70] Their primary differences are that they were introduced inadvertently and the plant species they attacked were highly valued by humans, rather than weeds. It is important to remember that the term "weed" is entirely anthropocentric, in that a weed is simply defined as a plant growing someplace where humans do not want it to grow.[71] Indeed, plants that are considered weeds in agricultural settings may serve critical ecological roles in wildland habitats.

Do mycoherbicides or other MPCAs present significant risks of becoming invasive and threatening biodiversity? Is this concern such that it deserves the level of international attention afforded by an instrument with the status of the Cartagena Protocol? The following example may serve as an illustration of why this may be the case.

68. *See Animals*, U.S. DEP'T OF AGRIC. (July 19, 2012), http://www.invasivespeciesinfo.gov/animals/main.shtml#.UKK76WnuVQY.

69. *See Microbes*, U.S. DEP'T OF AGRIC. (Aug. 9, 2012), http://www.invasivespeciesinfo.gov/microbes/main.shtml#.UKK_tmnuVQY.

70. *See* X.B. Yang & David TeBeest, *Epidemiological Mechanisms of Mycoherbicide Effectiveness*, 83 PHYTOPATHOLOGY 891 (1993).

71. VERNON VANDIVER, JR. & DAVID TEEM, GENERAL PRINCIPLES OF WEED MANAGEMENT (1998), *available at* http://university.uog.edu/cals/people/PUBS/Weeds/AG00100.pdf.

VII. PROPOSED DEPLOYMENT OF MPCAS: MYCOHERBICIDES FOR CONTROL OF ILLICIT DRUG CROPS

Periodically since the 1930s, severe plant disease epidemics have been observed on coca plants in Peru.[72] A similar epidemic was observed in 1997, in Hawaii.[73] The plant pathogen which causes infected coca plants to wilt and die has been identified as the fungus *Fusarium oxysporum* f. sp. *erythroxyli*.[74] Fungal plant pathogens have also been identified for other drug crops including *Cannabis* and opium poppy.[75] By the 1990s, the use of plant pathogenic fungi as mycoherbicides was being touted as a major new tool in the war on drugs.[76] Mycoherbicides were promoted as a safer alternative to the chemical herbicides which are extensively used for drug crop eradication, especially in Colombia. This position was, somewhat uncritically, given weight by a 2002 report produced by the United Nations Office on Drugs and Crime.[77] In 2006, Congress passed a provision attached to the Office of National Drug Control Policy (ONDCP) Reauthorization Act of 2006 (H.R. 2829), requiring that the potential use of mycoherbicides against drug crops be investigated and tested in field trials.[78] Currently, the U.S. government is investigating the potential for using mycoherbicides against coca, opium poppy, and *Cannabis*, in Colombia, Afghanistan, and worldwide, respectively.

72. COMM. ON MYCOHERBICIDES FOR ERADICATING ILLICIT DRUG CROPS, BD. ON AGRIC. AND NATURAL RES., NAT'L RESEARCH COUNCIL, FEASIBILITY OF USING MYCOHERBICIDES FOR CONTROLLING ILLICIT DRUG CROPS 63 (2011).

73. *See* David Sands et al., *Characterization of a Vascular Wilt of* Erythroxylum coca *Caused by* Fusarium oxysporum f. sp. erythroxyli Forma Specialis Nova, 81 PLANT DISEASE 501 (1997).

74. *Id.* at 501.

75. *See* N. O'Neill et al., Dendryphion penicillatum *and* Pleospora papaveraceae*, Destructive Seedborne Pathogens and Potential Mycoherbicides for* Papaver somniferum, 90 PHYTOPATHOLOGY 691 (2000).

76. *See* Bryan Bailey et al., *Formulations of* Fusarium oxysporum f. sp. erythroxyli *for Biocontrol of* Erythroxylum coca var coca, 46 WEED SCI. 682 (1998).

77. *See* COMM. ON MYCOHERBICIDES FOR ERADICATING ILLICIT DRUG CROPS, *supra* note 72, at 104.

78. Pub. L. No. 109-469 § 1111 (2006).

In 2010, the National Research Council of the National Academy of Sciences, at the request of ONDCP, formed an expert committee to examine scientific issues associated with the feasibility and potential environmental consequences of using mycoherbicides to eradicate coca and opium poppy crops.[79] One threat that was specifically identified in the committee's charge was potential adverse impacts of the mycoherbicide on the biodiversity of habitats where it is applied. Coca, especially, is grown in a diversity of situations, including intercropped with food plants (sometimes for camouflage), on mountain hillsides, and deep within jungle wildlands. Concerns about biodiversity are logical, when considering the proposed wide-scale deployment of an agent whose sole purpose is to eradicate, or at least drastically reduce, a plant species. The genus *Erythroxylum*, which includes the cocaine-producing species *Erythroxylum coca*, contains approximately 250 additional species of tropical flowering plants.[80] The ecological roles of these species, which are found in a variety of South American habitats, may include stabilization of steep hillside soils and serving as a food source for herbivorous insects. There currently is relatively little available information about the susceptibility of these other *Erythroxylum* species to the proposed mycoherbicide.

In addition, limited coca production for traditional use is legal in some countries, such as Peru, Bolivia, and Chile.[81] Some indigenous cultures value the coca leaf for its medicinal qualities in alleviating hunger, fatigue, and headaches.[82] Unlike chemical herbicides, mycoherbicides have the potential to proliferate in the environment and spread to areas outside the original zone of application. The extent to which this may occur is unknown, but the possibility of persistence and spread of the fungus has been touted as one advantage of the mycoherbicide approach, since it might provide long-term control of the target crop. Of course, this

79. *See generally* COMM. ON MYCOHERBICIDES FOR ERADICATING ILLICIT DRUG CROPS, *supra* note 72.

80. *Id.* at 52.

81. *Id.* at 56.

82. *Erythroxylum Coca*, SPICES & MEDICINAL HERBS, http://www.spicesmedicinalherbs.com/erythroxylum-coca.html (last visited Nov. 24, 2012, 11:28AM).

attribute of mycoherbicides may also allow them to spread indiscriminately and affect legal and other non-target plants, or, in other words, to become invasive.

It is important to bear in mind that the organisms in question are not LMOs, but are naturally occurring fungi (although they do not naturally occur in the highly concentrated formulations in which they would be applied as mycoherbicides). As non-recombinant organisms, these fungi fall completely outside the scope of the Cartagena Protocol, regardless of any potential they may have for adverse impacts on biodiversity. However, if mycoherbicides applied in one country proliferate and spread to other states, any resulting environmental harm clearly would constitute transboundary damage.[83] There is already precedent involving the use of chemical herbicides for a claim of transboundary harm resulting from attempts to eradicate drug crops in border regions. In 2008, Ecuador filed a lawsuit against Colombia in the International Court of Justice seeking to end Colombia's application of glyphosate herbicide against coca crops growing along the border between the two countries.[84] Ecuador made the claim that herbicide drift has killed legal crops in Ecuador and resulted in illness of Ecuadoreans living near the border.

It is possible that use of mycoherbicides by Colombia near the Ecuador border could provoke a similar suit. Liability for transboundary harm in such a case might extend to more than just the originating state (Colombia), since the United States has consistently applied diplomatic and economic pressure, as well as financial assistance, for Colombia's implementation of drug crop

83. XUE HANQIN, TRANSBOUNDARY DAMAGE IN INTERNATIONAL LAW 1 (2003) (defining transboundary damage as "environmental damage which is caused by or originates in one State, and affects the territory of another").

84. Aerial Herbicide Spraying (Ecuador v. Colombia), 2008 I.C.J. 138 (Mar. 2008) (as a basis for the Court's jurisdiction, Ecuador invoked Article XXXI of the American Treaty on Pacific Settlement of 30 April 1948 (Pact of Bogotá), to which both States are parties. Ecuador further claimed that Colombia had violated customary international law as a result of transboundary harms.); *see generally* Robert Esposito, *The ICJ and the Future of Transboundary Harm Disputes: A Preliminary Analysis of the Case Concerning Aerial Herbicide Spraying (Ecuador v. Colombia)*, PACE INT'L L. REV. ONLINE COMPANION 5 (2010).

eradication programs.[85] A decade ago, Congress imposed a requirement for Colombia to test biological agents in return for counterinsurgency funding, however President Clinton quashed that requirement.[86] Part of the President's concern was that the essentially unilateral deployment of these biological pest control agents might be perceived as an act of biological warfare.[87]

Could the use of mycoherbicides against illicit drug crops actually be construed as an act of biological warfare? Proponents of the program apparently do not think so, claiming that it falls under the "peaceful use" exemption of the Biological Toxins and Weapons Convention (BTWC).[88] They also point out that Article 26 of the Single Convention on Narcotic Drugs, a treaty promulgated with U.S. backing in 1961, states that: "The Parties shall so far as possible enforce the uprooting of all coca bushes which grow wild. They shall destroy the coca bushes if illegally cultivated."[89] However, critics of the program are not so sure, and point to both the language and the reality of the "war on drugs." For example, President George W. Bush declared

85. The question of potential U.S. liability in this example is certainly arguable. The U.S. has signed but has not ratified the Pact of Bogota and thus is not a party to the treaty. The question of whether prevention of transboundary harm has been, or should be, elevated to the status of customary international law has been hotly debated. *See generally* Daniel Bodansky, *Customary (and not so Customary) International Environmental Law*, 3 IND. J. GLOBAL LEGAL STUD. 105 (1995). To the extent that customary international law is implicated, liability may be reflected in the principle of independent responsibility of States. *See* Draft Articles on Responsibility of States for Internationally Wrongful Acts, in Report of the Int'l Law Comm'n, 53d Sess. A/56/10 (2001), U.N. GAOR, 56th Sess., Supp. No. 10, at 43, Article 47 (2001) ("Where several States are responsible for the same internationally wrongful act, the responsibility of each State may be invoked in relation to that act.").

86. Memorandum of Justification in Connection with the Waivers under Section 3201(a)(4) of the Emergency Supplemental Act, as Enacted in the Military Construction Appropriations Act 2001, 36 WEEKLY COMP. PRES. DOC. 1916 (Aug. 21, 2000).

87. *See* John Otis, *Franken-fungus Push in Drug War Greeted By Fear*, HOUSTON CHRON., Jan. 18, 2007, http://www.chron.com/news/nation-world/article/Franken-fungus-push-in-drug-war-greeted-by-fear-1838135.php.

88. Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, art. X, Apr. 10, 1972, 1015 U.N.T.S. 163.

89. UNITED NATIONS OFFICE ON DRUGS & CRIME, SINGLE CONVENTION ON NARCOTIC DRUGS (1961), *available at* http://www.unodc.org/pdf/convention_1961_en.pdf.

narcotics trafficking to be a form of terrorism in his frequent references to the "war on terror,"[90] and certainly one goal of coca eradication is to reduce the flow of income to the Colombian Marxist rebel movement, FARC (Revolutionary Armed Forces of Colombia).[91] In Afghanistan as well, drug crop eradication frequently takes place against a backdrop of armed conflict. Destruction of opium poppy fields supports the U.S. war against the Taliban, who allegedly reap large profits from the opium trade.[92] The United States' history of active biological warfare research at Fort Detrick, some of which involved mycoherbicides, lends credence to the viewpoint of critics.[93]

VIII. CURRENT INTERNATIONAL REGULATION OF MPCAS

Despite a clear potential for adverse effects on biodiversity, as illustrated by the above mycoherbicide examples, non-recombinant MPCAs nonetheless fall completely outside the consideration of the Cartagena Protocol.[94] Is there an international regulatory framework that effectively covers this gap? In the U.S., regulation of pesticides (including MPCAs) is administered by the U.S. EPA. EPA's guidelines recognize that biological pesticides are best characterized for environmental safety and health risks by testing schemes that take their unique characteristics into account.[95] Consistent with the Coordinated Framework for the Regulation of Biotechnology, EPA's guidelines apply to all microbial agents used as pesticides, regardless of whether they are naturally occurring or improved by genetic manipulation.[96] Also, in compliance with the Endangered

90. TED CARPENTER, BAD NEIGHBOR POLICY: WASHINGTON'S FUTILE WAR ON DRUGS IN LATIN AMERICA 6 (2003).

91. *Id.* at 71.

92. *Id.* at 233.

93. THOMAS PRESTON, FROM LAMS TO LIONS - FUTURE SECURITY RELATIONSHIPS IN A WORLD OF BIOLOGICAL AND NUCLEAR WEAPONS 207 (2007).

94. *See* Cartagena Protocol on Biosafety to the Convention on Biological Diversity, *supra* note 8.

95. *See generally* U.S. EPA, SUBDIVISION M OF THE PESTICIDE TESTING GUIDELINES (1989).

96. *Id.*

Species Act (ESA) of 1973 that prohibits any action that can adversely affect an endangered or threatened species or its habitat, EPA must ensure that use of the pesticides it registers will not result in harm to these species.[97] For federal actions, the National Environmental Policy Act (NEPA) requires all Federal agencies to consider the environmental impact of any proposed agency action prior to taking such action, and to prepare an Environmental Impact Statement (EIS) for any proposed action that is expected to significantly affect the environment.[98] Although NEPA applies to domestic federal activities, it also has extraterritorial effect in some instances through Executive Order 12,114 on the environmental effects abroad of major federal actions.[99] Executive Order 12,114 requires that responsible officials of federal agencies be informed of environmental considerations and take those considerations into account when making decisions on major federal actions which could have environmental impacts beyond the borders of the United States.[100] NEPA case law has reinforced the need to analyze environmental impacts of federal actions, including the decision-making process, regardless of geographic boundaries.[101]

Specific international guidelines are in place for the use of MPCAs, although some of these are largely advisory in nature. The International Organization for Biological Control of Noxious Animals and Plants (IOBC) is a professional organization that promotes the development of biological control and its application in integrated pest management.[102] The IOBC serves as a clearinghouse for information on biological control, organizes conferences and symposia, and publishes a journal.[103] It has worked with various organizations in developing standards for

97. *See* 16 U.S.C. §§ 1531 *et seq*. (1973).

98. *See* 42 U.S.C. § 4332(2)(C) (2006).

99. *See* Exec. Order No. 12,114, 44 Fed. Reg. 11957 (Jan. 4, 1979).

100. *Id.*

101. *See* CHARLES ECCLESTON, NEPA AND ENVIRONMENTAL PLANNING: TOOLS, TECHNIQUES, AND APPROACHES FOR PRACTITIONERS 153 (2008).

102. *See Mission*, INT'L ORG. FOR BIOLOGICAL CONTROL, http://www.iobc-global.org/mission.html (last visited Nov. 14, 2012).

103. *See Publications,* INT'L ORG. FOR BIOLOGICAL CONTROL, http://www.iobc-global.org/publications.html (last visited Apr. 1, 2011).

testing of pesticides and rules for transport and release of biological control agents.[104]

Additional guidelines and potential limitations for testing, approval, and application of mycoherbicides against illicit crops fall under the International Plant Protection Convention (IPPC)[105] and the International Standards for Phytosanitary Measures (ISPMs).[106] The IPPC creates an international framework to prevent the spread and introduction of plant and plant product pests.[107] It is premised on exchange of phytosanitary certificates between importing and exporting countries' National Plant Protection Offices (NPPOs).[108] The provisions of the IPPC extend to any organism capable of harboring or spreading plant pests, particularly where international transportation is involved.[109] NPPOs established according to the IPPC have authority in relation to quarantine control, risk analysis, and other measures to prevent the establishment and spread of invasive alien species that, directly or indirectly, are pests of plants.[110] However, the mandate and main focus of the IPPC is to prevent pest damage to economically important plants, rather than on microorganisms intentionally deployed as microbial herbicides. Microbial agents used for

104. *See Mission*, INT'L ORG. FOR BIOLOGICAL CONTROL, http://www.iobc-global.org/mission.html (last visited Nov. 14, 2012).

105. *See* International Plant Protection Convention, Apr. 3, 1952, 23 U.S.T. 2767, 1952 U.N.T.S. 68 (revised Nov. 1997) [hereinafter IPPC].

106. *See* INT'L PLANT PROT. CONVENTION, INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES (2012), *available at* https://www.ippc.int/index.php?id=13399&L=0 [hereinafter ISPM].

107. The IPPC was revised in 1997 in response to adoption of the 1995 World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures which designates IPPC as the international standard-setting body for plant health. *See* WTO Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, SPS Agreement, 1867 U.N.T.S. 493. The revision creates formal powers to develop International Standards for Phytosanitary Measures, and clarifies the principles of phytosanitary systems in relation to international trade. *See* Sandrine Durand & Jean-Pierre Chiaradia-Bousquet, *New Principles of Phytosanitary Legislation,* FAO LEGISLATIVE STUDY 62, 1999.

108. *See* ISPM 01: PHYTOSANITARY PRINCIPLES FOR THE PROTECTION OF PLANTS AND THE APPLICATION OF PHYTOSANITARY MEASURES IN INTERNATIONAL TRADE, *supra* note 106.

109. *See* IPPC, *supra* note 105, art. I.

110. *Id.* art. IV.

control of insects and other animal pests are not addressed by the IPPC.

Additional guidance is found within the ISPMs. ISPM No. 3 provides guidelines for risk management related to the export, shipment, import, and release of biological control agents and other beneficial organisms, including mycoherbicides.[111] The standard addresses biocontrol agents capable of self-replication (for example biocontrol fungi, including those packaged or formulated as commercial products).[112] Provisions are also included for import, for research in quarantine facilities of non-indigenous biological control agents, and other beneficial organisms.[113] The standard does not address genetically modified organisms or issues specifically related to biopesticide registration.[114] Although the primary context of the ISPM No. 3 standard relates to phytosanitary concerns, "safe" usage as defined in the standard is interpreted in a broader sense, and includes concerns about the possibility that a newly introduced biological control agent might affect non-target organisms, thereby resulting in harmful effects on plant species or plant health in habitats or ecosystems.[115] ISPM No. 3 also references other standards on pest risk analysis, including "ISPM No. 2: Guidelines for Pest Risk Analysis," and "ISPM No. 11: Pest Risk Analysis for Quarantine Pests including Analysis of Environmental Risks and Living Modified Organisms";[116] these help provide processes for carrying out pest risk assessments, including determination of environmental risks.

111. *See* ISPM 03: GUIDELINES FOR THE EXPORT, SHIPMENT, IMPORT AND RELEASE OF BIOLOGICAL CONTROL AGENTS AND OTHER BENEFICIAL ORGANISMS, *supra* note 106.
112. *Id.*
113. *Id.*
114. *Id.*
115. *See id.*
116. *Id.*

IX. IS THERE A HOME IN INTERNATIONAL JURISPRUDENCE FOR POTENTIALLY INVASIVE MPCAS?

While the above guidelines serve to increase the harmonization and transparency of data requirements and procedures for risk assessment related to international use of MPCAs,[117] they lack the authority of an internationally binding instrument of the stature of the Cartagena Protocol. Equally important, they do not provide for any sort of defined liability regime. In contrast, Article 27 of the Cartagena Protocol requires the Protocol's Conference of the Parties to develop a regime that establishes "liability and redress for damage resulting from transboundary movements of living modified organisms,"[118] which was subsequently accomplished by the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (Nagoya-Kuala Lumpur Protocol).[119] As Duall noted, a legally binding regime binds the ratifying parties to honor its commitments, and provides the legal certainty necessary to protect, deter, and compensate for damages.[120] Otherwise, the only recourse for an injured party is to invoke "soft" international environmental law, or to attempt international tort actions which may be ineffective.[121] Sachs listed some of the procedural hurdles, or what he called "liability walls," to transboundary tort actions.[122] These include, for

117. *See* THE USE AND REGULATION OF MICROBIAL PESTICIDES IN REPRESENTATIVE JURISDICTIONS WORLDWIDE (J. Todd Kabaluk et al. eds., 2010).

118. *See* Cartagena Protocol, *supra* note 8, art. 27.

119. Nagoya-Kuala Lumpur Supplementary Protocol, Oct. 15, 2010, UNEP/CBD/BS/COP-MOP/5/17, Report of the Fifth Meeting of the Conference of the Parties to the Convention on Biological Diversity Serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety, Decision BS-V/11, 62-71.

120. Elizabeth Duall, *A Liability and Redress Regime for Genetically Modified Organisms Under the Cartagena Protocol*, 36 GEO. WASH. INT'L L. REV. 173, 186 (2004).

121. Gregory C. Shaffer & Mark A. Pollack, *Hard versus Soft Law in International Security*, 52 B.C. L. REV. 1148 (2011); Mary E. O'Connell, *Enforcement and the Success of International Environmental Law*, 3 IND. J. GLOBAL LEGAL STUD. 47, 53 (1995).

122. *See* Noah Sachs, *Beyond the Liability Wall: Strengthening Tort Remedies in International Environmental Law*, 55 UCLA L. REV. 837, 839, 848–51 (2008).

example, obtaining personal jurisdiction, achieving extraterritorial service of process, resolving choice of law questions, and overcoming motions to dismiss on the grounds of forum non conveniens.[123]

Absence of a liability regime results in the victim bearing the costs of remedy, an inequitable result that contradicts the general principle that the harming party pays. To provide a regime under the Cartagena Protocol that would mitigate potential biodiversity, environmental, and human health problems posed by LMOs, the Nagoya-Kuala Lumpur Protocol was adopted at COP-MOP 5, the Conference of the Parties serving as the meeting of the Parties to the Protocol.[124] Potentially invasive but non-recombinant organisms, including some MPCAs as described above, might still someday find a home within a new or amended protocol to the CBD. However, to date, they have increasingly become orphaned with each iteration of the currently LMO-fixated instruments. It would be truly ironic if non-LMO mycoherbicides, applied to vast acreages of South American wildlands or the Afghan highlands, were to become a major transboundary assault on the biodiversity of a region, since their exporters would be impervious to the proscriptions of the Cartagena Protocol, as well as to the liability regime of the Nagoya-Kuala Lumpur Protocol. At the close of COP-MOP 5, Mr. Ahmed Djoghlaf, Executive Secretary of the Convention on Biological Diversity, remarked: "This is indeed a historic event not only for the biodiversity family but also for the world community at large."[125] Expanding the scope of these two protocols to include potentially invasive non-LMOs would only serve to enhance their significance to the biodiversity of the planet.

123. *Id.* at 848.

124. *See* Nagoya-Kuala Lumpur Protocol, *supra* note 119.

125. Press Release, Convention on Biological Diversity, The Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety: World Community Adopts a New UN Treaty on Living Modified Organisms (May 10, 2011) (on file with author), *available at* https://bch.cbd.int/protocol/NKL_pressrelease.shtml.