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More Sorry than Safe: Assessing the Precautionary Principle and the Proposed International Biosafety Protocol

Jonathan H. Adler
Case Western University School of Law, jonathan.adler@case.edu

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JONATHAN H. ADLER†

SUMMARY

I. INTRODUCTION

Recent advances in biotechnology promise tremendous benefits, including fast-growing, resilient crops, more nutritious foods, new medicines and vaccines, and even new technologies for environmental decontamination. Yet modern biotechnology also inspires fear and trepidation. Greenpeace International, one of the leading anti-biotechnology environmentalist groups, warns that genetically modified crops "threaten biodiversity, wildlife and truly sustainable forms of agriculture."[1] Luddite activist Jeremy Rifkin warns that "[v]irtually every genetically engineered organism released into the environment poses a potential threat to the ecosystem . . . . Each new synthetic introduction is tantamount to playing ecological roulette."[2] Some believe genetic engineering is part of a "human siege

† Jonathan H. Adler (jadler@cei.org) is a senior fellow in environmental policy at the Competitive Enterprise Institute in Washington, D.C. The author would like to thank David Barrett, John Cohrssen, Gregory Conko, Michael Gough, and Ken Green for their input and comments. Any errors or spotty arguments are the author's alone.

1. Greenpeace International, *Genetically Engineered Food* (visited Jan. 31, 2000) <http://www.greenpeace.org/~geneng/reports/food/intrfo06.htm> (chapter 6 entitled Public Concern).

2. Jeremy Rifkin, *The Biotech Century*, E: ENVTL. MAG., May 1998, at 36.

on the natural environment" and "agriculture worldwide is at risk" from the introduction of genetically engineered crops.[3] Others even claim that the "release of transgenic organisms is much worse than nuclear weapons or radioactive wastes."[4] Until international regulation is in place, some warn, a global moratorium on the development and utilization of genetically modified organisms (GMOs)[5] is required. In the meantime, environmentalist groups continue to protest the increasing use of biotechnology to develop new strains of existing crops. Environmental protesters dumped bushels of genetically-engineered soybeans in front of British Prime Minister Tony Blair's residence, while others engage in "eco-terrorism" by destroying fields where newly engineered crops undergo field tests.[6]

Like any technological development, the ability to alter living organisms can bring both good and bad. There are potential benefits, but also potential risks. The full promise of genetic engineering has yet to be discovered. For some, the possibility of unforeseen risks is cause for regulation until the uncertainty can be resolved, irrespective of the benefits that reliance on biotechnology could bring. Advocates of this "precautionary" approach urge adoption of an international biosafety protocol—negotiated under the United Nations Convention on Biological Diversity—to regulate the use and international transfer of GMOs.

Calls for precautionary regulation of biotechnology may seem compelling—until one considers the trade-offs. Government regulation of new technology inevitably slows its development and adoption. At the margin, such regulations increase the costs of developing and marketing new products and techniques. Imposing additional regulatory burdens on a given technology lowers the expected returns from new innovations. This, in turn, provides disincentives for research. As barriers to the marketing of innovations increase, funding for research will decline.[7] As a result, excessive regulation may sacrifice the benefits of innovation in the interest of "safety." In the case of biotechnology, excessive precautionary regulation could, for example, limit the introduction of high-yield crops, nutritionally-enhanced foodstuffs, or new vaccines. While regulation of new technology is supposed to make the world a safer place, precautionary regulation of biotechnology could leave the world less safe than it would be otherwise. In short, an international biosafety protocol could make us more sorry than safe.

Part I of this paper provides a brief overview of the development of biotechnology, its regulation and its use, with a particular emphasis on agricultural biotechnology. Part II outlines the United Nations Convention on Biological Diversity, which provides an international legal framework for a biosafety protocol and summarizes the results of recent protocol negotiations, such as those conducted in Cartagena, Colombia in February 1999,

3. Karen M. Graziano, Comment, *Biosafety Protocol: Recommendations to Ensure the Safety of the Environment*, 7 COLO. J. INT'L ENVTL. L. & POL'Y 179, 185, 188 (1996).

4. Dr. Mae-Wan Ho, *The Unholy Alliance*, ECOLOGIST, July-Aug. 1997, at 158.

5. A note on word usage: the terms "genetically modified organism" and "GMO" are somewhat misleading because they imply a fundamental difference between animals and plants created through recombinant DNA (rDNA) techniques and those that are the result of other biotechnological techniques. Yet, as discussed in Part I.A., there is no real scientific difference. Even conventional methods of selection and cross-breeding modify plant and animal cells at the genetic level. The relative risk posed by an organism is a function of its particular characteristics and traits, not the method with which it was produced. Nonetheless, "genetically modified organism" and "GMO" are used throughout this paper as these terms are so widely used in discussions of biotechnology policy, particularly in the international context.

6. *See* Pat Murphy, *The Raging Debate Over Biotech Foods*, Environmental News Network (visited Mar. 8, 2000) <http://www.enn.com/enn-features-archive/2000/03/03052000/gefood_5991.asp> (noting vandalism of fields planted with genetically modified crops in England).

7. As Willy De Greef, a European plant geneticist, commented to *Science* regarding proposals for regulation of biotechnology in Europe, "There's an immense danger in this sort of overregulation .... You burden people with such a load of paper that it deters them from entering the field in the first place." Michael Balter, *How Europe Regulates Its Genes*, 252 SCIENCE 1366, 1368 (1991).

which continued in Montreal in January 2000. Part III explains why the proposed protocol embodies a variant of the precautionary principle and why such policies may do more harm than good. This paper concludes with some brief thoughts on how to approach the potential and uncertain risks and benefits of new technologies in general and of biotechnology in particular.

II. BACKGROUND ON BIOTECHNOLOGY

Biotechnology is a broad term that encompasses nearly all human efforts to change living organisms to facilitate their use.[8] Under the Convention on Biological Diversity, for example, biotechnology is defined as "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use."[9] Under this definition, biotechnology ranges from traditional cross-breeding to the selection of a single gene from one organism for the insertion into another. In policy discussions, however, the term is generally used to refer to newer biotechnology techniques, particularly the use of recombinant DNA (rDNA) techniques to modify organisms at the genetic level.[10] Indeed, this is the only form of biotechnology that is generally subject to calls for greater regulation.

A. The Promise (and Potential Pitfalls) of Biotechnology

Human modification of living organisms is nothing new.[11] For centuries, humans have selectively bred crops and animals for desirable traits. According to the National Academy of Sciences, "[a]rtificial selection has been applied to thousands of traits in a vast array of organisms, ranging from the yeasts used in baking and wine making to the livestock and plants that constitute a major part of our diet."[12] What is new is the level at which such manipulation occurs. In the twentieth century, researchers have learned to engage in selection at the genetic level.

While humans have engaged in the genetic manipulation of plant and animal species for centuries, researchers did not discover the structure of DNA until 1953. Gregor Mendel outlined the basic principles of genetics in the 1860s, but his work was largely ignored until this century.[13] When James Watson and Frances Crick discovered the double helix structure of DNA, scientists quickly solved the mystery of genetic replication. Combined with the insights of Oswald Avery and his colleagues who developed bacterial genetics, Watson and Crick's discovery laid the groundwork for molecular genetics. It was only a

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8. *See* ERIC GRACE, BIOTECHNOLOGY UNZIPPED 2 (1997) ("[B]iotechnology is an umbrella term that covers various techniques for using the properties of living things to make products or provide services.").

9. United Nations Convention on Biological Diversity, June 5, 1992, art. 2, 31 I.L.M. 818, 823 (1992) [hereinafter CBD].

10. The European Union's directive on the release of genetically modified organisms, for example, defines a GMO as "an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination." Council Directive 90/220, art. 2, 1990 O.J. (L 117) 16. This definition includes the results of chemical and radiation mutagenesis in addition to rDNA techniques.

11. Indeed, prior to the 20th century, the term biotechnology was used to describe various uses of living organisms for fermentation and other purposes. *See* GRACE, *supra* note 8, at 2.

12. COMMITTEE ON THE INTRODUCTION OF GENETICALLY ENGINEERED ORGANISMS INTO THE ENVIRONMENT, INTRODUCTION OF RECOMBINANT DNA-ENGINEERED ORGANISMS INTO THE ENVIRONMENT: KEY ISSUES 10 (1987) [hereinafter COMMITTEE].

13. *See* Bernard D. Davis, *The Background: From Classical to Molecular Genetics*, *in* THE GENETIC REVOLUTION: PROSPECTS AND PUBLIC PERCEPTIONS 10 (Bernard D. Davis ed., 1991).

matter of time before scientists were able to isolate specific genetic sequences and identify their functions. Today, scientists are able to cut and remove specific genes or genetic sequences from one cell and transplant them into another. This technique is known as rDNA technology.

The ability of researchers to isolate individual genes through rDNA techniques has produced an explosion of innovation. Efforts to genetically modify crops and other organisms now occur with far more precision and predictability. They also expand the genetic combinations that can be created, as they enable the insertion of a gene from one organism into almost any other, irrespective of their sexual compatibility or genetic relation. Thus, a bacterium's ability to create a particular protein that is toxic to certain insects can be transferred to a crop, or one plant's ability to produce particular nutrients can be transferred to another.

More traditional forms of bioengineering are less precise and harder to control than DNA recombination. As the National Academy of Sciences noted, "a mutation made by traditional techniques may be accompanied by many unknown mutations, which often have deleterious effects on the organism."[14] Efforts to transfer one gene can lead to the transfer of other, unwanted genes, lengthening the time and expense required to develop a new hybrid with the desired traits. As a result, cross-breeding that once took seven to eight years or even longer can now be achieved in less than half the time with rDNA techniques.[15]

The fruits of the "new biotechnology," as it is called by some, have been tremendous. In the past decade alone, numerous new pharmaceuticals and beneficial products have been developed, from treatments for diabetes and hemophilia to microorganisms that can assist in pollution cleanup.[16] The use of rDNA techniques has been a particular boon for agriculture. Scientists have already developed pest- and herbicide-resistant crops, fruits that ripen slowly or resist frost, and many other modified plants. Acidic and metal-rich soils stunt agricultural productivity on as much as twelve percent of agricultural land worldwide, yet researchers are close to developing metal-resistant crop strains that have been difficult to develop through traditional hybridization techniques.[17] One popular GMO is a new tomato with increased solid content that improves the taste and texture of tomato paste and processed sauces. An earlier invention was a recombinant form of cow hormone that increases production of milk. Other developments still in the works include soybeans that produce healthier oils, rice and grains with greater nutritional content, and bananas and potatoes that provide doses of vaccines.[18] One company is even trying to develop cotton that is naturally colored, reducing the need for chemical dyes in textile manufacture.

The use of genetically modified crops has expanded rapidly since their introduction only a few years ago. Since 1986, researchers around the world have conducted over 2000 field trials with genetically engineered crops.[19] As of 1998, at least 30 million hectares

14. COMMITTEE, *supra* note 12, at 11.

15. *See* Richard A. Melcher et al., *Field of Genes*, BUS. WK., Apr. 12, 1999, at 64.

16. A listing of various products and processes produced through biotechnology can be found on the Biotechnology Industry Organization website <http://www.bio.org>. Examples of biotechnology drugs and vaccines approved by the FDA in the 1980s and late 1990s for various conditions include OncoScint® CR/OV (colorectal and ovarian cancer), Proleukin® (renal cell carcinoma), Humulin® (diabetes), KoGENate® (hemophilia A), Alferon® N (genital warts), and Engerix-B® (hepatitis B). *See* HENRY I. MILLER, POLICY CONTROVERSY IN BIOTECHNOLOGY: AN INSIDER'S VIEW 5–7 (1997).

17. *See* Anne Simon Moffat, *Engineering Plants to Cope with Metals*, 285 SCIENCE 369, 369 (1999).

18. *See* Anne Simon Moffat, *Toting Up the Early Harvest of Transgenic Plants*, 282 SCIENCE 2176, 2178 (1998).

19. *See* GRACE, *supra* note 8, at 109.

were planted with genetically modified crops around the globe.[20] In the United States, crops altered with rDNA techniques now account for at least forty-five percent of cotton, thirty-eight percent of soybeans, and twenty-five percent of corn grown.[21] Current estimates place the market for genetically engineered crops and derived products at $4 billion, and this value is expected to hit $20 billion within five years.[22]

The scientific community, on the whole, has been supportive of these developments and unconvinced that biotechnology poses substantial risks to human health or to the environment.[23] Most scientific reports stress that rDNA techniques are merely the latest form of genetic selection practiced by humanity and that the risks of new GMOs should be evaluated based upon the characteristics of the particular organism in question, not whether rDNA techniques were used to create it. For instance, in a 1987 review of the potential impact of releasing rDNA-engineered organisms into the environment, an expert panel convened by the Council of the National Academy of Sciences concluded that "[t]here is *no evidence* that unique hazards exist either in the use of R-DNA techniques or in the transfer of genes between unrelated organisms."[24] According to the Council, the risks posed by the release of GMOs into the environment, while real, "are the same in kind" as those posed by the introduction of unmodified organisms.[25] In its 1989 review of biotechnology, the National Research Council similarly concluded that "no conceptual distinction exists between genetic modification of plants and microorganisms by classical methods or by molecular techniques that modify DNA and transfer genes."[26]

Perhaps the strongest conclusions came from the 1992 report of the National Biotechnology Policy Board, which concluded that

> [t]he risks associated with biotechnology are not unique, and tend to be associated with particular products and their applications, not with the production process or the technology *per se*. In fact, biotechnology processes tend to reduce risk because they are more predictable. The health and environmental risks of not pursuing biotechnology-based solutions to the nation's problems are likely to be greater than the risks of going forward.[27]

Most private scientific groups reached similar conclusions. The Ecological Society of America, while a bit more cautious than the National Biotechnology Policy Board, proclaimed that "[g]enetically engineered organisms should be evaluated and regulated according to their biological properties (phenotypes), rather than the genetic techniques used to produce them."[28]

The prestigious British scientific journal *Nature* editorialized in 1992 that "no conceptual distinction exists between genetic modification of plants and microorganisms by

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20. *See* Moffat, *supra* note 18, at 2176.

21. *See* Siobhan Gorman, *Future Pharmers of America*, NAT'L J., Feb. 6, 1999, at 355.

22. *See* Melcher et al., *supra* note 15, at 64.

23. *See, e.g.*, Institute of Food Technology, *Appropriate Oversight for Plants with Inherited Traits for Resistance to Pests: A Report from 11 Professional Societies* (visited Feb. 19, 2000) <http://www.ift.org/sc/stat>.

24. COMMITTEE, *supra* note 12, at 6 (emphasis added).

25. *Id.*

26. NATIONAL RESEARCH COUNCIL, FIELD TESTING GENETICALLY MODIFIED ORGANISMS: FRAMEWORK FOR DECISIONS 14 (1989).

27. NATIONAL INSTITUTES OF HEALTH, 1992 REPORT OF THE NATIONAL BIOTECHNOLOGY POLICY BOARD, 2 (1992) [hereinafter NBPB REPORT].

28. James M. Tiedje et al., *The Planned Introduction of Genetically Engineered Organisms: Ecological Considerations and Recommendations*, 70 ECOLOGY 298, 298 (1989).

classical methods or by molecular techniques that modify DNA and transfer genes."[29] In 1999, after years of further research on the potential impacts of biotechnology, *Nature* declared again that "[t]here is as yet no substantial evidence that GM [genetically modified] foods are inherently more dangerous than conventional foods just because they have been produced using novel techniques."[30] According to Henry Miller, former head of the Food and Drug Administration's Office of Biotechnology, "[t]he introduction of a new gene—even one in a location unlikely to occur in nature—does not necessarily affect an organism's relative risk."[31]

Despite the near scientific consensus on relatively minor risks posed by the use of rDNA techniques, environmental activists are concerned that genetically modified plants could pose new, unprecedented threats to environmental protection and human health. The Union of Concerned Scientists calls for stringent regulation of biotechnology and cautions that "scientists have identified a number of ways in which genetically engineered organisms could potentially adversely impact both human health and the environment."[32] Karen Graziano, who helped develop the Center for International Environmental Law's call for a moratorium on the use or development of GMOs, argues that "new combinations of traits not naturally occurring in the environment can produce unexpected and unwanted environmental effects."[33] *Rachel's Environment & Health Weekly*, an anti-technology environmentalist newsletter, warns that "fundamentally, genetically-engineered crops substitute human wisdom for the wisdom of nature."[34] Jeremy Rifkin, a longtime opponent of all forms of genetic research, calls the introduction of GMOs "the most radical, uncontrolled experiment we've ever seen."[35] The Institute for Agriculture and Trade Policy's Kristin Dawkins echoes, "Genetic pollution is considerably more dangerous than oil spills. You can't just go out there and put a boom around it and put it back in."[36]

It must be remembered, however, as noted above, that humans have been modifying the genetic composition of crops since the dawn of agriculture. Research published in early 1999 indicates that the domestication of maize (corn) 7500 years ago was facilitated by genetic manipulation of teosinte by early farmers.[37] Interestingly enough, the domestication of maize did not lead to a reduction in its genetic diversity. Rather, researchers have found that "maize is more genetically diverse than many wild plants," including those from which maize was developed.[38]

It is a mistake to view modern biotechnology techniques as fundamentally new or particularly dangerous technologies. Rather, as Henry Miller explains, "[t]he techniques of the new biotechnology are best viewed as extensions, or refinements, of older techniques for genetic manipulation and domestication."[39] Just as human efforts to modify other living organisms are nothing new, concerns about the potential impacts of the hybridization of

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29. *U.S. Biotechnology Policy*, 356 NATURE 1, 2 (1992).

30. *GM Foods Debate Needs a Recipe for Restoring Trust*, 398 NATURE 639, 639 (1999).

31. Henry I. Miller, *UN-based Biotechnology Regulation: Scientific and Economic Havoc for the 21st Century*, TRENDS IN BIOTECHNOLOGY, May 1999, at 188.

32. Union of Concerned Scientists, *Risks of Genetic Engineering* (visited Jan. 28, 2000) <http://www.ucsusa.org/agriculture/gen.risks.html> [hereinafter UCS].

33. Graziano, *supra* note 3, at 185.

34. *Against the Grain, Part 2*, RACHEL'S ENVTL. & HEALTH WKLY., ¶ 22 (Feb. 18, 1999) <http://www.rachel.org/bulletin/bulletin.cfm?issue_ID=1253&bulletin_ID=48>.

35. Gorman, *supra* note 21, at 355.

36. Rick Weiss & Justin Gillis, *U.S. 'Observers' Lobby Against Trade Curbs on Biotechnology*, WASH. POST, Feb. 13, 1999, at A4.

37. *See* Svante Paabo, *Neolithic Genetic Engineering*, 398 NATURE 194, 194 (1999).

38. *Id.*

39. Henry I. Miller, *Regulation*, *in* THE GENETIC REVOLUTION: PROSPECTS AND PUBLIC PERCEPTIONS 207–08 (Bernard D. Davis ed., 1991).

species have been around for a century, if not longer. In 1906, decades before modern bioengineering methods were even contemplated, plant geneticist Luther Burbank warned: "We recently advanced our knowledge of genetics to a point where we can manipulate life in a way never intended by nature. We must proceed with utmost caution in the application of this new found knowledge."[40]

Modified organisms are not risk-free, whether developed through classical or modern techniques.[41] "There are hidden risks in any form of plant breeding," according to Ben Miflin, former director of England's Institute of Arable Crops.[42] Efforts to breed better vegetables with traditional techniques produced dangerously high levels of the natural carcinogen psoralen in celery and the natural pesticide solanine in potatoes.[43] Yet there is no evidence that such mishaps are any more likely as a result of genetic recombination techniques. In fact, many biotechnology proponents argue that such impacts are *less* likely because modern genetic engineering techniques enable researchers to insert genes with more precision. Using the latest techniques, it is less likely that efforts to give a particular organism a "positive" attribute will transfer a "negative" attribute as well. *Nature* notes that in conventional breeding "in addition to introducing a desired trait into a crop from a wild relative, breeders have no idea what other changes they may have introduced through the integration of large chunks of the donor genome."[44]

The Union of Concerned Scientists (UCS), among others, raises additional concerns.[45] For instance, the UCS warns that transferring a gene from one organism to another could trigger allergic reactions, as consumers would be unaware that one product, say carrots, contained genes from another to which a consumer is allergic. Pioneer Hi-Bred discontinued the development of a new soybean modified with a Brazil nut gene when the company's tests revealed that people allergic to Brazil nuts would also be allergic to the new soybean.[46]

While these risks are conceivable, they are not particularly unique to the use of rDNA techniques. As the Organization for Economic Cooperation and Development found in its 1993 report, although modern biotechnology expands the scope of possible sources of foods, "this does not inherently lead to foods that are less safe than those developed by conventional techniques."[47] Allergies, for instance, can be transferred through traditional cross-breeding techniques.

One prominent concern is that the introduction of modified organisms into the broader environment could disrupt local ecosystems. The introduction of non-indigenous animal and plant species, ranging from feral pigs in Hawaii and feral cats in Australia, to snails in Southeast Asia and kudzu throughout much of the United States, are testament to

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40. Thomas P. Redick et al., *Private Legal Mechanisms for Regulating the Risks of Genetically Modified Organisms: An Alternative Path Within the Biosafety Protocol*, 4 ENVTL. LAW. 1, 11–12 (1997).

41. Much the same can be said of *any* technology, no matter how primitive or advanced.

42. Declan Butler & Tony Reichhardt, *Long-term Effect of GM Crops Serves Up Food for Thought*, 398 NATURE 651, 652 (1999).

43. *See* Frank B. Cross, *Paradoxical Perils of the Precautionary Principle*, 53 WASH. & LEE L. REV. 851, 873 (1996). Ironically, in both cases breeders were attempting to develop pest-resistant crops to reduce the need for conventional pesticides.

44. Butler & Reichhardt, *supra* note 42, at 653.

45. Most of these concerns are outlined on the UCS web page, *see* UCS, *supra* note 32, at 1, as well as in JANE RISSLER & MARGARET MELLON, THE ECOLOGICAL RISKS OF ENGINEERED CROPS (1996).

46. *See* Rick Weiss, *Biotech Food Raises a Crop of Questions*, WASH. POST, Aug. 15, 1999, at A1. One of the reasons that Pioneer Hi-Bred opted not to market the modified soybean was a concern for potential liability and the fact that the FDA was likely to require labeling on products derived from the soybean. *See* Henry I. Miller, *A Rational Approach to Labeling Biotech-Derived Foods*, 284 SCIENCE 1471, 1472 (1999).

47. MILLER, *supra* note 16, at 26.

the havoc that exotic species can cause. The introduction of exotics is believed to be a substantial contributor to species extinction.[48] Historically, none of the culprits were created through modern biotechnology and only a small percentage of introduced species become destructive pests. As noted above, the additional precision offered by rDNA techniques, if anything, makes the introduction of a new "pest" species less likely, as it reduces the chances of inadvertently transferring unwanted genetic traits from one species to another. Moreover, those traits that are genetically transferred to crops, such as resistance to a particular chemical or pest, are unlikely to confer any competitive advantage over wild plants that would lead to a substantial invasion.[49] Indeed, pathogenicity and "weediness" are functions of multiple genetic traits, so the transfer of one or two is unlikely to transform a relatively innocuous crop into an invasive or disruptive species.[50]

Concerns about the ecologically disruptive impact of bioengineered crops peaked in May 1999 with the release of a study suggesting that "Bt" crops threaten butterfly populations. Bt crops—typically corn, cotton, or potatoes—are modified with a gene from the *Bacillus thuringiensis* (Bt) bacterium to produce a natural pesticide, thereby protecting the crops from pest species, such as the European Corn Borer. A preliminary study published in *Nature* found that monarch butterfly larvae raised on a diet of leaves dusted with pollen from Bt corn fared worse than those fed leaves with unmodified corn pollen or undusted leaves.[51] Environmental activists seized on this news to urge new limitations, if not an outright ban, on Bt crops.[52] Yet, it is not clear that the study indicated a serious threat to butterfly populations. Researchers at the National Biological Impact Assessment Program at Virginia Tech note that "experts predict little impact on monarch larvae beyond the edges of Bt corn fields," in large part because the exposure to Bt pollen in the study were far greater than what could ever be expected in the wild.[53] Indeed, the lead author of the study commented that the "study was conducted in the laboratory, and . . . it would be inappropriate to draw any conclusions about the risk to monarch populations in the field based solely on these initial results."[54]

While some of the concerns raised about the use and proliferation of genetically engineered organisms are legitimate, few, if any, of these concerns are unique to organisms modified through rDNA techniques. For this reason, most of the scientific community does not believe that biotechnology requires its own regulatory regime.[55] Nonetheless, in the

48. *See* Stephen R. Edwards, *Conserving Biodiversity: Resources for Our Future*, *in* THE TRUE STATE OF THE PLANET 222 (Ronald Bailey ed., 1995).

49. *See* Declan Butler et al., *Assessing the Threat to Biodiversity on the Farm*, 398 NATURE 654, 655 (1999).

50. *See* Miller, *supra* note 39, at 201.

51. *See* John E. Losey et al., *Transgenic Pollen Harms Monarch Larvae*, 399 NATURE 214, 214 (1999).

52. Friends of the Earth, for example, issued a letter to President Clinton calling for the cancellation of Bt crop registrations and new regulations on genetically modified crops. The letter also was signed by representatives of the Campaign for Food Safety, Community Nutrition Institute, Defenders of Wildlife, Green Choice Party of New York, Institute for Agriculture and Trade Policy, Migratory Species Project, Organic Consumers Association, and the Pure Food Alliance of Massachusetts. *See* Friends of the Earth, *Letter to President Clinton* (visited Jan. 28, 2000) <http://www.foe.org/safefood/lettertoclinton.html>. The Environmental Defense Fund also petitioned the Environmental Protection Agency to impose new limits on the planting of Bt crops. *See* Environmental Defense Fund, *EPA Asked to Limit Genetically Engineered Corn to Protect Butterflies* (visited Jan. 28, 2000) <http://www.edf.org/pubs/NewsReleases/1999/Jul/c_butterflies.html>; The Environmental Defense Fund, *Petition* (visited Jan. 28, 2000) <http://www.edf.org/issues/Btcompetition.html>.

53. Ruth Irwin, *Butterfly Brouhaha*, ISB NEWS REP., July 1999, at 2; *see also* Peter Kendall, *Data Show Corn Pollen Little Threat to Butterfly*, CHI. TRIB., Nov. 10, 1999, at E1.

54. Michael Fumento, *The World Is Still Safe for Butterflies*, WALL ST. J., June 25, 1999, at A18 (quoting John Losey of Cornell).

55. For a critique of several of the fears raised about the use of rDNA techniques, *see generally* Miller, *supra* note 39, at 197–203.

United States and elsewhere, plants modified with rDNA techniques are subject to special regulatory requirements.

B. Domestic Regulation of Biotechnology

No federal regulatory statute explicitly targets agricultural biotechnology. Nonetheless, genetically modified organisms are subject to regulation by three separate agencies: the Department of Agriculture's Animal and Plant Health Inspection Service (APHIS), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA).[56] Under all three programs, GMOs are regulated due to the method of their production rather than to any inherent or likely risks from specific products or creations.

One reason for the regulation of GMOs is their apparent novelty. After the discovery of DNA, advances in genetics occurred rapidly. The first successful transfer of genetic material from one organism to another through DNA recombination occurred in 1973.[57] These experiments prompted broad speculation about the potential unknown risks of biotechnology research. Some scientists were uncertain about the potential uses to which these new techniques could be put and how the public would respond. These concerns produced a voluntary moratorium on rDNA research in 1974. Two years later, the National Institutes of Health's Recombinant DNA Advisory Committee issued guidelines for rDNA research which were adopted, in turn, by all federal agencies sponsoring related research.[58]

The National Institutes of Health (NIH) relaxed its guidelines in 1978 as it became clear that the risks posed by rDNA techniques were overstated. In the words of one commentator, the NIH recognized "the shallowness of the thought that had led to the early restrictiveness."[59] Although the guidelines only applied to federally supported research, most, if not all, private firms complied with the rules. The emerging biotech industry sought regulatory certainty and was willing to accept government regulation of research and development if it prevented more extreme regulatory responses down the road.

A potential turning point in federal regulation occurred in the early 1980s when researchers at the University of California sought to field test bacteria—the ice-minus bacteria—that were genetically modified to retard frost damage in plants. Because the researchers received government research support, they applied for NIH approval of the field tests. When the NIH approved the application in 1983 after nearly a year of review, environmental activists sued, charging that the NIH violated the procedural requirements of the National Environmental Policy Act[60] by failing to conduct an environmental impact assessment of the test.[61] A federal court enjoined the test while the assessment was prepared, and the Environmental Protection Agency announced that it would require researchers to obtain experimental use permits for the field testing of any microbial agent used as a pesticide or plant regulator.[62]

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56. Other agencies are involved in the regulation of biotechnology outside of the agricultural context. For instance, the Occupational Health and Safety Administration (OSHA) regulates workplace safety as it relates to biotechnology, and the National Institutes of Health and the National Science Foundation regulate biotechnology research that is funded by federal tax dollars.

57. *See* NBPB REPORT, *supra* note 27, at E-2.

58. *See id.*

59. *Id.* at E-3 n.4.

60. 42 U.S.C. §§ 4321–4347 (1999).

61. *See* Foundation on Econ. Trends v. Heckler, 587 F. Supp. 753, 755–56 (D.D.C. 1984), *aff'd*, 756 F.2d 143 (D.C. Cir. 1985).

62. *See* NBPB REPORT, *supra* note 27, at E-10, E-11.

While the ice-minus tests finally occurred in 1987 (once the researchers obtained an experimental use permit from the EPA), the resulting controversy had produced significant federal regulation of genetically modified organisms. The FDA and the EPA established procedures for the review of pharmaceuticals and pesticides, respectively, that were produced with genetic engineering techniques. In July 1987, the APHIS also adopted regulations covering the "introduction of organisms and products altered or produced through genetic engineering which are plant pests or which there is reason to believe are plant pests."[63] Thus, from the beginning, plants developed through rDNA techniques were subject to precautionary regulation.

To this day, Congress has not authorized any specific measures to regulate biotechnology. Regulation of GMOs by the APHIS, FDA, and EPA is all based upon pre-existing statutory authority. In each instance, federal regulators are looking to see whether GMOs pose risks that these agencies are supposed to control. The APHIS, for instance, requires permits or notifications when a company seeks to move or release a genetically modified plant. Field tests of such plants, which the APHIS labels potential plant pests, constitute releases under the agency's regulations, irrespective of the size of the test.[64] Plants that are deemed to pose a relatively minor risk of escape into the broader environment can be released after a simpler notification procedure finalized by the APHIS in 1997.[65] Interestingly, there is no equivalent regulation of the introduction of species modified by more "traditional" cross-breeding techniques.

Under section 402(a)(1) of the Federal Food and Drug Cosmetic Act (FDCA),[66] the FDA is empowered to regulate "food additives," which are defined to include those compounds produced with rDNA techniques that could become components of food. Despite this authority, the FDA has not imposed additional regulatory burdens on biotechnology products beyond consultation requirements. Beginning in 1992, the FDA required companies to provide pre-market notification to the FDA of efforts to sell foods derived from GMOs. The FDA will require the labeling of GMO-containing foods if there is reason to believe that the introduced genes could act as allergens, or if the GMO-based product has a nutritive value that is different from what consumers could reasonably expect.[67]

The EPA probably imposes the strictest regulations on GMOs of the three relevant federal agencies. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),[68] the EPA is authorized to regulate the use of pesticides and their concentrations in foods. Under FIFRA, pesticides are defined to cover "any substance or mixture," including biological agents or organisms, "intended for preventing, destroying, repelling or mitigating any pest, and . . . intended for use as a plant regulator, defoliant, or desiccant."[69] The EPA has interpreted this definition to include substances produced by plants that enable crops to resist pests or disease and the genetic material used to create them.[70] Thus, the EPA has the authority to regulate crops that are genetically engineered for greater pest resistance and even plant hormones that regulate plant growth and maturation. At present,

63. 52 Fed. Reg. 22,892 (1987).

64. *See* Judith E. Beach, *No "Killer Tomatoes": Easing Federal Regulation of Genetically Engineered Plants*, 53 FOOD & DRUG L.J. 181, 182–83 (1998).

65. *See* 62 Fed. Reg. 23,945 (1997); *see also* Beach, *supra* note 64, at 183.

66. 21 U.S.C. § 348(a) (1999).

67. *See* Beach, *supra* note 64, at 184–85.

68. 7 U.S.C. § 136 (1999).

69. *Id.* at § 136(u).

70. *See* Beach, *supra* note 64, at 190.

the EPA is finalizing new regulations of these so-called "plant-pesticides" that will tighten testing and reporting requirements for genetically engineered plants.[71]

Before any pesticide can be sold, it must be registered with the EPA. This process requires the applicant to demonstrate, based on experimental data, that the pesticide in question, when properly used, will not impose an unreasonable risk to public health or the environment. Thus, applicants must typically conduct field tests of the pesticide, which themselves require experimental use permits.[72] Once data on the proposed pesticide is collected, it typically takes several additional years for the EPA to review the registration application, particularly if the pesticide in question is not "substantially similar" to one that is already registered.[73] Under FIFRA, the EPA is also authorized to grant "conditional registrations" of new pesticides while awaiting the experimental data necessary for a final decision on an application. Regulation of GMOs in the United States may be less stringent than in some other countries, but it is still strict enough to impose a serious chilling effect on biotechnology research and development. As the National Biotechnology Policy Board concluded, "[f]ield testing of genetically engineered plants is much more expensive than for other plants."[74]

C. *International Regulation of Biotechnology*

Many environmental activists allege that existing domestic and international regulation of biotechnology is insufficient to protect human health and the environment. In particular, they wish to adopt precautionary measures and increase the stringency of regulation of GMOs that cannot conclusively be demonstrated safe. Despite these efforts, there is, as of yet, no international regulation of biotechnology. Most other industrialized nations do regulate biotechnology, however, and there is pressure to tighten regulatory requirements in Europe. In addition, international trade rules certainly impact the development and sale of GMOs and GMO-derived products.

Europe and Japan currently regulate biotechnology more stringently than the United States. Japan, for instance, has regulations that specifically focus on the process with which foods and food additives are developed. The Japanese Ministry of Health and Welfare has implemented a regulatory regime that applies special standards to genetically modified products.[75] While Japan has a sizable biotechnology industry, at least for fermentation products, these regulations are blamed for the low number of field trials of genetically engineered plants in Japan.[76] Japan is also in the process of developing labeling rules for biotech foods. In August 1999, Japan's Ministry of Agriculture, Forestry, and Fisheries announced that, beginning in 2001, it will mandate labels on food products

71. *See* Proposed Policy; Plant-Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act, 59 Fed. Reg. 60,496 (1994); Plant-Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act; Proposed Rule, 59 Fed. Reg. 60,519 (1994) (to be codified at 40 C.F.R. pts. 152, 174) (proposed Nov. 23, 1994).

72. *See* Beach, *supra* note 64, at 189.

73. *See id.* at 189–90.

74. NBPB REPORT, *supra* note 27, at E-19.

75. *See* MILLER, *supra* note 16, at 162.

76. *See id.*

containing or derived from GMOs.[77] Additional regulation of agricultural biotechnology is also under consideration.[78]

Regulations in the European Union (E.U.) are even more stringent and are still evolving.[79] Germany's Genetic Technology Law, for example, requires the permission of the Federal Health Authority for the introduction of any GMO.[80] The European Union as a whole imposes strict regulatory standards on the use and introduction of GMOs and has banned the use of certain genetically engineered products.[81] For instance, dairy farmers in the European Union may not use recombinant bovine somatotropin, a growth hormone used in many dairy farms in the United States.[82] E.U. directives regulate the contained use of genetically modified microorganisms in laboratory research,[83] planting of genetically modified crops and other "deliberate releases" into the environment,[84] the marketing and sale of genetically modified products,[85] and the labeling of foods made from GMOs.[86]

E.U. Directive 90/220 regulates the "deliberate release" of genetically modified organisms, whether for field tests, agricultural production, or sale, as well as the marketing of GMOs for that purpose.[87] The directive requires that all E.U. member nations "ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or placing on the market of GMOs."[88] In particular, a company or researcher seeking to "release" a GMO, such as a genetically modified strain of corn that is being field tested, must submit notification to the relevant regulatory authority in the nation in which the release will occur.[89] This notification must include, among other things, "a statement evaluating the impacts and risks posed by the GMO(s) to human health or the environment from the uses envisaged."[90] The national authority must then evaluate the notification and render a decision as to whether the release will be allowed within ninety days.[91]

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77. *See Panel OKs List of 30 Food Products for GMO Labeling*, JAPAN ECON. NEWSWIRE, Aug. 10, 1999, *available in* LEXIS, News Library, Non-US News File; Irene Marushko, *Japan to Proceed with GMO Labeling* (visited Jan. 13, 2000) <http://biz.yahoo.com/rf/990930/9k.htm>.

78. *See* Toshio Aritake, *Japan Weighs Safety Guidelines for Production of GMO Crops*, INT'L ENV'T. REP., Sept. 1, 1999, at 719.

79. The "frequently changing" nature of European rules on biotechnology, particularly for the European Union, generates substantial legal uncertainty which "significantly impacts U.S. agricultural producers seeking access to the European market." Terence P. Stewart & David S. Johanson, *Policy In Flux: The European Union's Laws on Agricultural Biotechnology and Their Effects on International Trade*, 4 DRAKE J. AGRIC. L. 243, 246–47 (1999).

80. *See* Graziano, *supra* note 3, at 181.

81. For a useful overview of E.U. biotech regulation, *see generally* Rod Hunter, *European Regulation of Genetically Modified Organisms*, *in* FEARING FOOD: RISK, HEALTH & ENVIRONMENT (Julian Morris & Roger Bate eds., 1999).

82. Interestingly enough, there is no limit on the importation of milk from cows that were treated with growth hormones. This is probably because milk from hormone-fed cows is indistinguishable from other milk, and therefore such an import restriction would be challenged under World Trade Organization rules.

83. *See* Council Directive 90/219, 1990 O.J. (L 117) 1.

84. Council Directive 90/220, 1990 O.J. (L 117) 15.

85. *See id.*

86. *See* Council Regulation 258/97 Concerning Novel Foods and Novel Food Ingredients, art. 1, 1997 O.J. (L 43) 2. Other E.U. regulations impacting biotechnology are the directives on biological agents at work (90/679) and the transportation of "dangerous" goods (94/55).

87. The directive defines deliberate release as "any intentional introduction into the environment . . . without provisions for containment . . . ." Council Directive 90/220 on the Contained Use of Genetically Modified Micro-Organisms, Part A, art. 2, 1990 O.J. (L 117) 16.

88. *Id.* at Part A, art. 4; Council Directive 90/220, Part A, art. 4, 1990 O.J. (L 117) 17.

89. *See id.* at Part B, art. 5.

90. *See id.*

91. *See id.* at art. 6.

Directive 90/220's notification and consent requirements for the marketing of GMOs are more stringent. First, the GMO in question must either have been field tested in compliance with the "deliberate release" provisions of the directive, or have undergone an equivalent risk analysis. Second, once a notification has been submitted and accepted by the relevant national authority, it is submitted to the European Commission for approval by a qualified majority of E.U. members.[92] Once approved by the European Union as a whole, the product in question may be marketed throughout the European Union without any additional notification requirements, provided that no member country objects.[93]

Under Article 16 of Directive 90/220, any E.U. member country may "provisionally restrict or prohibit" use or sale of a product if it has "justifiable reasons" that an approved product poses "a risk to human health or the environment."[94] Then the European Commission must again review the product in question and determine whether such restrictions are justified and reach a decision within three months.[95] If the Commission fails to make a decision, the proposal is forwarded to the E.U. Council of Ministers, which votes on the proposal.[96] If the Council fails to vote on the proposal, the Commission will adopt it.[97]

This procedure has not worked well in practice. While many genetically modified products have been approved for sale in the European Union,[98] individual nations have nonetheless imposed bans on approved products under Article 16. France submitted a proposal to allow the marketing of Ciba-Geigy's[99] genetically modified maize in March 1995.[100] Despite the objections of several countries, the Commission approved the proposal in January 1997, in large part due to concerns about international competitiveness and favorable reports from the relevant E.U. scientific committees.[101] Within two months, Austria and Luxembourg banned its sale within their territories, citing their authority to "provisionally restrict" sale of an approved GMO if there are legitimate concerns that the product could threaten human health or the environment. Austria and Luxembourg's claims were reviewed by the scientific committees and found to be groundless.[102] As of October 1999, the Commission had yet to issue a ruling to require that Austria and Luxembourg allow the sale of the modified maize, and sale of the modified maize remained illegal in two E.U. nations, despite its official approval by the European Union.[103]

The European Union also requires the labeling of foods containing or derived from GMOs under Directive 90/220 and the Novel Food Regulation.[104] In particular, companies must provide labels that inform consumers of "any characteristic or food property such as

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92. *See id.* at arts. 12–13.

93. *See id.* at art. 15.

94. *See id.* at art. 16.

95. These procedures are laid out in article 21. *See id.* at art. 21.

96. *See id.*

97. *See id.*

98. *See* Hunter, *supra* note 81, at 213.

99. It is important to note that since the application was filed, Ciba-Geigy merged with Sandoz and adopted the new corporate name of Novartis.

100. These events are summarized in Hunter, *supra* note 81, at 213–15 and in Stewart & Johanson, *supra* note 79, at 260–68.

101. *See* Stewart & Johanson, *supra* note 79, at 262–63.

102. *See id.* at 266.

103. *See* Hunter, *supra* note 81, at 214. Austria also banned a modified maize engineered by Monsanto in May 1999, but the E.U. scientific committees found no scientific basis for this action either. *See EU Scientists Reject Austrian Evidence on GM Maize* (visited Feb. 19, 2000) <http://LegalNews.findlaw.com/science/s/19991020/genesmaize.htm>.

104. *See* Regulation 258/97 1997 O.J. (L 43) 1.

composition, nutritional value or nutritional effects," including the fact that it is derived from genetically modified organisms "which renders a novel food or food ingredient no longer equivalent to an existing food or food ingredient."[105] In addition, companies must label any foods that actually contain GMOs.[106] Products containing food ingredients that *may* contain GMOs must also be labeled to this effect.[107] How broadly these requirements will be interpreted is unclear, but it is worth noting that some E.U. member countries believe that the labeling requirements do not only apply to manufacturers and distributors. Indeed, some suggest that these rules could even require restaurants to disclose whether dishes are made from foods derived from GMOs.[108]

Most developing countries do not have biotechnology-specific regulation. However, the United Nations Industrial Development Organization (UNIDO) published a code of conduct in 1992 to assist such countries with the development of regulatory standards and infrastructure.[109] The UNIDO code, issued on behalf of the World Health Organization (WHO), United Nations Food and Agriculture Organization (FAO), and United Nations Environment Programme (UNEP), outlines the "minimum acceptable" regulatory standards that should govern the products of rDNA techniques.[110] The Code states that regulatory evaluation of GMOs "should focus on the characteristics of the product rather than the molecular or cellular techniques produce it."[111] Nonetheless, the Code also declares that "[e]very member country should designate a national authority or authorities to be responsible for handling enquiries and proposals, i.e., all contacts concerning the use and introduction of GMOs," and calls for greater scrutiny of the introduction of GMOs than is applied to the introduction of other organisms.[112]

While there is no formal international regulation, there are two international organizations that promulgate advisory sanitary (food safety) and phytosanitary (plant and animal safety) measures relevant to the regulation of GMOs: the Codex Alimentarius Commission (Codex) and the International Plant Protection Convention (IPPC).[113] These two entities address issues relating to human health and the protection of plant life, respectively, and seek to facilitate the international harmonization of sanitary and phytosanitary standards.

The Codex was created in 1962 by the United Nations Food and Agricultural Organization and the World Health Organization.[114] It was created "to guide and promote the elaboration and establishment of definitions and requirements for foods, to assist in

105. *See id.* at art. 8(1)(a). As this provision is interpreted, it also requires labeling when the fact that a product was derived from GMOs could have health implications for consumers, such as potential allergic reactions, or could raise ethical concerns. *See* Hunter, *supra* note 81, at 223.

106. *See id.* at art. 8(1)(d).

107. Some ingredients are shipped in bulk. Because GM and non-GM products are rarely separated at this stage, it is likely that many foods contain both GM and non-GM ingredients.

108. *See* Hunter, *supra* note 81, at 224.

109. *See* United Nations Industrial Development Organization, *Voluntary Code of Conduct for the Release of Organisms into the Environment* (visited Feb. 1, 2000) <http://binas.unido.org/binas/Regulations/unido/codes.shtml>.

110. *See id.* § I-C.

111. *See id.* § II-C-1a.

112. *See id.* § II-C-2a. The Cartagena Protocol on Biosafety similarly requires signatories to establish regulatory regimes covering biotechnology. *See* Cartagena Protocol on Biosafety to the Convention on Biological Diversity, *opened for signature* May 15–26, 2000, (visited Feb. 23, 2000) <http://www.biodiv.org/biosafe/BIOSAFETY-PROTOCOL.htm> [hereinafter CPB].

113. A third related organization, the International Office of Epizootics (IOE), promulgates standards relating to animal health, but has yet to be involved in the debate over the regulation of GMOs. *See* Redick et al., *supra* note 40, at 23.

114. *See* Terence P. Stewart & David S. Johanson, *The SPS Agreement of the World Trade Organization and International Organizations*, 26 SYR. J. INT'L L. & COM. 27, 41 (1998).

their harmonization and, in doing so, to facilitate international trade."[115] Today there are 162 member countries of the Codex, which has issued 200 food commodity standards, 40 hygiene codes, 700 evaluations of various food additives, and over 3200 pesticide residue standards.[116] As this paper is being written, the Codex is creating a working group to evaluate proposals to require the labeling of foods derived from GMOs.[117]

The IPPC was created in 1951 to "secure common and effective action to prevent the spread and introduction of pests and plants and plant products and to promote measures for their control."[118] Thus, the IPPC helps to coordinate regional and international quarantines and sets voluntary standards on pathogens and potential plant pests.[119] Despite pressure from environmental NGOs, the IPPC has not found any scientific justification, as of yet, for the development of GMO-specific standards.[120]

International trade rules limit the extent to which individual nations can regulate the importation of GMOs or GMO-derived products. Under Article XX of the General Agreement on Tariffs and Trade (GATT), nations are authorized to enact measures "relating to the conservation of exhaustible natural resources" or "necessary to protect human, animal or plant life or health."[121] Such measures cannot be "a disguised restriction on international trade" or "applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination."[122] In practice, this means that environmental measures must be scientifically based and no more trade restrictive than necessary to meet their goals.[123] These rules are enforced through the World Trade Organization (WTO), the successor organization to the GATT.

In practice, nations can regulate the importation of goods based on their actual characteristics, but not the manner in which they were produced. Thus, a country can limit the importation of a plant or animal species that would be a potential pest if introduced or bar the importation of a food product that does not meet that nation's food safety requirements. A country may not, however, limit the importation of a plant or product simply because it was genetically engineered.

Additionally, if an otherwise legitimate import restriction is not based upon solid science, such as the European ban on beef from hormone-fed cattle discussed below,[124] it will be ruled invalid by the WTO.[125] This requirement limits the ability of governments to enact protectionist trade measures under the guise of environmental protection. In

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115. Stewart & Johanson, *supra* note 114, at 41 (quoting CODEX ALIMNETARIUS COMMISSION, THIS IS CODEX ALIMENTARIUS 2 (2d ed.)).

116. *See* Redick et al., *supra* note 40, at 22.

117. *See Sticky Labels*, ECONOMIST, May 1, 1999, at 75.

118. *See* Food and Agricultural Organization of the United Nations, Conference, 29th Session, *Revision of the International Plant Protection Convention*, C 97/17, at 1 (Nov. 18, 1997), *quoted in* Stewart & Johanson, *supra* note 114, at 46.

119. *See* Redick et al., *supra* note 40, at 23.

120. *See id.*

121. *See* General Agreement on Tariffs and Trade, Oct. 30, 1947, art. XX(b), (g), *in* INTEREST GROUP ON INTERNATIONAL ECONOMIC LAW, AMERICAN SOCIETY OF INTERNATIONAL LAW, BASIC DOCUMENTS OF INTERNATIONAL ECONOMIC LAW (1990) [hereinafter GATT].

122. *See id.* at art. XX.

123. *See, e.g.*, James M. Sheehan, *The Greening of Trade Policy: "Sustainable Development" and Global Trade*, ENVIRONMENTAL STUDIES PROGRAM (Competitive Enterprise Institute, Wash., D.C.) Nov. 1994, at 29 (discussing interpretation of GATT Article XX by dispute resolution panels).

124. *See discussion infra* Part IV.B.3.

125. Of course, it is important to remember that countries cannot be forced to remove GATT-illegal trade restrictions. Rather, if a regulation is declared inconsistent with GATT rules, affected countries are authorized to enact retaliatory trade sanctions.

determining whether a given restriction is scientifically based, the WTO looks to existing scientific research and the relevant standards set by Codex, the IPPC, and other relevant international standards. Cases in which GATT arbitration panels have upheld trade-restrictive environmental measures are few and far between, though this could change with the enactment of a biosafety protocol.

III. THE BIOSAFETY PROTOCOL

Biotechnology's freedom from international regulation may not last long. For several years, environmentalist organizations, including the Union of Concerned Scientists, National Wildlife Federation, and the Center for International Environmental Law, called for the adoption of an international treaty to establish regulatory controls and liability rules for bioengineered products.[126] In 1999 and 2000, parties to the United Nations Convention on Biological Diversity met in Cartagena, Columbia and Montreal, Canada to formulate just such an agreement. In the wee hours of January 29, 2000, negotiators approved the text of the Cartagena Protocol on Biosafety.[127] If this protocol is adopted, it could have a profound effect on the future of biotechnology and international trade in agricultural products.

A. The United Nations Convention on Biological Diversity

The biosafety protocol was negotiated under the auspices of the United Nations Convention on Biological Diversity (CBD).[128] The CBD, signed at the 1992 United Nations Earth Summit in Rio de Janeiro, has three stated objectives: (1) "the conservation of biological diversity," (2) "the sustainable use of its components," and (3) "the fair and equitable sharing of the benefits arising out of the utilization of genetic resources."[129] The CBD obligates parties to develop "national strategies, plans or programs" for the conservation of biodiversity,[130] which shall include, among other things, (a) "a system of protected areas," such as parks or reserves, that include protective buffer zones and are to be managed to ensure "conservation and sustainable use";[131] (b) "measures for the recovery and rehabilitation of threatened species," including the reintroduction of species into their native range;[132] and (c) measures to "facilitate access to genetic resources for environmentally sound uses"[133] and the transfer of advanced technologies to other nations.[134]

Like many environmental treaties, the CBD explicitly endorses a precautionary approach to the protection of biodiversity. The preamble to the Convention states "where there is a threat of significant reduction or loss of biological diversity, *lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize*

126. *See* Graziano, *supra* note 3, at 199 (citing NGO Call for a Legally Binding Protocol on Biosafety, *opened for signature* Dec. 10, 1994).

127. *Report of the Resumed Session of the Extraordinary Meeting of the Conference of the Parties for the Adoption of the Protocol on Biosafety to the Convention on Biological Diversity: 24–28 January 2000*, EARTH NEGOTIATIONS BULL., Jan. 31, 2000, at 4–5 [hereinafter *Report of Resumed Session*].

128. *See* CBD, *supra* note 9.

129. *See id.* at art. 1.

130. *See id.* at art. 6.

131. *See id.* at art. 8.

132. *See id.* at art. 9.

133. *See id.* at art. 15.

134. *See id.* at art. 16.

such a threat."[135] In this regard, the CBD echoes Agenda 21, the Rio Declaration, and other international calls for adoption of the precautionary principle in environmental policy.[136]

The CBD requires parties "as far as possible and as appropriate" to "prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species."[137] In addition, parties to the Convention must:

> establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which *are likely* to have adverse environmental impacts that *could affect* the conservation and sustainable use of biological diversity, taking also into account the risks to human health.[138]

This language from Article 8(g) is sufficiently broad and tentative to justify almost any level of biotechnology regulation.

The Convention specifically provides for the negotiation and adoption of an international biosafety protocol. Under Article 19, the parties to the CBD are to "consider the need for and modalities of a protocol" regulating "the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have an adverse effect" on biological diversity.[139] In particular, a biosafety protocol under the CBD is to determine when "advance informed agreement" is necessary before genetically engineered organisms or GMO-derived products are imported to one country from another.[140] The procedures for adopting and amending protocols to the CBD are laid out in Articles 23, 28, and 29.

On December 29, 1993, the treaty went into effect after ratification by thirty nations.[141] Today, there are 176 parties to the CBD, but the United States is not among them.[142] While President Bush refused to sign the Convention, President Clinton signed it on June 4, 1993. The U.S. Senate, however, has yet to consider CBD ratification. Until the Convention is ratified, the United States is not bound by its terms, nor may it participate as more than an observer at Conference of the Parties (COP) meetings.[143]

B. Cartagena Protocol on Biosafety

While the CBD provides for the negotiation of a biosafety protocol, no such protocol is specifically required by the convention. Thus, the Clinton Administration proclaimed in November 1993 that "the United States does not believe that a protocol on biosafety under

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135. *See id.* at preamble (emphasis added).

136. *See discussion infra* Part IV.

137. *See* CBD, *supra* note 9, at art. 8(h).

138. *See id.* at art. 8(g) (emphasis added).

139. *See id.* at art. 19 §3. Note that the protocol focuses on "living modified organisms" or "LMOs," a subset of GMOs capable of replicating or transferring their genetic material. LMOs include seeds, sterile organisms and viruses. *See* CPB, *supra* note 112, at art. 3.

140. *See* CPB, *supra* note 112, at art. 3.

141. *See* David R. Purnell, *International Implications of New Agricultural Biotechnology*, 25 U. MEM. L. REV. 1189, 1202–03 (1995). Under Article 36, the CBD enters into force on the nineteenth day after ratification by 30 signatory nations. *See* CBD, *supra* note 9, at art. 36.

142. *Report of the Resumed Session*, *supra* note 127, at 1.

143. Of course, given U.S. influence in world affairs, U.S. policy positions have a substantial impact on COP negotiations despite the official observer status.

this Convention is warranted."[144] Similar skepticism about the need for a protocol was expressed by a scientific panel convened by UNEP in 1993 to consider issues relating to a protocol. According to the panel's report, "a protocol would, for no clear purpose: (i) divert scientific and administrative resources from higher priority needs; and (ii) delay the diffusion of techniques beneficial to biological diversity, and essential to the progress of human health and sustainable agriculture."[145] Nonetheless, many nations and environmentalist groups insist that a protocol is required to safeguard human health and the environment. Once the CBD entered into force at the end of 1993, negotiations on a biosafety protocol began, starting with the first Conference of the Parties (COP) meeting in 1994.[146]

As noted above, under the CBD, "biotechnology" is defined as "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use."[147] Despite this broad definition, which encompasses various hybridization techniques going back centuries, U.N. officials determined early on that a biosafety protocol would focus solely on "organisms in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination."[148] Specifically, the UNEP panel sought to exclude "organisms modified by traditional breeding methods" from regulation under a proposed protocol.[149]

Under this approach, "phenotypically identical organisms (that is, those exhibiting the same characteristics) could be subject to drastically different regulatory requirements, depending solely on the method of genetic modification used on them."[150] In other words, the level to which an organism would be regulated under the protocol is more a function of how it is produced than of the actual risks it poses to human health or the environment. The irrationality of this approach is that biologically invasive species, such as kudzu, could be field tested without regulation, yet an innocuous, but nonetheless bioengineered, tomato or strawberry would be subject to the protocol's regulatory restrictions.[151] Such an approach has no sound scientific basis and is, instead grounded on an inordinate fear of new technological innovations.

The second COP meeting, in November 1995, established the Open-ended *Ad hoc* Working Group on Biosafety (BSWG) chartered to "elaborate, as a priority, the modalities and elements of a protocol," including key definitions, categories of GMOs, procedures for advance informed agreement, and the incorporation of the precautionary principle.[152] From the beginning, there was substantial agreement that a protocol should cover all potential uses of GMOs that could impact biodiversity, including releases into the environment, the

144. Letter from the U.S. Department of State conveying the CBD to President Clinton, which was in turn submitted to the U.S. Senate, *quoted in* Henry I. Miller, *Is the Biodiversity Treaty a Bureaucratic Time Bomb?* ESSAYS IN PUB. POL'Y No. 56, 3 (Hoover Institution, 1995) [hereinafter *Bureaucratic Time Bomb*].

145. UNEP, *Report of Panel IV: Consideration of the Need for Modalities of Protocol Setting out Appropriate Procedures Including, in Particular, Advance Informed Agreements in the Field of the Safe Transfer, Handling and Use of Any Living Modified Organism Resulting from Biotechnology Diversity*, UNEP Arguments for a Protocol Pursuant to Article 19.3 of the Convention, ¶ 42(ii), at 11, U.N. Doc. UNEP/Bio.Div/Panels/Int.4 (1993), *quoted in* Redick et al., *supra* note 40, at 37.

146. *See* Redick et al., *supra* note 40, at 38.

147. *See* CBD, *supra* note 9, at art. 2.

148. Expert Panels Established to Follow Up on the Convention on Biological Diversity, Report of Panel IV, Apr. 28, 1993, U.N. Doc. UNEP/Bio.Div/Panels/Inf., *quoted in* Miller, *supra* note 144, at 5.

149. *See id.*

150. Miller, *supra* note 144, at 4.

151. *See id.* at 6.

152. *See Summary of the First Meeting of the Open-Ended Ad Hoc Working Group on Biosafety*, EARTH NEGOTIATIONS BULL., July 29, 1996, at 2.

transboundary movement of GMOs, whether due to international trade or migration, and information exchange on biotechnology. This was about the limit of the consensus, however, even without the United States' formal participation.

When the BSWG first met in July 1996, there was substantial disagreement among the participating countries, particularly in the developing world. Latin American nations with significant agricultural exports disagreed with other developing countries on the extent to which GMOs should be regulated. These nations see biotechnology as a key to their economic development, while African nations, few of which have any biotechnology development at all within their borders, see biotechnology more as a threat.[153] During the first BSWG meeting, approximately forty non-governmental organizations—ranging from the Center for International Environmental Law, Greenpeace International, and Friends of the Earth, to the Indigenous Peoples' Biodiversity Network, Institute for Agriculture and Trade Policy, and the Third World Network—called for an international moratorium on the use, development, handling, or transfer of all GMOs until an international biosafety protocol is negotiated and in place, lest there be a "catastrophic release" of GMOs.[154] This, despite the fact that to date an estimated 28 million hectares around the world have been planted with rDNA-engineered crops without significant incident.[155]

At the next several BSWG meetings, delegates sought to hammer out a draft protocol proposal and established a timetable for finalizing protocol negotiations at the February 1999 COP meeting in Cartagena, Columbia, but it was not to be.[156] Participating nations had substantial disagreement over liability for harms from GMOs, whether the protocol would conform to WTO rules and advance informed agreement procedures, and whether such procedures would apply to products derived from GMOs, such as textiles made from genetically engineered cotton or breakfast cereal made from genetically engineered corn.[157] In addition to the United States, which could only participate as an observer, Argentina, Australia, Canada, Chile, and Uruguay also opposed a stringent protocol, fearing the impact of biosafety regulations on their agriculture exports.[158]

One of the thorniest sticking points was the scope of advance informed agreement procedures required prior to the first import of any living GMO intended for release into the environment.[159] In the negotiating draft of the protocol, the exporting party would have to notify the country in writing of the intended import. The importer would have ninety days to acknowledge receipt of the notification and 270 days to decide whether the import will be allowed.[160] In deciding whether to allow the import, a member country could consider scientific, environmental, and even socio-economic considerations under Article

153. *See id.* at 9.

154. *See* Graziano, *supra* note 3, at 199 (citing NGO Call for a Legally Binding Protocol on Biosafety, *opened for signature* Dec. 10, 1994).

155. *See* Philip J. Abelson & Pamela J. Hines, *The Plant Revolution*, 285 SCIENCE 367, 367 (1999).

156. Technically, U.N. lingo defines the February Cartagena meeting as an "Extraordinary Conference of the Parties" or "ExCOP" as opposed to a traditional COP meeting.

157. *See* Andrew Pollack, *Biotechnology Treaty Stalls as U.S. and Developing Nations Quarrel*, N.Y. TIMES, Feb. 23, 1999, at A11.

158. *See id.*

159. The draft excludes pharmaceuticals and LMOs that are intended for testing in contained facilities.

160. *See Report of the Sixth Session of the Open-Ended Ad Hoc Working Group on Biosafety and the First Extraordinary Session of the CBD Conference of the Parties*, EARTH NEGOTIATIONS BULL., Feb. 26, 1999, at 5 [hereinafter *Report of the Sixth Session*]. The importing country would not actually have to make a decision within the 270-day window, as the draft protocol would allow the country to ask for additional information about the GMO in question or even extend the decision period by "a defined period of time." *See id.*

24 of the draft, though the delegations from developed countries sought to have this provision eliminated.[161]

The argument for requiring advance informed agreement of living organisms is that national governments have a right to know what is coming across their borders and should have the opportunity to ensure that the importation of new plant or animal species will not cause ecological harm. As noted above, non-genetically modified exotic species have caused substantial ecological disruptions around the globe, often due to inadvertent introduction. But this would be an argument for rules regulating the importation of *all* living organisms through existing quarantine rules and the like, irrespective of how they were developed. As a scientific matter, the question would be whether a particular seed or organism posed an ecological threat due to its particular characteristics, not whether it was manipulated with rDNA techniques. The scientific case for including advance informed agreement for GMO-derived products, as some developing countries demanded, is even more questionable, as such goods do not pose a unique environmental threat, if they pose a threat at all.[162] Such a rule would empower a country to deny importation of a new wheat strain or even, under some proposals, Levi's blue jeans made from genetically modified cotton, something that could not be defended on environmental grounds. This suggests that at least some advocates of such limits are motivated by factors other than protecting public health and ecological integrity, such as impeding market development for GMO-derived products, in the case of environmentalists, and increasing opportunities to use environmental rules as a cover for trade protectionism, for some developing countries.

A requirement for advance informed consent for each and every shipment of GMOs, such as crop seeds and GMO-derived products, would directly conflict with international trade rules. Article 31 of the draft protocol stated that nothing in the agreement affects the rights and obligations that member nations have under other agreements, "except where exercise of those rights and obligations would cause serious damage or threat to biodiversity."[163] As noted above, the WTO does not allow countries to impose import restrictions on products based on the manner in which they were made, and grain exporting countries, including the United States and many Latin American countries, refused to adopt a protocol that violates this principle.[164] Developing nations, the European Union, and environmental organizations, however, seek a protocol that creates an exception to WTO rules.

The February 1999 meeting in Cartagena ended without agreement on a biosafety protocol. "Biotechnology can contribute enormously to human well-being, but it poses potential risks," commented UNEP Executive Director Klaus Toepfer at the close of the Cartagena meeting. "For this reason, the global community will continue to work on establishing a legally binding biosafety regime."[165] Intent on developing a binding international instrument, negotiators met again during 1999 and convened for a final formal negotiating session in January 2000 in Montreal.

Negotiations in Montreal were more successful than prior rounds and protocol language was finally agreed upon. While environmental activists engaged in demonstrations and street theater outside, negotiators hammered out a compromise

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161. *See id.* at 8.

162. Some developing country delegates argued that any living GMO could be potentially released into the environment, and therefore all living GMOs should be covered by advance informed agreement procedures. *See id.* at 5.

163. *See id.* at 8.

164. *See* Ehsan Masood, *Collapse of Talks on Safety of GMO Trade*, 398 NATURE 6, 6 (1999).

165. UNEP, *Governments Postpone Adoption of Biosafety Treaty* (visited Jan. 28, 2000) <http://www.biodiv.org/press/pr2-99-BSWG6.html>.

protocol.[166] While less restrictive than some nations wanted, the protocol explicitly embraces the precautionary principle in its operative provisions and will empower nations to restrict imports of genetically modified products. The protocol will be open for signature beginning in May 2000.

The Cartagena Protocol on Biosafety provides for advance informed agreement for the importation of "living modified organisms" (LMOs) that will be planted as crops or otherwise intended for deliberate release into the environment. These provisions apply to the first time a given LMO is imported into a country that is a party to the protocol.[167] Once notice of a transboundary shipment is given, the importing nation is to respond within ninety days, indicating whether the shipment may proceed or whether additional information is required.[168] This provision will be difficult to enforce, however, as failure to respond does "not imply . . . consent" to the shipment.[169]

LMOs that are to be used for food, feed, or processing are exempt from the advance informed agreement provisions, but bulk shipments must be labeled.[170] Such shipments must indicate that they "may contain" LMOs.[171] The protocol's language also implies that developing nations that lack a "domestic regulatory framework" for biotechnology may reject for any reason importation of LMOs to be used for food, feed, or for processing.[172] The protocol also provides for the creation of a Biosafety Clearing-House to which member nations must provide information about approved LMOs, transboundary shipments, and the like.[173]

The protocol explicitly embraces the precautionary principle at several points. The preamble states that parties "[r]eaffirm[] the precautionary approach" to environmental protection.[174] In addition, Articles 10 and 11 of the protocol explicitly state that "lack of scientific certainty" shall not prevent countries from barring importation of LMOs.[175] Parties to the protocol are also permitted to take "socio-economic considerations" into account when deciding whether or not to allow the importation of an LMO.[176] These provisions may permit member nations to block importation due to unfounded environmental scares or special interest pressure.[177]

The protocol negotiations did not settle every issue. The United States and other exporting countries sought to ensure that the protocol would not conflict with international trade rules under the WTO. The European Union and some developing countries, on the other hand, sought a protocol that would not be so limited. The protocol's final language on this point is deliberately vague and inconclusive. The preamble both "emphasiz[es]" that the protocol does not alter the rights and obligations of parties under other international agreements and "understands" that this does not mean that the protocol is "subordinate" to

166. *See, e.g.*, David Sanger, *Protesters March Through Montreal*, ASSOCIATED PRESS, Jan. 22, 2000; *see also* Andrew Pollack, *130 Nations Agree on Safety Rules for Biotech Food*, N.Y. TIMES, Jan. 30, 2000, at A1.

167. *See* CPB, *supra* note 112, at art. 7.

168. *See id.* at arts. 9–10.

169. *See id.* at art. 9(4).

170. Under Article 5, pharmaceuticals are also exempt from the protocol's advance informed agreement provisions and need not be labeled.

171. *See* CPB, *supra* note 112, at art. 18(2)(a).

172. *See id.* at art. 11(6).

173. *See id.* at art. 20.

174. *See id.* at preamble.

175. *See id.* at arts. 10(6), 11(8).

176. *See id.* at art. 26(1).

177. *See discussion infra* Part IV.B.

other agreements.[178] Other issues, such as potential liability for any harm caused by the introduction of genetically engineered organisms, will be resolved at a later date.[179]

IV. THE PRECAUTIONARY PRINCIPLE & ITS PERILS

Calls to regulate GMOs and the other products of rDNA techniques until the uncertainty about their potential risks is reduced, if not eliminated, are all variants of the precautionary principle, the idea that new technologies and substances should be regulated before they can cause harm rather than after their harmful potential has been demonstrated. A typical version of the precautionary principle can be found in the *Wingspread Consensus Statement*, a document drafted and endorsed by a group of environmental activists and scholars. According to the statement, the precautionary principle holds that "[w]hen an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically."[180] In other words, regulate first, assess the risks later. As applied in the environmental context, this means that it is better to err on the side of regulating or controlling new technologies than to risk new or unforeseen problems. In the ideal, new technologies should be proven "safe" before they are used.[181]

The precautionary principle has become a staple of international environmental law. The Rio Declaration, agreed to at the 1992 U.N. Earth Summit, declares that "[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," and that "[i]n order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities."[182] Similar precautionary statements can be found in other environmental treaties, including the Vienna Convention for the Protection of the Ozone Layer,[183] the United Nations Framework Convention on Climate Change,[184] and the Convention on Biological Diversity, among others.[185] The European Union has also embraced reliance on the precautionary principle in the fields of environmental protection and human, animal and plant health.[186] Yet while the

178. *See* CPB, *supra* note 112, at preamble.

179. *See id.* at art. 27.

180. *The Precautionary Principle*, RACHEL'S ENV'T & HEALTH WKLY, (Feb. 19, 1998) <http://www.rachel.org/search/index.cfm?st=1>. Signatories of the statement included representatives of Greenpeace, Physicians for Social Responsibility, the W. Alton Jones Foundation, the Silicon Valley Toxics Coalition, and the Indigenous Environmental Network, among others. *See id.* Other statements of the precautionary principle are essentially the same. *See, e.g.*, Gregory D. Fullem, Comment, *The Precautionary Principle: Environmental Protection in the Face of Uncertainty*, 31 WILLAMETTE L. REV. 495, 497–98 (1995) ("The principle asserts that regulators and decision makers should act in anticipation of environmental harm, without regard to the certainty of the scientific information pertaining to the risk of harm."); Brian Wynee & Sue Mayer, *How Science Fails the Environment*, NEW SCIENTIST, June 5, 1993, at 32, 34 ("precautionary principle demands that the environment must not be left to show harm before action is taken").

181. Of course, proving that a new technology or product will cause no harm would require proving a negative, something that science cannot do. In this sense, the precautionary principle establishes a default rule for regulating new innovations irrespective of the relative risk that they actually pose to human health or the environment.

182. Rio Declaration on Environment and Development, U.N. Conference on Environment and Development, Agenda Item 21, at 10, U.N. Doc. A/CONF.151/5/Rev.1 (1992), *reprinted in* 31 I.L.M. 876, 879, principle 15 (1992).

183. Vienna Convention for the Protection of the Ozone Layer, Mar. 22, 1985, 26 I.L.M. 1529 (1985).

184. United Nations Framework Convention on Climate Change, May 9, 1992, 31 I.L.M. (1992).

185. Until the Cartagena Protocol on Biosafety, however, precautionary statements were not incorporated into operative treaty provisions.

186. Commission of the European Communities, COMMUNICATION FROM THE COMMISSION ON THE PRECAUTIONARY PRINCIPLE, Feb. 2, 2000, at 30.

precautionary principle is common in international environmental agreements, it is not clear that it advances environmental protection.

A. The Perils of Precaution

The precautionary principle appeals to the common sense idea that "it is better to be safe than sorry." In practice, the precautionary principle biases regulatory decisions against the introduction of any new technology.[187] While those who advocate adoption of the precautionary principle purport to be acting in defense of public health and the environment, the precautionary principle may well leave us more sorry and less safe. As noted by the late Aaron Wildavsky, "The empirical question is whether the health [and environmental] gains from the regulation of the substances involved are greater or lesser than the health [and environmental] costs of the regulation."[188] In the case of biotechnology, unduly restricting the development of GMOs in agriculture could have substantial negative impact on human health and the environment, making it unclear whether adoption of the precautionary principle would make us safer at all.

The problem is that by focusing on one set of risks—those posed by the introduction of new technologies with somewhat uncertain effects—the precautionary principle turns a blind eye to the harms that occur, or are made worse, due to the lack of technological development. "The truly fatal flaw of the precautionary principle, ignored by almost all the commentators, is the unsupported presumption that an action aimed at public health protection cannot possibly have negative effects on public health."[189] The unfortunate reality is that efforts to regulate one risk can create other, often more dangerous risks. As Supreme Court Justice Stephen Breyer noted in his book *Breaking the Vicious Circle*, "One can find many examples of regulators' ignoring one program's safety or environmental effects upon another . . . ."[190] Other commentators have noted that "when agencies regulate a particular substance or technology, they often fail to consider the secondary impacts of regulation, such as the risks presented by substitute products or activities."[191]

Perhaps the most prominent example of the harm caused by excessive "precaution" in regulatory policy is FDA-induced "drug lag." The FDA must approve new pharmaceuticals and medical devices before they may be used or prescribed in the United States. The purpose of FDA approval is to ensure that only those drugs deemed "safe and effective" are approved for use. In a precautionary fashion, the FDA seeks to prevent the release of an unsafe drug. Delaying the availability of potentially life-saving treatment, however, poses risks of its own.[192] Consider the question posed by one prominent FDA critic: "If a drug that has just been approved by FDA will start saving lives tomorrow, then how many people died yesterday waiting for the agency to act?"[193]

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187. *See* Søren Holm & John Harris, *Precautionary Principle Stifles Discovery*, 400 NATURE 398, 398 (1999) ("The [precautionary principle] will block the development of any technology if there is the slightest theoretical possibility of harm.").

188. AARON WILDAVSKY, BUT IS IT TRUE? 428 (1995).

189. Cross, *supra* note 43, at 860.

190. STEPHEN BREYER, BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION 22 (1993).

191. Edward W. Warren and Gary E. Merchant, *"More Good Than Harm": A First Principle for Environmental Agencies and Reviewing Courts*, 20 ECOLOGY L.Q. 379, 390 (1993).

192. *See, e.g.*, Sam Kazman, *Deadly Overcaution: FDA's Drug Approval Process*, 1 J. REG. & SOC. COSTS 35 (1990).

193. *Id.* at 35.

A good example is the approval of Misoprostol, a drug that prevents gastric ulcers.[194] The FDA approved Misoprostol in December 1988. At the time, Misoprostol was already approved in several dozen foreign countries. The drug had been available in some nations as early as 1985. Nonetheless, the FDA subjected Misoprostol to a nine-and-one-half month review after clinical trials for safety and efficacy had been completed. Given Misoprostol's high rate of effectiveness, and the fact that gastric ulcers claimed between 10,000 and 20,000 lives at the time of its approval, as many as 8000 to 15,000 lives could have been saved if Misoprostol had been approved more quickly. In other words, the FDA's delay—even of only several months (short by FDA approval standards)—costs lives, just as surely as does the approval and use of unsafe treatments.[195] Thus, the FDA's application of the precautionary principle does not necessarily make people safer.

Cases in which efforts to address one risk or environmental problem have perverse, even anti-environmental, consequences are all too common. Consider just a few examples.

Ethylene dibromide (EDB) was a powerful fungicide used to prevent the growth of molds on grain and other foods. Molds produce some of the most potent carcinogens found in nature, such as aflatoxin. Yet EDB was also deemed a potential carcinogen and was banned by the EPA without any consideration of whether the risk of EDB was greater or lesser than that posed by aflatoxin. Moreover, EDB was replaced with fungicides that had to be applied in greater quantities, increasing the risk for exposed workers.[196] Thus, the EDB ban may have, in net, *increased* risks to human health.

In 1994, the EPA enacted changes to the reformulated gasoline program under the Clean Air Act Amendments of 1990. The changes were designed to increase the use of "renewable" fuel sources by mandating that a minimum percentage of oxygen-enhancing fuel additives for reformulated gasoline come from ethanol or ethanol-derived sources. This rule would have done nothing to improve environmental quality. Indeed, the EPA "even conceded that use of ethanol might possibly make air quality worse."[197] The EPA's narrow focus on one type of air pollution risked increasing another.

In 1996, the EPA proposed to tighten the National Ambient Air Quality Standard for ozone. Yet in its zealous pursuit of lower tropospheric ozone levels, the EPA ignored some of the public health impacts that significant reductions could cause.[198] In particular, the EPA ignored data suggesting that reducing ground-level ozone could increase human exposure to ultraviolet-B radiation, and consequently increase skin cancer rates. According to one study, "a 'health optimal' [ozone standard] might differ significantly from a [standard] set without consideration of UV-B-related deaths and disease, and it could even be less stringent than the current [ozone standard]."[199]

The ill effects of undue precaution can be even broader as "at all times regulation imposes costs that mean less real income available to individuals for alternative expenditure . . . [which] itself has adverse health effects, in the form of poorer diet, more heart attacks, more suicides."[200] Insofar as regulations divert resources away from

194. This discussion is based on the Kazman article. *See id.* at 47–48.

195. For a fuller discussion of drug lag, *see generally* H.G. GRABOWSKI & J. M. VERNON, THE REGULATION OF PHARMACEUTICALS (1983); SAM PELTZMAN, REGULATION OF PHARMACEUTICAL INNOVATION (1974).

196. *See* Cross, *supra* note 43, at 875–76.

197. 59 Fed. Reg. 39,268 (1994), *cited in* American Petroleum Inst. v. U.S. Envtl. Protection Agency 52 F.3d 1113, 1119 (1995) (invalidating EPA reformulated gasoline regulations due to lack of statutory authority).

198. *See* American Trucking Ass'ns, Inc. v. U.S. Envtl. Protection Agency, 175 F.3d 1027, 1051 (D.C. Cir. 1999). The U.S. Court of Appeals for the District of Columbia Circuit held that the EPA's refusal to consider the radiation-blocking potential of tropospheric ozone violated the Clean Air Act. *See id.* at 1051–53.

199. *See* Randall Lutter & Christopher Wolz, *UV-B Screening by Tropospheric Ozone: Implications for the National Ambient Air Quality Standard*, 31 ENVTL. SCIENCE & TECH. 142A, 145A (1997).

200. *See* BREYER, *supra* note 190, at 23.

potentially life-saving or safety-enhancing activities, they make people worse off. At the extreme, regulations that impose substantial costs can even increase overall mortality.[201] Higher economic growth and aggregate wealth strongly correlate with reduced mortality and morbidity.[202] This should be no surprise as the accumulation of wealth is necessary to fund medical research, support markets for advanced life-saving technologies, build infrastructure necessary for better food distribution, and so on. In a phrase, poorer is sicker, and wealthier is healthier.[203] "There is no free health."[204] Much the same can be said for environmental protection.[205]

B. The Perils of a Protocol

Like any precautionary measure, a Biosafety Protocol will entail costs. These costs will not only be financial. "Unnecessary governmental scrutiny in the form of case-by-case reviews will cause delays in the testing of biotechnological products, increase the potential for corruption and markedly inhibit the diffusion of this useful technology to the developing world."[206] Reducing the development and diffusion of biotechnology will, in turn, limit the environmental and social benefits that GMOs could provide.[207]

Some advocates of a highly precautionary biosafety protocol recognize that "[m]aking disease-resistant and immune crops is a necessity for future generations, whose increasing populations will require increased agricultural output."[208] Yet there does not seem to be much recognition that a "strong" biosafety protocol could retard increases in agricultural productivity, thereby increasing the risks of global food shortages and habitat loss. Indeed, there is a reason to believe that a highly regulatory biosafety protocol, or even one that sanctions greater regulations by member countries, could make it increasingly difficult to meet the food demands of a growing world population and undermine the stated goals of the Convention on Biological Diversity by increasing rates of habitat destruction. Given that the risk of famine and loss of biodiversity are most acute in the developing world, "the support of many developing companies for a restrictive protocol is perplexing."[209] But perhaps it is explained by the third threat posed by a precautionary treaty: the use of protocol-authorized restrictions on trade in GMOs for economic rent-seeking.

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201. *See generally* Frank B. Cross, *When Environmental Regulations Kill*, 22 ECOLOGY L.Q. 729 (1995).

202. *See, e.g.*, Susan L. Ettner, *New Evidence on the Relationship Between Income and Health*, 15 J. HEALTH ECON. 67 (1996); John D. Graham et al., *Poorer is Riskier*, 12 RISK ANALYSIS 333 (1992); Ralph L. Keeney, *Mortality Risks Induced by Economic Expenditures*, 10 RISK ANALYSIS 147 (1990).

203. This phrasing is attributed to the late Aaron Wildavsky.

204. WILDAVSKY, *supra* note 186, at 445.

205. *See, e.g.*, Indur Goklany, *Richer Is Cleaner*, *in* THE TRUE STATE OF THE PLANET (Ronald Bailey ed., 1995); Frank B. Cross, *A Syncretic Perspective on Environmental Protection and Economic Growth*, 2 KANSAS J.L. & PUB. POL'Y 53, 61 (1992).

206. Henry I. Miller, *supra* note 31, at 189.

207. It is important to recognize that the potential for overly stringent regulations to chill technological development is more than theoretical. For instance, a 1989 survey of agricultural researchers working with GMOs, 20 percent of those in the private sector and ten percent of those in the public sector, elected not to field test GMOs that they had developed, with approximately 75 percent identifying government regulation as the reason. *See* Miller, *supra* note 39, at 207–08.

208. *See* Graziano, *supra* note 3, at 183.

209. *See* Redick et al., *supra* note 40, at 31.

1. Impact on Food Production

For many environmentalists, the continuing growth in global population is the most pressing environmental problem. They look with alarm at the dramatic increase in human numbers over the twentieth century. A century ago there were 1.6 billion people on the planet. By 1960, global population reached 3 billion and 5 billion by 1987.[210] 1999 was heralded as the year the earth's population reached 6 billion.[211] At present, global numbers increase by 1 billion people every twelve to thirteen years. While many expect this rate of increase to slow, most analysts believe that there could be approximately 10 billion people on the planet by 2050.[212]

While not all environmental analysts believe that human populations are nearing the earth's carrying capacity,[213] it is well accepted that a growing world population means an escalating potential human impact on the world around us. More people means more bodies to house and clothe, more consumers to satisfy, and, most relevant to this paper, more mouths to feed. Whether or not one believes that dramatic increases in population foretell ecological disaster, agricultural production will need to increase substantially just to keep pace with the inevitable increase in human numbers.[214] According to the International Food Policy Research Institute, global demand for basic agricultural commodities, such as wheat, maize, and rice, will increase an estimated forty percent by 2020, or 1.3 percent per year.[215]

Global food production has kept pace with population increases for the past several decades, largely due to technological advances in production. Despite proclamations in the 1960s and 1970s that massive famines were imminent and that "[t]he battle to feed all of humanity is already lost,"[216] the world's farmers have met the rising demand for food. Between the late-1930s and late-1980s, global per capita calorie availability increased nearly thirty percent, with the largest increases occurring in lesser developed countries in Africa, Asia, and Latin America.[217] From 1961 to 1994, per capita food production increased nearly twenty percent, according to independent analyses,[218] and per capita agriculture production increased nearly as much.[219] The U.N. Food and Agriculture Organization reached similar conclusions.[220] In developing countries alone, grain yields rose thirty-two percent from 1980 to 1992.[221]

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210. *See* POPULATION REFERENCE BUREAU, 1998 WORLD POPULATION DATA SHEET: DEMOGRAPHIC DATA AND ESTIMATES FOR THE COUNTRIES AND REGIONS OF THE WORLD (1998).

211. *See, e.g.*, Michael Satchell, *Global Population: Six Billion and Counting*, U.S. NEWS & WORLD REP., Oct. 11, 1999, at 46.

212. *See* Jonathan Adler et al., *Benchmarks: The Ecological and Economic Trends that Are Shaping the Natural Environment and Human Societies*, *in* THE TRUE STATE OF THE PLANET 398–99 (Ronald Bailey ed., 1995).

213. *See, e.g.*, Nicholas Eberstadt, *Population, Food and Income*, *in* THE TRUE STATE OF THE PLANET (Ronald Bailey ed., 1995), and the various works of the late economist Julian Simon.

214. While changes in economic and political arrangements could improve the availability and distribution of food considerably, such reforms cannot sustain a growing population absent concurrent increases in agricultural productivity.

215. *See* Charles C. Mann, *Crop Scientists Seek a New Revolution*, 283 SCIENCE 310, 310 (1999).

216. PAUL EHRLICH, THE POPULATION BOMB 36 (1968).

217. *See* Eberstadt, *supra* note 213, at 28.

218. *See* Paul Georgia et al., *Benchmarks: The Ecological and Economic Trends that Are Shaping the Natural Environment and Human Societies*, *in* EARTH REPORT 2000: REVISITING THE TRUE STATE OF THE PLANET 260–61 (Ronald Bailey ed., 1999).

219. *See id.* at 256–57.

220. *See* Eberstadt, *supra* note 213, at 28.

221. *See* Dennis Avery, *Saving the Planet with Pesticides*, *in* THE TRUE STATE OF THE PLANET 60 (Ronald Bailey ed., 1995).

The rise in food production did not happen by accident. By and large, it was the product of the so-called "green revolution." The explosion in productivity resulted from the work of plant breeders, such as Nobel laureate Norman Borlaug, who figured out how to increase the technological sophistication of agriculture.[222] Using new types of agricultural chemicals, pest control techniques, and irrigation methods, researchers were able to increase the per-acre productivity of cropland. But perhaps the most important element in the revolution was the increased sophistication of plant breeding. As agriculture expert Dennis Avery explains:

> Plant breeders like Norman Borlaug have turned out a profusion of new plant varieties that start earlier, grow faster, resist pests, tolerate drought stress, and preserve more of the harvest. Many have shorter stalks so more of their energy goes into producing grain, and the sturdier stems support bigger seed heads. Hybridization offers faster gains in yield potential and greater ease in maintaining the vigor of seed breeding lines. The new crop plants permit higher yields and more double-cropping, and they protect the land more effectively than the old "land-race," or farmer-bred, varieties.[223]

In other words, increased agricultural production has been the direct result of "biotechnology": the selective breeding of plant species for particular traits.

The increases in agricultural productivity over the past few decades have been impressive, but they are not guaranteed to continue. Indeed, annual increases in agricultural productivity appear to have been slipping; cereal yields per hectare rose 2.2 percent per year in the late 1960s and 1970s, but only 1.5 percent per year in the 1980s and early 1990s.[224] Some scientists believe that new breakthroughs are imminent, but most agree that modern biotechnology techniques will be required to continue increases in agricultural productivity. "We may be able to create the new plant type without biotech," commented Shaobing Peng of the International Rice Research Institute, "but that is where new opportunities will have to come from in the future."[225] According to *Science*, "[t]o break yield barriers, the plants will have to be thoroughly reengineered."[226]

Genetic modification of crops can increase yields in many ways, ranging from enhancing plant resistance to frost, pests, soil toxicity or salinity, and droughts, to regulating flowering and reducing spoilage. A scientific panel convened by the World Bank and Consultative Group on International Agricultural Research (CGIAR) concluded that genetic engineering could increase agricultural yields by as much as twenty-five percent.[227] Even delaying ripening in fruits and vegetables could substantially enhance food supplies, as post-harvest and end-use losses are estimated to be as high as forty-seven percent.[228]

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222. *See* Gregg Easterbrook, *Forgotten Benefactor of Humanity*, ATLANTIC, Jan. 1997, at 75–82 (explaining how Borlaug's work sparked the Green Revolution and arguably saved millions of lives by increasing food production).

223. Avery, *supra* note 221, at 57–60.

224. *See* Mann, *supra* note 215, at 310.

225. *Id.* at 313.

226. *Id.*

227. *See* Roger Beachy et al., *Bioengineering of Crops Could Help Feed the World; Crop Increases of 10–25 Percent Possible* (visited Jan. 14, 2000) <http://www. worldbank.org/html/cgiar/press/biopress.html>.

228. *See* Indur M. Goklany, *Meeting Global Food Needs: The Environmental Trade-Offs Between Increasing Land Conversion and Land Productivity*, 6 TECH. 107, 120 (1999).

The harvest-increasing potential of GMOs is already being demonstrated by the first generation of genetically engineered crops. One prominent GMO is corn modified to contain a gene from the *Bacillus thuringiensis* (Bt) bacterium to protect it from pests, such as European Corn Borer, which cause an estimated $1 to $2 billion in crop damage to corn fields each year.[229] Bt occurs in nature and is often cultivated and used as a "natural pesticide" by farmers. The bacterium protects crops because it produces a protein that is toxic to the corn borer but is harmless to humans and most other wildlife. Inserting a Bt gene enables corn plants to produce the defensive protein, protecting them from borers and reducing crop damage (as well as the need to apply additional Bt or other pesticides). The result, among other things, is increased productivity. For instance, in 1997 the per-acre yields of corn modified to produce Bt were seven percent higher than unmodified corn.[230] Bt cotton yields reported in 1996 were even further above conventional crops—fifteen to seventeen percent higher than unmodified cotton treated with conventional pesticides.[231] A 1999 industry-financed study estimated that farmers produced an additional 60 million bushels of corn and 85 million pounds of cotton in 1998 with Bt strains.[232]

Biotechnology not only holds the potential to increase per-acre yields, it could also increase the nutritional value of the crops that are grown. This is tremendously important because an estimated 800 million people receive insufficient nutrition in their diets.[233] "Modifying the nutritional composition of plant foods is an urgent worldwide health issue as basic nutritional needs for much of the world's population are still unmet."[234] Substantial research in this regard is underway. Scientists have already developed a sweet potato with greater protein quality,[235] and soybean and corn plants have been modified to improve their oil, protein, and carbohydrate content.[236] One week before negotiators met in Montreal to finalize the protocol, researchers announced the creation of a new strain of rice fortified with additional Vitamin A.[237] The development of this "golden rice" was instantly deemed a "major advance in global nutrition" because vitamin A deficiency, which can cause blindness and other ills, affects up to 250 million children worldwide.[238] Genetically modified crops may well make food both more abundant *and* more nutritious.

Few would argue at this point in time that bioengineering of crops, in and of itself, will address all of the globe's future food needs, but the use of bioengineering will be essential to feed a growing world population especially, as noted below, if we wish to protect biodiversity at the same time. A biosafety protocol, however, could make this task that much more difficult by slowing the introduction and development of new productivity-enhancing GMOs, particularly in those areas that need them the most.

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229. *See YieldGard Corn Hybrids Can Help Recover Lost Income*, HIGH PLAINS J., Feb. 17, 1997, at 9-A, *cited in* Sara M. Dunn, Comment, *From Flav'r Sav'r to Environmental Saver? Biotechnology and the Future of Agriculture, International Trade, and the Environment*, 9 COLO. J. INT'L ENVTL. L. & POL'Y 145, 151 (1998).

230. *See* Moffat, *supra* note 18, at 2177.

231. *See* Judy Stringer, *Monsanto Poised to Reap Biotech Harvest*, CHEM. WEEK, Nov. 6, 1996, at 51, 51.

232. *See* Leonard P. Gianessi & Janet E. Carpenter, *Agricultural Technology: Insect Control Benefits* (National Center for Food and Agriculture Policy, July 1999), p. 86.

233. *See* D.H. CALLOWAY, HUMAN NUTRITION: FOOD AND MICRONUTRIENT RELATIONSHIPS (International Food Policy Research Inst. 1995).

234. Dean DellaPenna, *Nutritional Genomics: Manipulating Plant Micronutrients to Improve Human Health*, 285 SCIENCE 375, 375 (1999).

235. *See* Anne Simon Moffat, *Crop Engineering Goes South*, 285 SCIENCE 370, 371 (1999).

236. *See* Barbara Mazur et al., *Gene Discovery and Product Development for Grain Quality Traits*, 285 SCIENCE 372, 372 (1999).

237. *See* Xudong Ye et al., *Engineering the Provitamin A (B-Carotene) Biosynthetic Pathway into (Cartenoid-Free) Rice Endosperm*, 287 SCIENCE 303, 303 (2000).

238. *See* Guy Gugliotta, *New Vitamin A-Rich Rice Strain Termed Nutrition Breakthrough*, WASH. POST, Jan., 14, 2000, at A6.

2. Impact on Biodiversity

There are ways to increase food production other than through the development and use of GMOs. Perhaps the easiest way of producing more food would be to put more acres under plow. Paul Waggoner, for one, estimates that feeding a global population of 10 billion could readily be achieved by simply doubling the amount of cropland.[239] But at what cost?

Even if one assumes that lands not already used for farming will match the productivity of those that are already farmed, there is another problem: most of the land that would be available for farming is currently undeveloped habitat. Habitat loss is already one of the greatest threats to biodiversity. Over one-third of documented animal extinctions were due to habitat destruction,[240] and most biodiversity experts believe that continuing loss of habitat could claim at least one quarter of the species alive today.[241] Most habitat loss is caused by human conversion of land to other uses.[242] "In particular, conversion of land to agriculture is the single greatest agent of habitat conversion, and associated displacement of species and increasing stress on biological diversity."[243] As a consequence, if per acre agricultural yields are not increased, biological diversity will be placed under greater strain.

The importance of agricultural productivity for habitat conservation is readily evident. Consider that from 1961 to 1993, the earth's population increased eighty percent but cropland increased only eight percent, despite increases in per capita food supplies.[244] In other words, increased food demand was met largely by increasing per acre yields. Had this not been the case and agricultural productivity in 1993 remained what it had been in 1961, producing the same amount of food would have required increasing global cropland by eighty percent or more.[245] In other words, an additional 3550 million hectares—or twenty-seven percent of the world's land area (excluding Antarctica)—would have had to come under plow.[246] This is merely the acceleration of a longer-term trend. Since 1800, global population has increased approximately six-fold, yet cropland has yet to quadruple.[247]

As noted above, global population may well hit 10 billion in the next century. This will require substantial increases in food production. Increasing per capita caloric intake will require producing even more. This increase will be achieved through some combination of increases in cropland acreage and increases in agricultural productivity. To illustrate, increasing agricultural productivity 1.4 percent per year from 1993 to 2050 would produce an overall increase in agricultural output of 121 percent. To achieve this same increase through the use of more cropland alone would probably require increasing the

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239. *See* PAUL E. WAGGONER, HOW MUCH LAND CAN TEN BILLION PEOPLE SPARE FOR NATURE? 26–27 (1994), *cited in* Goklany, *supra* note 228, at 115.

240. *See* Edwards, *supra* note 48, at 222.

241. *See, e.g.*, Paul O. Ehrlich & Edward O. Wilson, *Biodiversity Studies: Science and Policy*, 253 SCIENCE 758, 758 (1991).

242. *See, e.g.*, Peter M. Vitousek et al., *Human Domination of Earth's Ecosystems*, 277 SCIENCE 494, 494 (1997).

243. Goklany, *supra* note 228, at 108.

244. *See* Indur M. Goklany, *Saving Habitat and Conserving Biodiversity on a Crowded Planet*, 48 BIOSCIENCE 941, 941 (1998).

245. *See id.*

246. *See id.* If anything, this estimate is optimistic, as it assumes that the new cropland acreage would be as productive as those lands already farmed, a highly unlikely scenario.

247. *See* Goklany, *supra* note 228, at 111.

amount of cropland by *more than* 121 percent, or over 3200 million hectares.[248] Even small annual changes in productivity can have a big impact on the demand for cropland.

Because of this trade-off in efforts to increase food production between increased agricultural productivity and cropland acreage, regulations that inhibit the development and use of agricultural technologies, such as GMOs, could have a negative impact on habitat conservation. Limiting the availability of GMOs will leave farmers fewer means with which to increase yields, other than converting habitat to farmland.[249] Allowing more widespread use of biotechnology, on the other hand, could greatly reduce the stresses placed upon species habitat by a growing world population.

Biotechnology can help reduce the strain on habitat by increasing per-acre timber yields as well. Cloned and tissue-cultured strains of Georgia yellow pine are now grown in Brazil to produce sixteen times as much pulpwood per hectare as a natural forest in Sweden.[250] As Dennis Avery notes, this means that "each acre of the high-yielding trees can protect fifteen wild acres from being logged."[251] While commercial logging is not a major cause of deforestation, it does play a role, and biotechnology can help alleviate some of this stress. "Just as agriculture reduced food foraging pressures on natural habitats by increasing crop productivity, so too plantation forests, with their high level of productivity, are reducing the pressures on the remaining natural forests."[252]

Efforts to increase per-acre agricultural yields, whether through biotechnology or some other means, can have negative environmental impacts. Nonetheless, as John Barton notes, "the environmental costs of expanding the area tilled are enormously greater than those of increasing yield."[253] Without the contribution of new generations of GMOs, it will be immensely difficult to meet the rising food demands of the world's peoples and still preserve large areas of undeveloped habitat. Thus, adoption of a precautionary biosafety protocol could well counteract other efforts under the CBD to protect biological diversity.

3. Potential for Rent Seeking

While environmental regulations are typically promoted as measures to protect public health or improve environmental quality, there are often other motivations at work. As with most other sorts of policy, special interest politics can influence the shape and course of environmental measures.[254] Recall the example of reformulated gasoline regulation cited above.[255] In that instance, the EPA was well aware that its regulation could cause more harm than good. Indeed, the history behind the proposed ethanol rule suggests that it was politics, not environmental protection, driving the EPA's decision.[256] In promulgating the ethanol rule, EPA Administrator Carol Browner and Agriculture Secretary Mike Espy

248. *See id.* at 120.

249. Given environmentalist pressures for farmers to reduce the use of agricultural chemicals, this is an even greater concern. Without access to GMOs or agricultural chemicals, farmers will be very constrained in their ability to increase yields.

250. *See* Avery, *supra* note 221, at 68.

251. *See id.*

252. Roger Sedjo, *Forests: Conflicting Signals*, *in* THE TRUE STATE OF THE PLANET 180 (Ronald Bailey ed., 1995).

253. John H. Barton, *Biotechnology, The Environment, and International Agricultural Trade*, 9 GEO. INT'L ENVTL. L. REV. 95, 99 (1996).

254. *See, e.g.*, ENVIRONMENTAL POLITICS: PUBLIC COSTS, PRIVATE REWARDS (Michael S. Greve & Fred L. Smith eds., 1992).

255. *See supra* note 197 and accompanying text.

256. *See generally* Jonathan H. Adler, *Clean Fuels, Dirty Air*, *in* ENVIRONMENTAL POLITICS: PUBLIC COSTS, PRIVATE REWARDS (Michael S. Greve & Fred L. Smith eds., 1992).

explicitly acknowledged that the rule was issued, in part, to assuage the concerns of the ethanol industry.[257]

International trade policy is potentially subject to greater rent-seeking pressures than most areas. The primary instruments of trade policy—tariffs and subsidies—have little economic value other than to provide concentrated benefits to particular interest groups at the expense of the larger public. Industries that traditionally sought protection from global competition through tariffs and other trade barriers see a new opportunity in the push for increased international environmental efforts. "Because environmental standards have a growing national constituency, they are especially attractive candidates for disguised protectionism," notes C. Ford Runge of the University of Minnesota.[258] Daniel Esty, who participated in the NAFTA negotiations on behalf of the EPA, concurs, noting that "environmental standards can be crafted chiefly to benefit domestic producers, not to protect the environment."[259] Allowing importing nations to restrict imports of GMOs, or products derived from GMOs, would create tremendous pressure for the erection of trade barriers, particularly if nations are not required to provide a scientific basis for their decision. As attorney Thomas Redick notes, "[m]any developing countries would like 'socioeconomic' impacts of GMOs to be a factor in risk assessment, allowing trade barriers to protect local interests."[260] Article 26 of the Cartagena Protocol on Biosafety provides just such a mechanism.[261]

A prominent example of alleged trade protectionism disguised as environmental protection is the European Community's 1989 ban on the importation of U.S. beef produced with bovine growth hormones. Most observers see this action as an attempt to exclude U.S. producers from the lucrative European beef and offal markets.[262] Nonetheless, the European Union defended the restriction as a health measure despite the lack of any credible scientific evidence indicating that the use of the hormones in beef production had any negative health impacts. Growth hormones occur naturally in beef, scientists note, dismissing the European claims that the hormones pose a health risk.[263] Thus, in 1997, a WTO dispute resolution panel sided with the United States, ruling that the import ban was a protectionist measure and not a neutral environmental regulation. The European Union appealed, but to no avail, as the WTO panel again sided with the United States. As this is being written, the European Union continues to maintain that the ban is justified, and is resisting compliance with the WTO ruling.[264]

Regrettably, these sorts of disputes are only likely to become more common. "If anything, the temptation to use environmental and health standards to deny access to home markets is stronger now than in the 1980s," notes Runge.[265] As the use of GMOs boosts

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257. *See* John Dillin, *EPA Stirs Debate On Benefits Of Ethanol Fuel Additive*, CHRISTIAN SCIENCE MONITOR, June 30, 1994, at 1.

258. *See* C. Ford Runge, *Trade Protectionism and Environmental Regulations: The New Nontariff Barriers*, 11 NW. J. INT'L L. & BUS. 47, 47 (1990).

259. *See* DANIEL C. ESTY, GREENING THE GATT: TRADE, ENVIRONMENT, AND THE FUTURE 45 (1994).

260. *See* Thomas P. Redick, *Biotechnology, Biosafety and Sustainable Development*, 12 NAT. RESOURCES & ENV'T 114, 117 (1997).

261. *See* CPB, *supra* note 112, at art. 26.

262. *See* ESTY, *supra* note 259, at 103.

263. As this paper is being written, the European Union is preparing another report that will purportedly demonstrate a cancer risk from the use of hormones. U.S. officials, however, maintain that this new study is simply a regurgitation of old, discredited claims.

264. *See* Julie Wolf, *EU Moves to Keep Ban on Hormone-Treated Beef*, WALL ST. J., May 5, 1999, at A2.

265. Runge, *supra* note 258, at 51. For this reason, many developing nations oppose the integration of environmental considerations into the WTO framework. According to *The Economist*, "they fear that

agricultural productivity, farmers in some countries will increase pressure on domestic politicians to "protect" them from foreign competition. The fact that a product was made with or from GMOs could be used as a pretense for protectionist trade measures. Insofar as such restrictions are permitted under the biosafety protocol, this may make it difficult to counter protectionist measures through the WTO. Indeed, then-Undersecretary of State Stuart Eizenstat alleged that the European Union's insistence on a mandate for labeling GMO-derived products is simply a pretense "to justify keeping its trade restrictions in place."[266]

It should go without saying that increased trade protectionism under the guise of environmental protection would impose a substantial toll on consumers and producers.[267] Consumers would be faced with fewer choices and be forced to pay higher prices for agricultural products. Similarly, producers would face smaller markets. The beef hormone dispute alone was estimated to cost U.S. beef producers $100 million.[268] Insofar as the dispute triggered retaliatory measures by the United States, it costs tens of millions more.

Trade restrictions on GMOs and other agricultural products could also have a negative environmental impact, further demonstrating the peril of adopting "precautionary" measures. As Interior Department analyst Indur Goklany notes, international trade "helps to reduce the exploitation of marginal lands for growing crops."[269] This is because international trade allows specialization at the global level, so that crops are grown on the most productive lands. A shortage in one part of the world can be compensated for by a surplus in another. Goklany estimates that had there been no international trade in cereals, an additional 35 million hectares would have needed to be harvested in 1993 to maintain existing production levels.[270] International trade is also a key component of economic growth, which is necessary to sustain the technological development and willingness-to-pay upon which much environmental protection relies.[271] Thus, insofar as the Cartagena Protocol on Biosafety provides a new avenue for protectionists to erect trade barriers, it could have substantial negative impacts on economic well-being, as well as environmental protection.

V. CONCLUSION

Genetic engineering, like any technology, can pose new risks. That alone is insufficient to justify regulation, international or otherwise. For while new technologies pose risks, they also present benefits—benefits that cannot be realized if the risks are avoided at all costs. In the case of crops, the risks of accidentally introducing a new pest species or "contaminating" the wild must be weighed against the risks posed by a growing world population and demands for increased food production. From the standpoint of biodiversity, it is difficult to argue that the risks posed by biotechnology are greater than the risks it could alleviate. The loss of biodiversity due to conversion of habitat into corn fields is as irreversible as the accidental introduction of a genetically engineered species.

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environmental issues will be used by rich countries as yet another excuse to adopt protectionist policies." *Embracing Greenery*, ECONOMIST, Oct. 9, 1999, at 89.

266. *See* Ehsan Masood, *Europe and US in Confrontation Over GM Food Labelling Criteria*, 398 NATURE 641, 641 (1999).

267. However, increasing environmentalist arguments against the expansion of global trade suggest that the economic value of free trade needs to be reiterated.

268. *See* Serge Romensky, *US Seems Set for Victory in EU Hormone-Treated Beef Case*, AGENCE FRANCE PRESSE, July 1, 1997, *available in* LEXIS, News library, News Group File.

269. *See* Goklany, *supra* note 244, at 943.

270. *See id.*

271. *See, e.g.*, Indur M. Goklany, *Strategies to Enhance Adaptability: Technological Change, Sustainable Growth and Free Trade*, 30 CLIMATIC CHANGE 427 (1995).

The precautionary principle should not alter this evaluation for two reasons. First, insofar as the precautionary principle asks that a technology be demonstrated to be without risk, it is asking the impossible. "The best that research can do is narrow the limits on uncertainties, not eradicate them."[272] Second, and perhaps more important, as noted throughout this paper, the lack of biotechnology also poses risks. If the goal is to minimize risk, the focus should be on *which risk is greater*—the risk of a new technology, or the risk of doing without it. In this respect, the precautionary principle is rarely applied evenhandedly. That is, rarely are governmental actions subjected to the same scrutiny, the same proof of "no harm" that new technologies are. Indeed, precautionary regulation reverses the traditional presumption under the American constitutional scheme, that the burden should be on the government to identify the interest that justifies its restriction of private activity.[273]

Advocates of a precautionary approach to new technologies stress that greater regulation is justified by uncertainty. Yet this same argument can be made *against* the regulation of new innovations. It is certainly true that new technologies can pose unknown risks; a technology that appears relatively benign today may be revealed to have a disturbing potential to cause harm tomorrow. By the same token, regulations that seem to improve safety and environmental protection may in fact cause substantial harm.[274] Government regulations can have as many unintended consequences as technological advances.[275] The presence of uncertainty about a technology, without more, cannot establish a presumption that more regulation is required.

The Cartagena Protocol on Biosafety, like many of the international environmental agreements that have gone before it, suffers from this defect. While meeting delegates paid lip-service to the beneficial impact advances in biotechnology could have, they negotiated a treaty that could forestall many of those benefits. Ironically, it is the people of the developing world, and global biodiversity, which may end up suffering the most. A stringent biosafety protocol is unlikely to make the world any safer, but it certainly could make us more sorry than safe.

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272. *GM Foods Debate Needs a Recipe for Restoring Trust*, *supra* note 30, at 639.

273. As Wildavsky notes,

> The immensity of the change requires reemphasis: private action requires proof of the absence of harm; governmental action requires no proof of harm. The relative role of the citizen and the state have been reversed. In the past it was the citizen who was entitled to act and the state that had to justify its intervention; now it is the state that intervenes by right and the citizen who has to give reasons for acting. The reversal of the usual course of action has profound implications.

WILDAVSKY, *supra* note 188, at 430.

274. *See supra* Part III.A.

275. It should be noted that private companies that market dangerous technologies are typically more amenable to suit for damages than government agencies that impose harmful regulations.