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Agricultural Biotechnology and the Negotiation of the Biosafety Protocol

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I. INTRODUCTION

For most people, the words "genetic engineering" conjure up mental images of a Hollywoodesque parade of horribles: alien-human hybrid monsters, miserably deformed mutants, and uber-humans cloned with evil intent.[1] Even the popular media these days is filled with real-life impossibilities such as bionic oil-digesting bacteria,[2] tobacco plants that glow in the dark,[3] cloned sheep,[4] mice that can grow human ear structures,[5] and bacteria that produce human insulin.[6] These images may create concern, or even fear, among the public. Nevertheless, most consumers in the United States are in much more frequent and personal contact with genetically modified organisms (GMOs) than they may realize. Almost without notice, the bounty produced through agricultural biotechnology has become a staple of modern existence.[7] Do consumers feel chills run up their spines when they come eye-to-eye with that transgenic[8] potato at the market? How about when they reach for that Ben and Jerry's ice cream with the label specifying that it is "bovine growth hormone-free?"[9] How many consumers question the meaning of the label?

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1. *See, e.g.*, MULTIPLICITY (Columbia Pictures, Corp. 1996); SPECIES (Metro-Goldwyn-Mayer 1995); JURASSIC PARK (Universal Pictures 1993).

2. *See, e.g.*, Diamond v. Chakrabarty, 447 U.S. 303 (1980) (finding patentable a live, human-made, genetically-engineered bacterium capable of breaking down crude oil).

3. *See, e.g.*, *Tobacco Plant Glows with Firefly Gene Implant*, APPLIED GENETICS NEWS, Dec. 1986, at 10-11.

4. *See, e.g.*, Rick Weiss, *Researchers Fuse Cells in Lab to Clone Sheep*, WASH. POST, Mar. 7, 1996, at A1.

5. *See, e.g.*, *Pig Arteries Lab Grown, Implanted, Functioning Normally*, MED. INDUS. TODAY, Apr. 19, 1999.

6. *See, e.g.*, Tom Abate, *All-Day Party to Honor the Discovery That Launched Biotech Revolution*, S.F. CHRON., Mar. 15, 1999, at B1. For an interesting overview of several biotechnology research projects, see Justin Gillis, *Cows and Clones on a Virginia Pharm*, WASH. POST, Feb. 28, 1999, at A1.

7. In 1998, around one quarter of all U.S. corn acreage was planted with transgenic varieties, as was one third of U.S. soybean acreage. *See Agricultural Biotechnology: Hearings Before the Subcomm. on Risk Management, Research and Specialty Crops of the House Comm. on Agric.*, 106th Cong. 13-16 (1999) (statement of James M. Murphy Jr., Assistant U.S. Trade Representative for Agricultural Affairs, Office of the U.S. Trade Representative); *Hearings on the Status of Agricultural Trade Issues and Negotiations with the People's Republic of China and the European Union Before the Subcomm. on Int'l Trade of the Senate Fin. Comm.*, 106th Cong. (1999) (statement of Allen F. Johnson, President of National Oilseed Processors Association), *available at* <http://www.senate.gov/~finance/3-15john.htm>.

8. Transgenic refers to plants that have been genetically modified using genetic engineering techniques. *See* Gabrielle J. Persley & James N. Siedow, *Issue Paper — Applications of Biotechnology to Crops: Benefits and Risks*, 12 COUNCIL FOR AGRIC. SCI. & TECH. 2 (1999).

9. Bovine growth hormone (BGH), also known as bovine somatotropin, is a natural substance synthetically produced through genetic engineering and injected into cattle to increase beef and milk yields. *See* International Information Programs, U.S. Dep't of State, *Biotechnology Lexicon* (visited Jan. 6, 2000) <http://www.usia.gov/

Most consumers are unaware of the possible ecological, economic, health, and safety risks and benefits associated with this technology, despite the growing prevalence of such products in the marketplace. In many cases, consumers may not even be aware that they are consuming transgenic products.[10] Although agricultural biotechnology issues have been in and out of the public spotlight for years, a dramatic development in international policy recently has led to increased attention to this topic. After years of negotiations, 138 countries finally reached agreement on the provisions of an international biosafety protocol that will govern the export, use, and sale of transgenic products — in most cases agricultural biotechnology products — in international commerce.[11] Formulated as an adjunct to the Convention on Biological Diversity,[12] the Protocol has proven highly controversial because it raises conflicts between countries that already possess developed biotechnologies and countries that seek access to such technologies. The United States found itself in an unenviable position during the negotiations. Although the United States is a major player in the international agricultural biotechnology industry, it is not a party to the Convention on Biodiversity, and hence was unable to formally participate in the negotiations.

Considering the scientific, legal, and political tempest that surrounds agricultural biotechnology, it is surprising how infrequently all three facets have been linked. Thus, the purpose of this note is not to parse every regulatory aspect of agricultural biotechnology, but rather to examine the scientific and historical developments that have led to the negotiations of the new Biosafety Protocol.[13]

Focusing on the agronomical[14] applications of biotechnology, Part II of this note will provide an introduction to basic principles of genetics as they relate to crop breeding. Part III will discuss applications of biotechnology in agronomy. Part IV will discuss the role of crop plants in biodiversity. Part V will highlight recent changes in modern agricultural methods. Part VI will provide a brief

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journals/ites/1099/ijee/bio-terms2.htm>; JACK DOYLE, ALTERED HARVEST 26 (1985). This use of BGH has proven controversial in both the United States and abroad, especially in the European Union countries where there has been a strong governmental and consumer backlash against transgenic products. *See* Report of the WTO Appellate Body, European Communities — Measures Affecting Meat and Meat Products (Hormones), WT/DS26/AB/R, WT/DS48/AB/R (Jan. 16, 1998) [hereinafter Beef Hormones].

10. The Natural Law Party posts an e-mail newsletter in which it warns subscribers of common foods that may contain transgenic products. Some of these common foods include Fritos corn chips, McDonald's French fries, and Coca-Cola. *See* Natural Life, *Shop to Avoid Genetically Engineered Food* (visited Feb. 2, 2000) <http://www.life.ca/n1/60/avoidbiotech.html>.

11. *See* Maggie Farley, *Deal Struck to Regulate Genetically Altered Food*, L.A. TIMES, Jan. 30, 2000, at A1; *see also* Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Feb. 23, 2000 (visited Apr. 5, 2000) <http://www.biodiv.org/biosafe/BIOSAFETY-PROTOCOL.htm> [hereinafter Biosafety Protocol].

12. Convention on Biological Diversity, U.N. Conference on Environment and Development, June 5, 1992, U.N. Doc. UNEP/Bio.Div/N7-INC.S/4, *reprinted in* 31 I.L.M. 818 (entered into force Dec. 29, 1993) [hereinafter Convention]. Provisions regarding biosafety are primarily in Article 19.

13. Many people have moral, religious, and other objections to various uses of biotechnology. This note will not discuss such issues, leaving judgment, instead, to the reader.

14. This term is a derivative of "agronomy: the science of farm management and the production of field crops." RANDOM HOUSE WEBSTER'S COLLEGIATE DICTIONARY 28 (1992).

overview of the U.S. objections to the Convention for Biodiversity, the first Biosafety Protocol negotiation sessions, the results of the most recent negotiating session in Cartegena, Columbia, and U.S. objections to the proposed Biosafety Protocol draft.

II. BASICS OF AGRONOMY (GENETICS 101): WHAT ARE LMOS AND WHERE DID THEY COME FROM?

To understand biotechnology, it is important to have at least a basic understanding of the underlying science of genetics. In very simple terms, genetics is the study of the inheritance and inheritability of traits.[15] For example, genetic principles allow scientists to predict the probability of two people with auburn hair producing a red-headed child. With respect to agriculture, agronomists can use genetics to manipulate characteristics that are commercially important to crop production and the agribusiness industry. Specifically, agronomists work towards four main objectives. For each crop, agronomists seek to improve: (1) agronomic suitability of the crop plant to its environment, (2) quality of the crop produced, (3) yield of the crop produced, and (4) the resistance of plants to disease and pests.[16]

Historically, the only way to improve qualities of crop plants has been to selectively breed the plants to enhance the desired characteristics.[17] Cross-breeding different varieties of self or cross-pollinating plants[18] results in the development of many unique and genetically diverse landrace varieties, also called *cultiv*ated *var*ieties ("cultivars"), of crop plants that possess the qualities sought by the farmer. Although cross-breeding is an effective means of improving crop plants on a large scale,[19] it can be incremental, time-consuming, and imprecise. There is no way to precisely control individual traits, such as resistance to a certain fungus, without concurrently altering a variety of other traits.[20] Additionally, cross-pollinating plants do not discriminate as to what other

15. Note that this discussion is an extremely simplistic overview. For a more complete discussion in layman's terms, see RAOUL A. ROBINSON, RETURN TO RESISTANCE: BREEDING CROPS TO REDUCE PESTICIDE DEPENDENCE 3-18 (1996). For a more technical discussion in the context of biotechnology, see generally AGRICULTURAL BIOTECHNOLOGY (Arie Altman ed., 1998).

16. *See* ROBINSON, *supra* note 15, at xiv.

17. For a general overview of plant breeding techniques, see NATIONAL ACADEMY OF SCIENCES, GENETIC VULNERABILITY OF MAJOR CROPS 59-60 (1972).

18. Plants can either self-pollinate, meaning that all genetic material is self-contained within the plant, or cross-pollinate, meaning that plants exchange genetic material. Using various methods to develop "pure" hybrid lines, breeders can then cross the hybrids to produce an entirely new variety.

19. One fascinating example is the sugar beet. The sugar beet was used as a source for sugar extraction by Europeans during the Napoleonic wars, when cane sugar shipments from the West Indies were blocked by the British blockade. By selectively breeding the fodder beet (commonly used to feed farm animals) to improve yield and sugar content, farmers succeeded in both areas, resulting in a new crop — the sugar beet. Yields had increased, as had the sugar content, rising from 4% to 16%. *See* ROBINSON, *supra* note 15, at 13-14.

20. *See* AGRICULTURAL BIOTECHNOLOGY, *supra* note 15, at 295-315.

plants with which they will reproduce. The plants will cross within their variety and across varieties, and can outcross with wild relatives. While such outcrossing can be seen as beneficial because it increases diversity of the genetic base, it can result in the expression of traits unexpected or contrary to the intention of the breeder.[21] Consequently, agronomists have turned to biotechnology in seeking a better way to breed for the expression of specific desired traits.

Agronomic applications of biotechnology center on altering characteristics of crop plants from within the existing cellular and genetic structures.[22] All living things, from the simplest single-cell organisms to the most complex multicellular organisms contain the molecule deoxyribonucleic acid — DNA. Each strand of DNA is comprised of thousands of genes, each of which, in turn, controls the existence or expression of a specific function or trait.[23] It is the different combinations of genes within the strands of DNA that make different organisms, even organisms of the same species, unique.

Biotechnology allows scientists to manipulate genetic material, whether it involves the cloning and propagation of plants that possess the desired characteristics, or the creation of new varieties from existing stock. Biotechnological procedures allow scientists to move specific genes within an organism[24] or from one organism to another, whether the gene is from an organism of the same species or a different species.[25] Generally speaking, the product of these processes can be described as "bioengineered," "genetically engineered," or "transgenic."[26] In the broadest sense, an agricultural product that has been genetically altered using biotechnological techniques is frequently called a "Genetically Modified Organism" (GMO) or a "Living Modified Organism" (LMO).[27] As this

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21. *See* CARY FOWLER & PAT MOONEY, SHATTERING: FOOD, POLITICS, AND THE LOSS OF GENETIC DIVERSITY 50 (1990); *cf.* STEPHAN L. BUCHMAN & GARY PAUL NABHAN, THE FORGOTTEN POLLINATORS 6-9 (1996) (describing anecdotal examples of wild gourds and peppers in the Southwest United States).

22. *See* DOYLE, *supra* note 9, at 22.

23. The potential of each gene to influence an organism depends on whether the gene is actually expressed — meaning whether it actually produces the protein for which it codes. For example, it is possible for plants to carry insecticidal genes, but these genes are useless unless they are somehow turned on.

24. The first consumer product to utilize this type of biotech was the Flavr Savr Tomato created by the California-based genetics firm Calgene. By locating, removing, reversing, and reinserting the gene responsible for cueing the fruit to ripen, researchers were able to create a fruit that could be left on the vine to ripen, yet still stand up to the rigors of machine harvesting. For a discussion of bioengineering and food production, see WILLIAM P. CUNNINGHAM & BARBARA W. SAIGO, ENVIRONMENTAL SCIENCE 208 (3d ed. 1995).

25. *See, e.g.*, F. Georges et al., *Design and Cloning of a Synthetic Gene for the Flounder Antifreeze Protein and its Expression in Plant Cells*, 91 GENE 159-65 (1990) (insertion of antifreeze genes from cold water flounder species into plant cells).

26. Although these terms are frequently used in technical literature as signifying precise products or processes, for the purposes of this paper, they will be used in a more general sense. *See* T.J. Mullin & S. Bertrand, *Environmental Release of Transgenic Trees in Canada — Potential Benefits and Assessment of Biosafety*, 74 FORESTRY CHRON. 203, 204 (1998).

27. It is interesting to note the proposed change in terminology from the use of GMO to LMO. While negotiating the provisions of the Convention on Biodiversity, the biotechnology companies repeatedly asserted that genetically altering plants by biotechnological means was equivalent to conventional plant breeding

is the terminology adopted in most U.S. political and policy-oriented discussions, it will also be used in this note. The next section discusses the potential environmental and health benefits and risks of LMOs.

III. BIOTECHNOLOGY IN AGRONOMY

A. POTENTIAL BENEFITS OF AGRONOMIC BIOTECHNOLOGY

Biotechnology potentially offers many advantages over traditional plant breeding methods. Breeders may be able to select and obtain particular traits more precisely, thus leading to a shorter development time for new varieties.[28] New varieties of plants engineered for disease and pest resistance may require fewer applications of chemical pesticides than traditional varieties. This could result in financial savings and environmental and health benefits.[29] Increased yields on existing agricultural land due to biotechnological advances may prevent conversion of virgin habitats to agricultural lands.[30] Potential benefits of agronomic biotechnology include greater selectivity and precision in obtaining desired traits, reduction in the amount of agrochemicals used, and facilitation of the creation of better consumer products.

1. Greater Selectivity and Precision in Obtaining Desired Traits

Traditional plant breeding techniques result in fairly random outcomes, as individual traits cannot be altered without changing others. Further, it may take many generations to create the target variety or it may be impossible to breed for the selected trait. In contrast, biotechnology may allow for greater selectivity of genetic composition. Once the genes controlling the desired trait are identified and located, these genes can be isolated, removed, and then inserted into the DNA of the receiving plant. Rather than taking generations of focused breeding to enhance the expression of a certain trait, these techniques provide a much quicker means of developing new lines. For some perennial crops, development of a new hybrid plant can be reduced from thirty or forty years to seven or eight.[31]

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techniques. To minimize the perceived difference between the two types of organisms, the representatives pushed for a change in the terminology used in the Convention. *See* Third World Network, *Position Paper for the Sixth and Final Biosafety Protocol Negotiations in Cartagena* (visited Mar. 27, 1999) <http://www.southside.org.sg/souths/twn/title/key-cn.htm>.

28. *See* DOYLE, *supra* note 9, at 196.

29. *See* Thomas O. McGarity, *International Regulation of Deliberate Release Biotechnologies*, 26 TEX. INT'L L. J. 423, 426-27 (1991). For example, see discussion of the bacterium *Bacillus thuringiensis infra* Part III.A.2.

30. *See* 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, 7, 13 (1997). However, it is important to keep in mind that actual or realized benefits may be difficult to assess due to a lack of conclusive evidence on some points and the proliferation of rhetoric on other points.

31. *See* FOWLER & MOONEY, *supra* note 21, at 208; Mullin & Bertrand, *supra* note 26, at 208. It is interesting

Additionally, genetic material can be incorporated either from the same species or from a completely different type of organism. Thus, transgenic plants are not subject to the limits nature places on combining available genetic material. Such flexibility has been demonstrated by experimental attempts to increase the resistance of crop plants to cold weather by inserting cold resistance genes from bacteria and fish.[32]

2. Reduction in the Amount of Agrochemicals Used

One potentially amazing application of agronomic biotechnology is the ability to insert into crop plants genes that confer a genetic resistance to diseases[33] and pests.[34] Inherent resistance may lead to a lessening of farmers' dependence on topically applied chemicals, which have proven to be environmentally dangerous.[35]

The most prevalent example of a "natural pesticide" is derived from the bacterium *Bacillus thuringiensis* (*Bt*). For years, organic gardeners have been using a topical *Bt* spray to control various species of the order Lepidoptera,[36] and now there are several lines of crop plants that contain the genetic coding for the *Bt* protein.[37] When the targeted pest consumes a *Bt*-treated product, an enzyme present in the digestive tract of the insect activates the *Bt* gene. There, it turns into an insecticide that destroys the lining of the insect's digestive tract.[38] While the primary benefit of genetic *Bt* is that it limits yield losses caused by insect predation on plants, at least one industry representative claims that it confers ancillary benefits as well.[39] Healthier plants utilize fertilizer more efficiently,

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to note the potential applications of biotechnology to environmental concerns other than agriculture. The benefit of being able to shorten development time is of particular interest to forestry experts, due to the elongated breeding cycles and lifespans of trees. *See* FOWLER & MOONEY, *supra* note 21, at 207.

32. *See, e.g.*, Dawn A. Baertlein et al., *Expression of a Bacterial Ice Nucleation Gene in Plants*, 100 PLANT PHYSIOLOGY 1730 (1992) (insertion of genes isolated from bacteria); Georges, *supra* note 25.

33. *See* C.T. Harms, *Engineering Genetic Disease Resistance into Crops*, 11 CROP PROTECTION 291-306 (1992).

34. For an interesting discussion of the benefits and risks posed by the so called "plant pesticides," see Mary Jane Angelo, *Genetically Engineered Plant Pesticides: Recent Development in the EPA's Regulation of Biotechnology*, 7 U. FLA. J.L. & PUB. POL'Y 257, 284-88 (1996).

35. *See* Dilip M. Shah et al., *Resistance to Diseases and Insects in Transgenic Plants: Progress and Applications to Agriculture*, 13 TRENDS IN BIOTECHNOLOGY 362 (1995). However, it is speculated that these applications could have the opposite result. *See* discussion of risks and accompanying notes *infra* Part III.B.

36. Lepidoptera means scale wing, in reference to the colorful scales that cover the wings of Lepidopterous insects. This order of insects includes butterflies and moths, of which some species' larvae feed on the leaves of crop plants.

37. *See* Ronald L. Meeusen & Gregory Warren, *Insect Control with Genetically Engineered Crops*, 34 ANN. REV. OF ENTOMOLOGY 373, 374 (1989).

38. *See* Sara M. Dunn, *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, 151-52 (1998). Additionally, *Bt* is said not to have negative effects on non-target organisms such as humans and livestock, a claim that is discussed *infra* Part III.B.3.

39. *See World Trade Organization Agriculture Agreement: Hearings Before the Subcomm. on Int'l Econ.*

which can result in increased crop yields and a decreased need for heavy fertilization. Decreased use of fertilizers may in turn reduce the amount of harmful runoff from farmland.[40]

Another potential benefit is the possibility of reducing applications of herbicides.[41] Most herbicides are non-discriminatory in nature and will kill all plants they contact, including the crop plants they are intended to aid.[42] Thus, farmers traditionally applied herbicide to entire fields in order to pre-clear the field of weeds before the crop plants emerged. This method had varying levels of efficacy and increased the chances of air and water pollution by the herbicide.[43] However, new plant varieties have been engineered to resist certain herbicides, and thus farmers can now selectively use herbicides after the crop emerges.[44] The biotechnology industry claims that this will result in economic savings to the farmer and environmental savings as fewer herbicides are released into the environment.[45]

3. Facilitation of Creating Better Consumer Products

According to industry representatives, transgenic products offer a multitude of benefits to consumers. For example, the American Seed Trade Association (ASTA) predicts that biotechnology can create food products that are more convenient[46] and easier to process.[47] The ASTA also predicts that these creations can contain fewer toxins, higher concentrations of nutrients,[48] and reduced concentrations of harmful substances. Finally, the ASTA predicts these products can have increased shelf lives, as well as improved flavor, texture, and

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Policy and Trade of the House Comm. on Int'l Relations, 106th Cong. (1999) (statement of L. Val Giddings, Vice President for Food and Agriculture, Biotechnology Industry Organization).

40. *See id.* It is important to note that these claims may be slightly exaggerated. While such reasoning sounds logical, the author was unable to substantiate the claims given in the testimony.

41. *See id.* While this "benefit" has been proposed by the industry as a justification for the development and marketing of various products, some scientists question whether exclusive use of one herbicide poses a danger of evolved resistance. Also, the use of "terminator" technology may ultimately increase the amounts of chemicals needed. *See* discussion *infra* Part III.B.1 (discussing "terminator" genes).

42. One example is the chemical glyphosate, the active ingredient in Monsanto's popular Round-Up herbicide, which is extremely toxic to all green plants. *See* Rudy Baum, *Herbicide-Resistant Crops Focus of Biotechnology Debate*, CHEMICAL & ENGINEERING NEWS, Mar. 8, 1993, at 38, 39.

43. *See* Margie Patlak, *Designer Seeds*, BEYOND DISCOVERY (Nat'l Acad. Sci., Wash., D.C.) (visited Apr. 6, 2000) <http://www4.nas.edu/beyond/beyonddiscovery.nsf/web/seeds?OpenDocument>.

44. *See Agricultural Biotechnology: Hearings Before the Subcomm. on Risk Management, Research and Specialty Crops of the House Committee on Agric.*, 106th Cong. 88-92 (1999) (statement of Roger N. Beachy, President of Donald Danforth Plant Science Center).

45. *See id.* This claim, however, has been widely disputed. Such varieties can only be cultivated using a complete "package" of products from the company, which may actually raise costs rather than lower them.

46. Small, single serving size melons are one example. *See Agricultural Biotechnology: Hearings Before the Subcomm. on Risk Management, Research and Specialty Crops of the House Comm. on Agric.*, 106th Cong. 85-88 (1999) (statement of Harry Collins, American Seed Trade Association).

47. For example, high starch potatoes absorb less oil when used to make french fries or potato chips. *See id.*

48. Two examples are rice and peanuts with higher protein. *See id.*

appearance.[49] Additionally, genetic modifications may enhance qualities in some plants that may fight cancer or heart disease.[50]

Some proponents of agricultural biotechnology see the ability to alter crop plants as a way to improve the quality of life of people around the world. Some proponents of agricultural biotechnology claim that plant viruses can be engineered to stimulate the human immune system when consumed, thus creating a food that acts in a manner similar to a vaccination.[51] Genetic alterations of crops can be used to increase the variety of crops and the yield of crop plants grown in areas where starvation is a problem[52] and to boost the nutritional composition of crop plants to prevent common micronutrient deficiencies, such as iron and vitamin A deficiencies.[53]

While the biotechnology industry heralds the advent of each new product as another example of the superiority of technology over nature, as with many other technologies, there are very real concerns about the safety of and the risks posed by the new technology. These concerns include the risk of migration of transgenes into non-target organisms, the creation of herbicide-resistant weeds, and the adulteration of foods by transgenes.

B. POSSIBLE RISKS OF AGRONOMICAL BIOTECHNOLOGY

1. Migration of Transgenes into Non-Target Organisms

The overarching concern about transgenic plants is that the engineered genes will migrate or escape into other organisms. The most likely way for plants to exchange transgenes is through outcrossing. Outcrossing is the process through which domesticated plants hybridize with wild relatives, producing a new variety. Although outcrossing is a common occurrence in conventional agronomy, outcrossing in transgenic plants may occur at significantly higher rates. Startlingly, a recent study found that genes from transgenic plants might be up to twenty times more likely to outcross into relative species than the plant's natural genetic material.[54]

Another way by which transgenes might spread is by conjugation among bacteria.[55] While the transfer of transgenes by cross-breeding is a generally

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49. Peppers, strawberries, raspberries, bananas, sweet potatoes, and melons exhibit such characteristics. *See id.*

50. Potential products include tomatoes with higher levels of the antioxidant lycopene, produce fortified with or containing higher levels of vitamins (C and E, for example, for protection against cancer, heart disease, and other maladies), garlic cloves which produce more allicin (a compound which may lower cholesterol levels), and strawberries with increased levels of ellagic acid (a natural-cancer fighting agent). *See id.*

51. *See* Thomas R. DeGregori, *Genetically Modified Nonsense* (visited Apr. 7, 2000) <http://www.biotech-knowledge.com/showlib_biotech.php3?2769>.

52. *See id.*

53. *See id.*

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

55. Conjugation is the normal means by which bacteria exchange genetic material. *See* Mullin & Bertrand,

accepted occurrence,[56] there are conflicting opinions within the scientific community as to whether bacteria can incorporate transgenes from plants or bacteria. Further, there is debate as to whether such transfer poses any risks. Although there is inadequate research in the area so far, one study has raised the concern that some bacteria can cross evolve, giving rise to the fear that engineered genes or antibiotic resistant genetic markers could jump out of the transgenic plant and into the surrounding environment.[57]

One proposed solution is to engineer sterile plants, which cannot reproduce and pass on the transgenes through normal propagation or outcrossing.[58] However, transgenes would still be present and available for conjugation with bacteria. Therefore, there is no guarantee that plant sterility would prevent an accidental "escape" of the transgene into other plants. Another proposed solution that addresses both outcrossing and conjugation problems is to insert so-called "suicide" genes into the transgenic plant along with the genes coded for the desired traits.[59] It is speculated that suicide genes would prevent the transgene from surviving or expressing itself once outside of the original host organism.[60] However, the suicide genes themselves are transgenic, and they too could be passed on to other plants.

Thus, as appealing as these strategies sound, they cannot ensure that the transgenes will behave as intended. Studies have shown that the stability of many transgenes is affected by both environmental factors and propagation.[61] One study has noted, "The relevant question with respect to [cross-pollination] gene transfer is not whether the gene flow will or will not occur, but rather what will be the fate and impact of the escaped transgene in the natural environment."[62]

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supra note 26, at 210. It has been speculated that bacteria might be able to incorporate the antibiotic-resistant genes routinely used as research markers, thus conferring a resistance to antibiotics. *See also* Michael G. Lorenz & Wilfried Wackernagel, *Bacterial Gene Transfer by Natural Genetic Transformation in the Environment*, 58 MICROBIOLOGY REV. 563 (1994); M. Syvanen, *Horizontal Gene Transfer: Evidence and Possible Consequences*, 28 ANN. REV. OF GENETICS 237 (1994); Debora MacKenzie, *Gut Reaction*, NEW SCIENTIST, Jan. 30, 1999, at 4 (finding that, in an artificial gut, antibiotic resistant transgenes can be transferred to other, indigenous bacteria). *But see* T.W. Prins & J.C. Zadoks, *Horizontal Gene Transfer in Plants, A Biohazard? Outcome of a Literature Review*, 76 EUPHYTICA 133 (1994) (asserting that horizontal gene transfer is irrelevant to evaluating risks posed by transgenic plants); Kirsten Schluter et al., *"Horizontal" Gene Transfer From a Transgenic Potato Line to a Bacterial Pathogen (Erwinia chrysanthemi) Occurs — If at All — at an Extremely Low Frequency*, 13 BIO/TECHNOLOGY 1094-98 (1995).

56. *See, e.g.*, Statement of Roger N. Beachy, *supra* note 44 (asserting that gene transfer should not cause concern as it is a common occurrence in conventional, as well as biotechnological, plant development).

57. *See* MacKenzie, *supra* note 55, at 4.

58. *See* Steven H. Strauss et al., *Benefits and Risks of Transgenic Roundup Ready Cottonwoods*, 95 J. FORESTRY 12, 17 (1997).

59. *See* Robert F. Service, *Plant Biotechnology: Seed-Sterilizing "Terminator Technology" Sows Discord*, 282 SCIENCE 850, 850 (1998).

60. *See id.*

61. *See* H.J. Rogers & H.C. Parkes, *Transgenic Plants and the Environment*, 46 J. EXPERIMENTAL BOTANY 467 (1995).

62. Mullin & Bertrand, *supra* note 26, at 10.

Further, the use of a similar "terminator" technology raises other concerns. Such technology is used to create seeds that will not germinate without the application of proprietary chemicals supplied by the seed company.[63] These seeds were developed to help seed companies enforce licensing requirements and preserve profits from the annual sale of engineered seeds and chemicals. While this may prove an effective means of enforcing intellectual property rights, the result could be disastrous if plants incorporating this technology outcrossed with other plants.[64]

Terminator technology also has the potential to pose many other problems, particularly for the 1.4 billion people who rely on farm-saved seed.[65] Requiring farmers to purchase seed and chemical "packages" could prove prohibitively expensive for many and may further narrow the genetic base by preventing farmers from breeding and cultivating their own unique hybrids.[66] One concern is that some governments might force farmers to buy the engineered seed, thus displacing native varieties.[67] Another concern is that farmers' unique varieties may be rendered sterile through cross-pollination with terminator or suicide engineered varieties planted in adjoining plots.

2. Creation of Resistant "Superweeds" and "Superpests"

One long-standing phenomenon is that both weeds and insects can evolve resistance to herbicides and pesticides, thus increasing the amounts and kinds of chemicals that must be used. Therefore, another risk of biotechnology is that weeds and insects also will evolve resistance to transgenic products such as pesticidal proteins (*Bt*, for example),[68] and thus become even more difficult to control. Weeds, for instance, may bear close genetic resemblance to the crop plants, making successful outcrossing more likely.[69]

Genetically speaking, the ability of plants to outcross with wild relatives is beneficial because it increases the genetic base from which farmers may build new varieties. For example, contemporary subsistence farmers rely on such

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63. *See* Natural Life, *Over Two Dozen "Suicide Seed" Patents Are Registered* (visited June 7, 1999) <http://www.life.ca/nl/67/terminator.html>.

64. *See* Farhad Mazhar, *Destructive Consequences of "Controlling Plant Gene Expression" or "TERMINATOR" Technology for Food Security and Biodiversity*" (visited June 8, 1999) <http://www.capside.org.sg/souths/twn/title/express-cn.htm>.

65. *See* Danielle Knight, *Cheers for Monsanto's Reversal on "Terminator"* (visited Mar. 6, 2000) <http://www.twnside.org.sg/title/cheers-cn.htm>.

66. *See* Mazhar, *supra* note 64.

67. *See* Knight, *supra* note 65.

68. *See* Dunn, *supra* note 38, at 155. Farmers planting *Bt* corn are advised to plant 20% to 25% of their acreage with non-*Bt* corn, as a preventive measure against resistance. *See id.*

69. Outcrossing in this manner, sometimes called introgressive hybridization, occurs when two closely related plants exchange genetic material, thus creating a new variety of plant. *See* BUCHMAN, *supra* note 21, at 7-9.

outcrossing to improve landrace varieties, and agrotechnology firms utilize non-domesticated and outcross varieties as banks from which to find new genetic material.[70] However, the ability to integrate genes from outside plants also poses the danger that engineered or resistant genes can escape from cultivated plants into the wild, creating new varieties of "superweeds."[71]

Superweeds are the result of a weed cross-pollinating with a transgenic plant that results in the weedy plant inheriting various genes that are agriculturally beneficial when expressed in a crop plant, but undesirable when expressed in a weed.[72] Thus, the weed may take on a number of enhanced characteristics and become immune to disease, natural insect predators, or herbicides. Given an advantage over other weeds, the superweed may outcompete surrounding foliage to the detriment of any plants or animals that rely on those species for food or shelter. Further, superweeds that are immune to herbicides may be uncontrollable by conventional chemical means.[73]

Although the inheritance of resistance through outcrossing is not unique to biotechnology, this type of interaction is arguably more dangerous than that posed by conventional breeding techniques. Combined with the rapidity with which transgenes may jump into wild populations[74] and the high levels of immunity transgenes can confer, the threat of the superweed is one that cannot be ignored. There are already examples of herbicide resistant genes that have migrated from transgenic oilseed rape[75] and sugar beet[76] into wild relatives.

It is claimed that a benefit of transgenic crops is that inherent immunities to weeds and pests will reduce the amount of agri-chemicals needed, resulting in

70. This is not a surprising result considering that such outcrossing is a known method for purposefully changing plant characteristics. For example, when agronomists breed crop plants to enhance herbicide resistance traits, one genetic resource has been to cross the crop plant with one of the 30 or more species of weeds that have evolved resistance to herbicides since the early 1970s. *See* DOYLE, *supra* note 9, at 216.

71. Angelo, *supra* note 34, at 287.

72. *See* Third World Network, *World Scientists' Statement: Supplementary Information on the Hazards of Genetic Engineering Biotechnology* (visited Mar. 27, 1999) <http://www.southside.org.sg/souths/twn/title/worldsp-cn.htm>.

73. *See id.*

74. *See* Bergelson, *supra* note 54, at 25.

75. Working with a team of researchers at the Risoe National Laboratory in Denmark, Ohio State University researcher Allison Snow crossed an herbicide resistant transgenic oilseed rape plant with a weedy relative, and then cultivated the progeny in the laboratory in Denmark. The researchers found that within three generations, the transgenic weed was resistant to herbicide, but was otherwise indistinguishable from the original weedy parent plant — it retained traits of hardiness, aggressiveness, and the ability to reproduce. The results of this experiment are worrysome because studies have shown that pollen from transgenic oilseed rape can reach weeds almost a mile away, and the two frequently grow in close proximity to each other in the field. Thus, the ability to cross-breed will accelerate the spread of the transgene to weedy relatives, resulting in the creation of a herbicide resistant "superweed." *See* Kathleen Hart, *Herbicide-resistant Oilseed Rape Leads to Hardy Transgenic Weeds, Researchers Find*, PESTICIDE & TOXIC CHEMICAL NEWS, Aug. 13, 1998; A. Snow & R. Jorgensen, *Costs of Transgenic Glufosinate Resistance Introgressed From Brassica napus into Weed Brassica rapa* (Ecologic Society of America, Baltimore, Md., Aug. 6, 1998).

76. *See* M. Brookes, *Running Wild*, NEW SCIENTIST, Oct. 31, 1992, at 38.

less environmental damage and reduced costs to farmers. However, these new combinations may actually lead to the use of more chemicals, and the proprietary chemicals that must be used will lead to increased costs for farmers.

Even ignoring the effects of transgenic plants on chemical use, the transgenic aspects of the plants might have adverse environmental effects. For example, transgenic *Bt* plants might affect non-target organisms, including beneficial insects and soil organisms.[77] Further, transgenic crops themselves have not proven trouble-free. Monsanto's Round-Up Ready cotton was the subject of a recent lawsuit brought by farmers who sustained heavy crop losses due to problems with the product.[78]

Superpests pose resistance dangers similar to those of superweeds. However, the main difference is that insects, due to their extremely short life spans, have a greater capacity to rapidly adapt to changes in crops and pesticides.[79] Thus, the co-evolution of pests to avoid natural defenses of plants is a continuing battle,[80] and the advent of chemical pesticides created a new wave of co-evolution, as insects rapidly adapted to the pesticides in use.[81] As one commentator dryly noted, "[T]oday's super pest could enjoy several doses of yesterday's pesticide for dessert, ask for more and live to tell about it."[82]

As resistance to chemical means increased and pesticides began to lose effect, researchers turned to biotechnology to find a new means of pest control. However, there is no guarantee that insects won't develop resistance to the new transgenic "plant pesticides"[83] as well. If they do, farmers will then have to revert to chemical methods, which may not work due to the previously established resistance, or they will have to continually hope that biotechnologists can find new "cures" for the problem.

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77. *See* Bt *Petition Summary* (visited Jan. 6, 2000) <http://www.biotech-info.net/btsummary2.html>.

78. *See* Michele Landsberg, *Please Chew on This, Monsanto: Modified Food Has Eaters Fed Up*, TORONTO STAR, Dec. 26, 1999.

79. *See* DOYLE, *supra* note 9, at 178.

80. In both natural and human-influenced environments, insects have shown a strong propensity to evolve new traits in response to traits of the plants consumed. This is a form of co-evolution. For example, the International Rice Research Institute conducted an experiment in which the invidious brown planthopper, a serious rice pest in Asia, was raised on a poor quality but hopper-resistant variety of rice called Mudgo. In the early trials, many of the planthoppers refused to eat Mudgo and consequently starved to death. However, within ten generations, the planthoppers had evolved to the point where they thrived on the Mudgo variety. *See* FOWLER & MOONEY, *supra* note 21, at 48-49.

81. As of 1990, an estimated 400 pest species of insects had developed resistance to once-lethal pesticides. *See id.* at 48.

82. *Id.*

83. There is great debate in Congress right now over the proper term to be used for the so called "plant pesticides." Rather than being a case of "a rose by any other name . . . ," the name and description used can mean the difference between being virtually unregulated or being regulated as a pesticide under the Federal Insecticide, Fungicide, Rodenticide Act. *See The Environmental Protection Agency's Proposed Plant Pesticide Rule, Hearings Before the House Comm. on Agr., Risk Management, Research and Specialty Crops Subcomm., and the Dept. Operations, Oversight, Nutrition, and Forestry Subcomm.*, 106th Cong. 80-84 (1999) (statement by R. James Cook, The Endowed Chair of Wheat Research, Washington State University).

3. Adulteration of Foods by Transgenes

One large concern is that because transgenic products are not segregated or monitored, there may be no way to track temporary or long-term impacts on human health. Biotechnology proponents advance two main arguments as to why transgenic foods do not need monitoring. First, they claim that the seed production companies follow internal protocols that prevent the release of seeds shown to be unfit for human consumption, rendering additional monitoring superfluous.[84] Second, the FDA regulates transgenic products and has found many of them to be chemically and nutritionally equivalent to existing products.[85] Therefore, any long-term impacts would be indistinguishable from the impacts of existing products, again rendering monitoring superfluous. However, these claims may be somewhat disingenuous.

Studies have shown substantial and potentially dangerous differences between some of the transgenic products and their unmodified counterparts. For example, soybeans modified to contain genes from brazil nuts were found to contain brazil nut allergens, posing potential problems for individuals who are allergic to nuts.[86] Other transgenic soybeans were found to contain almost 27% more of a major allergen — trypsin-inhibitor — than unmodified soybeans.[87] There has also been one report that the toxin produced by *Bt* may cause diarrhea in humans.[88] Despite the fact that such products are touted as nutritionally equivalent, they may pose substantial threats to health and safety,[89] which can only be ascertained through a system of monitoring.[90]

Not only is it important to look at the possible risks and benefits directly posed by biotechnology, but it is also important to look at the immediate and likely indirect effects of biotechnology. Perhaps the largest concern is the likelihood

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84. *See* Statement of Roger N. Beachy, *supra* note 44.

85. *See id.*

86. *See* Julie A. Nordlee et al., *Identification of a Brazil-Nut Allergen in Transgenic Soybeans*, 334 NEW ENG. J. MED. 688 (1996).

87. *See* Stephen R. Padgette et al., *The Composition of Glyphosate-Tolerant Soybean Seeds Is Equivalent to That of Conventional Soybeans*, 126 J. NUTRITION 702-16 (1996). Although Padgette et al. claim to find no differences between modified and unmodified soybeans, their data shows a difference in levels of trypsin-inhibitor. In addition to allergenicity, another concern is the potential for unknown health effects of glyphosate-tolerant products, as this author was unable to find studies addressing potential mutagenic or teratonogenic effects.

88. *See* McGarity, *supra* note 29, at 431.

89. In a particularly frightening episode, 38 people died from *Eosinophilia-myalgia* syndrome caused by exposure to a synthetic amino acid. *See* Karen M. Graziano, *Biosafety Protocol: Recommendations to Ensure the Safety of the Environment*, 7 COLO. J. INT'L ENVTL. L. & POL'Y 179, 188-89 (1996).

90. As evidenced by the furor created by the Biosafety Protocol negotiations, the biotechnology industry is willing to utilize both deep pockets and a powerful lobby to protect itself. Thus, while post-market monitoring may aid in tracking potential problems, it costs money and may appear as a public admission that transgenic products may not be entirely safe. This could cause a drop in the consumption of transgenics, consequently causing a loss in profits to the companies. Thus, as with any other issue where big money and government regulation is involved, there may be a lot more going on than first meets the eye.

that widespread use of such technologies will accelerate erosion of the genetic basis for agriculture. Such erosion can pose risks to both agribusiness and to international food security as a whole.

IV. CROP PLANTS AND BIODIVERSITY

A. GENETIC EROSION IN CROP PLANTS

Genetic uniqueness forms the basis for biodiversity. Thus, biotechnology has the potential to increase global biodiversity by expanding the pool of existing genetic combinations. However, there is evidence that the use of biotechnology, when combined with modern agricultural methods[91] may actually accelerate the current rate of decrease in genetic diversity, a phenomenon known as "genetic erosion."[92] Although not as high profile as some other environmental concerns, genetic erosion continues to be an important source of controllable biodiversity losses.[93] As discussed earlier, the four objectives of agronomy are as follows. First, agronomists seek to improve the suitability of the crop plant to its environment. Second, they seek to improve the overall quality of the crop produced. Third, they seek to increase the yield of the crop produced. Finally, they seek to increase the plants' resistances to disease and pests.[94]

Approaches to reaching these goals have changed drastically over the years, and now vary widely in modern agricultural systems.[95] Rapid industrialization and commercialization of farming resulted in the use of monoculture techniques[96] and the breeding of crop varieties in which individual plants are as uniform as possible.[97] Uniformity translates into predictability of yield and ease of cultivation, which further translates into profit. If all plants within a

91. *See, e.g.*, discussion *supra* Part III.B.2 (discussing "terminator" technology).

92. Genetic erosion is not a new phenomenon. As plant breeders have bred for certain genetic characteristics over the years, many other traits have been lost. *See* DOYLE, *supra* note 9, at 179-80. For example, it is estimated that 8,000 to 10,000 different varieties of apples have been named and recorded throughout the history of the world. About 100 of these are currently grown in the United States, and only 12 to 15 varieties account for 95% of all commercial apple production. *See id.* at 176. *See generally* Thomas J. Orton, *New Technologies and the Enhancement of Plant Germplasm Diversity*, *in* SEEDS AND SOVEREIGNTY 145 (Jack R. Kloppenburg, Jr. ed., 1988) (discussing effects on germplasm diversity of seeking to improve very specific traits).

93. For a historical discussion of the evolution of agriculture, see CALESTOUS JUMA, THE GENE HUNTERS 37-67 (1989).

94. *See* ROBINSON, *supra* note 15, at xiv.

95. *See generally* Keith Schneider, *In an Old Orchard, Tastes the Supermarket Forgot*, N.Y. TIMES, June 2, 1998, at G2. It is worthwhile to note that most subsistence-based agrarian societies grow mixed crops — different species within the same field, and different varieties of each species. While this increases the genetic diversity of the crops cultivated, providing insurance that there will be a harvest even if some of the crop does not survive, this type of farming is labor intensive and would prove impracticable in the modern U.S. agricultural setting.

96. Monoculture is the modern agricultural practice of only growing one type of crop or one variety of seed per plot of land.

97. For a discussion of the three methods of propagation resulting in uniform crops, see ROBINSON, *supra* note 15, at 50-51.

monocultured crop bear the same requirements for water, nutrients, growing season length, etc., farmers can maximize growing and harvesting conditions simultaneously, without having to custom-tailor cultivation programs to different varieties.[98]

While uniformity fulfills important agricultural needs, it also poses new dangers. Theoretically, the success of a uniformity approach depends on the rigors of nature remaining constant.[99] In such a static system, it would be beneficial for plants to be uniformly resistant to certain diseases, pests, or weather conditions, while resistance to non-existent problems would be a frivolous waste of resources the plants could instead devote to production. Conversely, in a dynamic system with constantly changing conditions, including insects and diseases that co-evolve methods to overcome plant defenses,[100] uniformly resistant plants may instead be uniformly vulnerable. The use of genetically uniform seed stock increases the risk that entire crop failures could occur. Whereas part of a genetically diverse crop may be more likely to succumb to a new threat, it is also more likely that at least part of the crop will survive.[101]

To "solve" crop failure problems, the agrotechnology companies claim that they can constantly provide new varieties custom-tailored to thwart new threats. However, this solution only works if there is a readily available pool of diverse genes from which to find and borrow the particular resistance genes necessary. As new "miracle" varieties replace traditional varieties of crops and farmers' own unique landrace varieties, the pool from which researchers may draw is further narrowed.[102] Although this is a problem in the United States, it is a potentially disastrous situation in foreign countries traditionally rich in crop plant diversity[103] upon which researchers have consistently relied for the new genetic material needed to create the next new miracle variety.[104] As these countries begin to replace their own varieties with engineered ones, biotechnology companies and the world at large lose the genetic base on which this new type of agriculture is founded.[105] For example, one commentator has noted:

> A few years ago, the famous "miracle strain" of rice in the Philippines, IR-8, was hit by tungro disease. Rice growers switched to a further form, IR-20, whereupon this hybrid soon proved fatally vulnerable to grassy stunt virus and

98. *See* FOWLER & MOONEY, *supra* note 21, at 60.

99. *See id.*; *cf.* DOYLE, *supra* note 9, at 180-81 (discussing adaptability of wild plants in contrast with the "regime of agricultural predictability" and genetic uniformity).

100. *See supra* note 80 and accompanying text (discussing the brown planthopper).

101. *See* Klaus Bosselmann, *Plants and Politics: The International Legal Regime Concerning Biotechnology and Biodiversity*, 7 COLO. J. INT'L ENVTL. L. & POL'Y 111, 128 (1996).

102. *See id.* at 131.

103. Subsistence farming countries, for example, tend to have broad diversity as a result of multi-variety cropping. *See id.* at 128-30.

104. *See* Jack R. Kloppenburg, Jr. & Daniel Lee Kleinman, *Seeds of Controversy: National Property Versus Common Heritage*, *in* SEEDS AND SOVEREIGNTY 173, 188-94 (Jack R. Kloppenburg, Jr. ed., 1988) (discussing of North-South battles over rights to germplasm).

105. *See id.* at 131.

> brown hopper insects. So farmers moved on to IR-26, a super-hybrid that turned out to be exceptionally resistant to almost all Philippine diseases and insect pests. But it proved too fragile for the islands' strong winds, whereupon plant breeders decided to try an original Taiwan strain that had shown unusual capacity to stand up to winds — only to find that it had been all but eliminated by Taiwan farmers as they planted virtually all their ricelands with IR-8.[106]

Two approaches to preserving a broad base of genetic material are *in situ* and *ex situ* conservation. *In situ* refers to on-site preservation of genetic material through propagation, while *ex situ* refers to an off-site preservation effort, such as a collection or storage facility or seed bank. Both *in* and *ex situ* conservation are mandated by the Convention on Biodiversity.[107] The relative value of each type of preservation has been debated. While some entities have encouraged more *ex situ* preservation, the Commission on Genetic Resources for Food and Agriculture (CGRFA)[108] recommends an ambitious, large-scale *in situ* program to broaden the agricultural genetic base.[109] For example, the CGRFA proposes a system where trained agriculturalists would supervise local cross-breeding and self-selection of genetically diverse materials.[110]

B. EXAMPLES OF CROP FAILURES CAUSED BY GENETIC EROSION

Although food production has steadily increased throughout history, occasional widespread crop failures have underscored the importance of maintaining agricultural biodiversity. One of the most well known examples is that of the Great Irish Famine in the 1800s, during which an estimated one million people in Ireland — almost 12% of the population — died of starvation.[111] The Famine was the result of a potato blight caused by the parasitic fungus *Phytophthora infestans,* which largely destroyed the potato crops upon which the Irish were dependant for nutrition.[112] Potatoes are tubers which can be propagated sexlessly, resulting in genetically identical offspring.[113] Thus, prior to the Famine, the entire Irish potato crop consisted of clones that had been propagated from only a few original varieties.[114] When the blight invaded the crops, the genetically uniform

106. *See* FOWLER & MOONEY, *supra* note 21, at 70 (quoting Norman Myer).

107. *See* Convention, *supra* note 12. For a discussion on these provisions, see Catherine Tinker, *A "New Breed" of Treaty: The United Nations Convention on Biological Diversity*, 13 PACE ENVTL. L. REV. 191, 199 (1995).

108. The CGRFA is a permanent international forum with a membership of 160 countries and the European Union, dedicated to the conservation, sustainable use, and equitable sharing of genetic resources for food and agriculture. *See* Commission on Genetic Resources for Food and Agriculture (visited Mar. 13, 2000) <http://www.fao.org/ag/cgrfa/default.htm>.

109. *See* Symposium, Commission on Genetic Resources for Food and Agriculture: Broadening the Genetic Base of Crops, CGRFA-8/99/Inf.20 (Sept. 17-20, 1997).

110. *See id.*

111. *See* ROBINSON, *supra* note 15, at 138-39.

112. *See id.* at 135, 138.

113. *See id.* at 140.

114. *See id.*

plants were uniformly susceptible, resulting in almost complete destruction of the crops and widespread famine.

Another example of widespread crop failure is the partial loss of the U.S. corn crop in 1970. Approximately one billion bushels of the U.S. corn crop were lost as a result of Southern Corn Leaf Blight, against which few varieties were resistant.[115] Eventually it was discovered that all the affected varieties carried the same gene for male-sterility, an innovation in plant breeding that allows agronomists to easily produce uniformly hybridized seed by preventing cross-pollination amongst the different varieties.[116] Although seed companies were able to produce enough blight-resistant seed to avert widespread disaster for the 1972 growing season, the episode demonstrated the vulnerability of genetically uniform crops, a vulnerability that is likely to increase if genetic engineering further narrows the genetic base.[117]

One main force behind the changing agricultural methods that are partially responsible for genetic erosion and crop failures is the advent of the agribusiness conglomerate. While seed stock, chemicals, harvesters, and other tools of the agricultural trade were previously developed and manufactured by independent entities, most of these entities have been bought, merged, or destroyed by large all-in-one conglomerates. Thus, the face of modern agriculture has changed from small proprietors breeding many varieties of seed to conglomerates who control production from genetic engineering to consumption. This change, in turn, may bring its own potentially deleterious effects.

V. THE CHANGING FACE OF MODERN AGRICULTURE: NEW COMPANIES, NEW BIOTECHNOLOGIES, AND NEW REGULATIONS

A. TYING IT ALL TOGETHER: THE AGRICULTURAL CONGLOMERATES

The face of agronomy has changed drastically in the past fifty years. As farms moved towards commercialization, more emphasis was put on higher yields, use of mechanized harvesting methods, ease of transport to market, and increased shelf life and cosmetic appearance of agricultural products. Seed companies have consolidated and merged, and many have developed strong associations with agrichemical and biotechnology firms.[118]

The world's food supply is primarily controlled by three dominant food chains — Cargill/Pharmacia,[119] ConAgra, and Novartis/ADM — which all hold large

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115. *See* DOYLE, *supra* note 9, at 12.

116. *See id.* at 13.

117. For a fascinating discussion of the agricultural, political, and economic factors that were involved in the corn blight epidemic, before and after, see *id.* at 1-15.

118. *See* JUMA, *supra* note 93, at 83.

119. On April 3, 2000, Monsanto and Pharmacia & Upjohn merged to become the Pharmacia Corporation. *See* David Shook, *Monsanto, Pharmacia $ 1 Billion Sale of Chemical Stock*, KNIGHT-RIDDER TRIB. NEWS, Apr. 4, 2000.

shares of the "gene to dinner table" market.[120] Further, there was discussion of a possible merger between Cargill and ADM, a move that would have brought almost 75% of the global grain trade under the control of the two companies.[121] Currently, only a few companies control thirty percent of the global seed trade, an industry with a value of U.S.$ 23 billion per year, a value approximately equal to the gross domestic product of Vietnam.[122] Further, U.S.-based companies, including Monsanto (the so-called "Microsoft of Micro-biology"), DuPont, Aventis, and the soon-to-be-merged Novartis and AstraZeneca firms control nearly all of the world's trade in genetically modified crops.[123] These changes in agronomy toward commercialization have led to the development of products and farming techniques that discourage environmentalism and the preservation of biodiversity.

Agronomy has become less environmentally tenable.[124] Crops now require large amounts of pesticides, herbicides, and fertilizers, and agricultural practices have become vastly more reliant on fossil fuels.[125] One claim of the biotechnology industry is that by genetically engineering resistance to pests, weeds, diseases, and adverse weather conditions into the new varieties, dependence on chemical controls will ultimately decline.[126] While good in theory, this may not be entirely accurate.[127] A criticism of the biotechnology conglomerates is that research and development is aimed at fostering, rather than reducing, dependence on company products.[128]

One of the main products developed by the aggregate seed/chemical corporations is a type of packaged farm. In addition to engineering plants to resist natural hazards, corporations engineer plants to resist certain chemicals as well. For example, some of the most publicized and widely used "packages" are the "Round-Up Ready" soybeans, cotton, corn, and canola by Monsanto/Cargill. These varieties have been "genetically improved" to tolerate the popular "Round-Up" herbicide, also a product of Monsanto.[129] However, while Monsanto claims that use of its compatible products will decrease overall reliance on chemicals, it

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120. *See Agribusiness Consolidation: Hearings Before the Subcomm. on Int'l Trade of the House Comm. on Agric.*, 106th Cong. 65-70 (1999) (statement of Leland Swenson, President of National Farmers Union).

121. *See id.*

122. *See* Mario Osava & Gumifai Mutume, *Seed Companies Hauled Into Court*, INTER PRESS SERVICE, Sept. 24, 1999, *available in* 1999 WL 27374204.

123. *See id.*

124. An interesting and frightening sidebar is how much precedence ease of processing takes over other food qualities. As varieties of produce have been developed with the rigors of mechanical harvesting, shipping, and processing in mind, taste, color, and nutritional quality have declined. *See* DOYLE, *supra* note 9, at 136-58.

125. *See* ERNEST LESTER SCHUSKY, CULTURE AND AGRICULTURE: AN ECOLOGICAL INTRODUCTION TO TRADITIONAL AND MODERN FARMING SYSTEMS 186-87 (1989). For a discussion of the energy-intensive agricultural practices used in the Northern hemisphere, see *id.* at 103-23.

126. *See* discussion *supra* Part III.A.2.

127. *See* discussion *supra* Part III.B.2.

128. *See id.* For a discussion of Monsanto's activities in China, see also *Agriculture News — GM With Chinese Characteristics*, CHINA ECON. REV., May 23, 1999 (speculating that development of Round-Up Ready crops is aimed at mitigating an expected loss of profits when Monsanto's patent on Round-Up expires).

129. *See* Monsanto, *Biotechnology: Promise for a Brighter Future* (visited Mar. 6, 2000) <http://www.monsanto.com//ag/_asp/monsanto.asp>; Strauss, *supra* note 58, at 12-19.

may actually encourage chemical use and discourage use of other, potentially less environmentally dangerous methods.[130] An increased use of glyphosate, the main ingredient in Round-Up, may pose a wide range of dangers to people and the environment,[131] and there have been questions as to whether modified seeds represent a substantially different composition than conventional seeds.[132]

Monsanto is not the only company to create chemical-resistant or chemical-tolerant genetic combinations. Other companies' products include STS soybeans, which are resistant to DuPont herbicides; Liberty Link, glufosinate-resistant corn and soybeans; BXN cotton, which is resistant to Buctril herbicide; and IMI, imidazolinone-resistant corn.[133] In addition to creating chemical resistant products, many agrichemical companies are developing "stacked" products that combine genetic resistances to chemicals with genetic resistances to insects and diseases.[134]

B. REGULATION OF BIOTECHNOLOGIES IN THE UNITED STATES

Despite having the largest share of the biotechnology market,[135] the United States does not utilize a separate regulatory system for transgenic technologies or products. Instead, in 1986 President Reagan established the "Coordinated Framework for Regulation of Biotechnology" (Framework).[136] This framework was established with a focus on the product, rather than the process, and was predicated on the assumption that creation of new agencies or statutory authority was not necessary.[137] Instead, the framework provides that transgenic products

130. *See* Bosselmann, *supra* note 101, at 128.

131. Possible health effects include an increased exposure of workers to glyphosate which is known to cause severe health problems and higher incidence of allergic reactions due to the changed genetic composition of the soybeans. Environmental effects may include increased use of glyphosate and development of weed resistance to glyphosate. Beatrix Tappeser & Christine von Weizsacker, *Possible Human Health Impacts of Monsanto's Transgenic Glyphosate-Resistant Soybeans* (visited Mar. 27, 1999) <http://www.southside.org.sg/souths/twn/title/weiz-cn.htm>.

132. One recent study found a 12% to 14% overall decrease in the amount of phytoestrogens contained in herbicide-resistant soybeans. As phytoestrogens are biologically active components of soybeans and it is unknown whether this difference will cause any adverse health effects, further study has been suggested. *See* Lisa Seachrist, *Ag-Biotech Concerns Gain Momentum in United States*, BIOWORLD TODAY, Nov. 15, 1999.

133. *See* Dunn, *supra* note 38, at 152.

134. *See id.*

135. Sales for the U.S. biotechnology firms totaled around U.S.$ 4 billion in 1991, and sales are predicted to top U.S.$ 50 billion per year by the year 2000. *See* Bosselmann, *supra* note 101, at 115. Additionally, U.S. patents account for 41% of global biotechnology patents, compared with 36% for Japan and 19% for European countries combined. *See* Valerie Szczepanik, *Regulation of Biotechnology in the European Community*, 24 LAW & POL'Y INT'L BUS. 617, 621-22 (1993).

136. For current regulations regarding the introduction into the environment of transgenic organisms and products, see 7 C.F.R. § 340 (1997).

137. *See* Alek P. Szecsy, *From the Test Tube to the Dinner Table in Record Time: Liberalizing Effects on Domestic and International Regulatory Frameworks for Controlled Environmental Introduction of Genetically Engineered Agricultural Organisms*, 2 DICK. J. ENVTL. L. & POL'Y 177, 184 (1993).

are to be evaluated by the already existing statute and agency that regulates equivalent technologies or products.[138] Thus, under the Framework, the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA) share primary responsibility for regulating the products of biotechnology.[139]

Initially, this approach worked well as most of the transgenic products were pharmaceuticals, an area of industry with an established history of regulation by the FDA.[140] However, newer biotechnology products were introduced and agencies began to chart unfamiliar territory.[141] Regulation of agricultural applications has proven particularly confusing, as different agencies frequently hold concurrent regulatory jurisdiction over such products.[142] For example, the USDA, EPA, and FDA all regulate crop plants bioengineered to tolerate herbicide applications — the USDA regulates whether the plants are safe to grow; the EPA regulates whether the plants are safe for the environment; and the FDA regulates whether the products are safe to eat.[143]

The failure to create a new statutory structure dealing with biotechnology issues or resolving jurisdictional conflicts within the existing structures has left many transgenic organisms unregulated.[144] Recently, the biotechnology industry has been pushing for some form of self-regulation,[145] an idea that has garnered some support domestically[146] and has been proposed in relation to an international regulatory scheme.[147] Further, the industry has gradually moved the terminology of transgenics from "genetically modified organisms" or "GMOs,"

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138. *See U.S.-European Union Trade Issues: Hearings Before the Subcomm. on Int'l Trade of the Senate Comm. on Fin.*, 106th Cong. (1999) (statement of Ambassador Stuart E. Eizenstat, Under Secretary for Economic, Business and Agricultural Affairs, U.S. Dept. of State), *available in* <http://www.senate.gov/~finance/3-15eize.htm>.

139. *See* John H. Barton, *Biotechnology, the Environment, and International Agricultural Trade*, 9 GEO. INT'L ENVTL. L. REV. 95, 108-09 (1996).

140. *See* David R. MacKenzie, Regulatory Risk Assessment: A View from the Potomac, Lecture Before the National Agricultural Biotechnology Council, *in* NABC REPORT 5, AGRICULTURAL BIOTECHNOLOGY: A PUBLIC CONVERSATION ABOUT RISK 47, 49 (June Fessenden MacDonald ed., 1993).

141. *See id.*

142. One area of contention is the regulation of "plant pesticides," as the EPA recently claimed jurisdiction to regulate transgenic plant-expressed pesticides (*Bt*, for example) under the Federal Insecticide, Fungicide, and Rodenticide Act, possibly conflicting with FDA or USDA jurisdiction over those products. *See* Redick et al., *supra* note 32, at 51-53. For a comprehensive discussion of EPA's past role in the regulation of "plant pesticides," see Angelo, *supra* note 34, at 275-84.

143. *See* U.S. Dep't of Agriculture, *U.S. Regulatory Oversight in Biotechnology* (visited Jan. 6, 2000) <http://www.aphis.usda.gov/biotech/OECD/usregs.htm>.

144. *See* Graziano, *supra* note 89, at 180-81.

145. *See, e.g., Resistance Management for Plant Pesticides Already Conducted Voluntarily Industry Says*, 20 Chem. Reg. Rep. (BNA) No. 15, at 1665 (1997).

146. *See* Redick et al., *supra* note 30, at 49-76.

147. For a comprehensive discussion of liability issues in the United States, see Stephen Kelly Lewis, *"Attack of the Killer Tomatoes?" Corporate Liability for the International Propagation of Genetically Altered Agricultural Products*, 10 TRANSNAT'L LAW. 153, 178-88 (1997).

to "living modified organisms" or "LMOs" in an effort to portray the products as more natural.[148]

C. INTERNATIONAL REGULATION OF BIOTECHNOLOGY

As the products of biotechnology have become more prominent in the global marketplace, it has become clear that countries have widely varying views on the acceptability of such products, and regulation thereof. Equitable concerns about disparities in access to technology and unequal exposure to potential risks are frequently expressed.[149] Further, much of the debate can be characterized in terms of a "North" versus "South" split, with contention over use and regulation of the various resources between the typically gene-rich but technology-deficient "Southern" countries and the typically gene-poor but technology and economically rich "Northern" countries.[150] The chasm between countries with existing domestic regulations and countries with virtually no regulations for biotechnology further hampers the international efforts to regulate biotechnology. Germany and Denmark — countries with strong biotechnology regulations — and Argentina — a country with virtually no regulations — are discussed to give the reader a sampling of the breadth of the existing regulatory philosophies.

Of the countries that have implemented domestic biotechnology regulations regarding the release of GMOs, Germany and Denmark have developed the most stringent regulations of GMOs while concurrently maintaining strong biotechnology industries.[151] However, industry representatives in those countries have expressed reservations about their ability to remain internationally competitive in light of the increasingly trade-oriented regulations imposed by other countries such as the United States.[152]

Denmark was the first European country to impose a law specifically dealing with biotechnology.[153] The Environmental and Gene Technology Act of 1986 was initially so restrictive that it imposed a virtual ban on the deliberate release of transgenic organisms.[154] Later, the regulation was modified and has become more relaxed to allow for deliberate releases in accordance with procedures set forth by the Ministry of Environment.[155]

Germany's biotechnology regulations are very stringent and contain strong

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148. *See supra* note 27 and accompanying text.

149. At least one commentator has expressed concern over the lack of participation of indigenous peoples and non-governmental organizations in the development of international regulations regarding biodiversity conservation. *See* Gregory F. Maggio, *Recognizing the Vital Role of Local Communities in International Instruments for Conserving Biodiversity*, 16 UCLA J. ENVTL. L. & POL'Y 179 (1998).

150. *See* Bosselmann, *supra* note 101, at 132-34.

151. *See* Judy J. Kim, *Out of the Lab and Into the Field: Harmonization of Deliberate Release Regulations for Genetically Modified Organisms*, 16 FORDHAM INT'L L.J. 1160, 1170-71 (1993).

152. *See id.* at 1171.

153. *See id.*

154. *See id.*

155. *See id.*

provisions regarding manufacturer liability for creation of environmental risks and civil and criminal penalties for non-compliance with the law.[156] This is due, in part, to strong political opposition to the biotechnology industry.[157] In 1990 the German National Parliament passed the Genetic Technology Law, which permits deliberate releases of transgenic organisms but places proposed deliberate releases into risk categories.[158] Permission for release is dependent upon the predicted level of risk and is subject to a provision providing for public comment on proposed releases.[159] However, this provision has been criticized by the German biotechnology industry as interjecting too much delay, and thus expense, into the research process, causing some researchers to move to less restrictive countries such as the United States.[160]

In contrast, many countries do not regulate biotechnology, either through existing statutory frameworks or through laws specifically aimed at biotechnology.[161] While many of the unregulated countries have sent representatives to the United States to gain information about regulating biotechnology,[162] in the absence of regulatory implementation, these unregulated countries have proven appealing to researchers hampered by testing regulations in their own countries. For example, Argentina was used by the Wistar Institute of Philadelphia, Pennsylvania as an unregulated testing ground for a new transgenic vaccine.[163] In fact, some countries that have declined to regulate releases of transgenic organisms have actually adopted legislation and other measures to promote such unrestricted biotechnology research activities.[164]

Given this broad range of regulatory structures, there has been an increasing need to implement some form of international agreement or accord to guide the development, testing, and use of biotechnologies. Under Article 19 of the Convention on Biodiversity, an ad hoc group of experts was convened to draft an international biosafety protocol to govern the export, use, and sale of transgenic products in international commerce. On January 29, 2000, the Biosafety Protocol was finally adopted.

VI. THE BIOSAFETY PROTOCOL

A. CONVENTION ON BIODIVERSITY

Although many individual nations had long recognized the value of biodiversity, for years there was a dearth of international law regarding species and

156. *See* Graziano, *supra* note 89, at 182.
157. *See* Kim, *supra* note 151, at 1172.
158. *See id.* at 1172-73.
159. *See id.*
160. *See id.* at 1173-74.
161. *See* Graziano, *supra* note 89, at 182.
162. *See id.*
163. *See* Kim, *supra* note 151, at 1184.
164. For example, South Korea has passed legislation to encourage biotechnology research and Taiwan has passed various tax incentives to stimulate investing in research of biotechnology. *See id.* at 1183, 1183 n.153.

habitat preservation.[165] And, whether for historical or cultural reasons, the countries that possessed the richest biodiversity assets were frequently the least protective of their resources.[166] One area of concern for countries rich in biodiversity is the spectre of bioprospecting — the search for new biological materials upon which the development of pharmaceuticals is based — frequently without compensation to the country of origin.[167] This is an area of increasing concern as the granting of intellectual property rights — mostly to private corporations in developed countries — limits the amount of control the countries of origin have over their resources.[168]

Recognizing that there needed to be some sort of international protection for biodiversity, the United States sponsored a resolution before the United Nations Environment Programme (UNEP) Governing Council in 1987, requesting that an ad hoc group of experts evaluate the need for such a treaty.[169] In February of 1991, eighteen months of negotiations began on what was to be the first global treaty on biodiversity. The Biological Diversity Convention negotiations were plagued by disagreement, and the final product was produced only after a series of late night, last-minute negotiations, which were compressed to accommodate the June 1992 deadline set by UNEP.[170] With many objections still unsettled, the Intergovernmental Negotiating Committee unveiled the Convention on Biological Diversity ("Convention") which was introduced to and signed by over 150 countries attending the Earth Summit in Rio de Janeiro in June of 1992.[171] The United States was not one of them.

Considering the role the United States played in the creation of the Convention, it surprised many states, commentators, and politicians that the United States refused to sign the Convention.[172] U.S. refusal, however, should have been

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165. *See generally* Daniel M. Bodansky, *International Law and the Protection of Biological Diversity*, 28 VAND. J. TRANSNAT'L L. 623 (1995) (overview of international legal principles involved in the regulation of biodiversity); Lee A Kimball, *The Biodiversity Convention: How to Make it Work*, 28 VAND. J. TRANSNAT'L L. 763 (1995).

166. *See* Edgar J. Asebey & Jill D. Kempenaar, *Biodiversity Prospecting: Fulfilling the Mandate of the Biodiversity Convention*, 28 VAND. J. TRANSNAT'L L. 703, 707-08 (1995).

167. For an in-depth discussion of private contract theories and bioprospecting, see Christopher J. Hunter, *Sustainable Bioprospecting: Using Private Contracts and International Legal Principles and Policies to Conserve Raw Medicinal Materials*, 25 B.C. ENVTL. AFF. L. REV. 129 (1997). For a discussion of bioprospecting controls under the Convention on Biodiversity, see Asebey & Kempenaar, *supra* note 166.

168. *See* Asebey & Kempenaar, *supra* note 166, at 709-13.

169. *See Rationalization of International Conventions on Biological Diversity*, U.N. Environment Programme, 14th Sess., Annex I, at 58, U.N. Doc. UNEP/GC.14/26 (1987).

170. *See* David Eugene Bell, *The 1992 Convention on Biological Diversity*, 26 GEO. WASH. J. INT'L L. & ECON. 479, 507-08 (1993).

171. *See* Convention, *supra* note 12; SUSAN R. FLETCHER, BIOLOGICAL DIVERSITY: ISSUES RELATED TO THE CONVENTION ON BIODIVERSITY (Congressional Research Service, Order No. 95-598 ENR, 1995). As of February 14, 2000, 168 countries had signed and 177 countries had ratified the Convention. *See UNEP, Convention on Biological Diversity, Ratification* (visited Apr. 5, 2000) <http://www.biodiv.org/conv/pdf/ratification-alpha.pdf>.

172. For a critical commentary on the U.S. position, see David P. Hackett, *Was the United States Right Not To Sign the Biodiversity Convention?*, 78-SEP A.B.A. J. 43 (1992).

expected, as the United States had repeatedly voiced three substantive objections to the provisions of the Convention.[173] First, the Convention required developed countries to help fund environmentally sound development in developing countries, without imposing definite restrictions on the funding power that could be levied against the developed countries.[174] Paragraph 2 of Convention Article 20 states that: "The developed country parties *shall* provide new and additional financial resources to enable developing country parties to meet the agreed full incremental costs to them of implementing measures which fulfill the obligations of this Convention and to benefit from its provisions. . . ."[175] Additionally, the funding provisions did not impose any reciprocal obligations on the recipient countries.[176] Thus, the funding provisions were seen by some as providing developing countries with a "blank check" from developed countries.[177]

Second, the Convention called for essentially open technology transfer — specifically including transfer of biotechnologies in Article 16, Paragraph 1 — between developing and developed countries.[178] Article 16, Paragraph 2 states that "[a]ccess to and transfer of technology referred to [above] to developing countries *shall be provided and/or facilitated under fair and most favourable terms*."[179] This, when analyzed in conjunction with other related provisions, disregards patents and other intellectual property rights. Not only does this provision require transfer of publicly owned technology, but also transfer of technology that is privately owned, despite the proprietary intellectual property rights of the owner.[180]

Third, the Convention calls for regulatory measures to be applied to biotechnology that are not required for other potentially environmentally harmful or

173. Several provisions of the treaty were roundly criticized in the U.S. Senate. *See* 140 CONG. REC. S13790 (1994) (statement of Sen. Hutchison). For an in-depth discussion of the U.S. objections to the Convention, see Bell, *supra* note 167.

174. *See* Bell, *supra* note 170, at 511-13.

175. *See* Convention, *supra* note 12 (emphasis added). "The extent to which developing country parties will effectively implement their commitments under this Convention will depend on the effective implementation by developed country parties of their commitments under this Convention related to financial resources and transfer of technology . . . ." *Id.* art. 20(4).

176. *See id.*

177. *See* Hutchison, *supra* note 173.

178. *See* Bell, *supra* note 170, at 517-18.

179. Convention, *supra* note 12, art. 16(2) (emphasis added).

180. *See* Bell, *supra* note 170, at 515-25. Of the Convention provisions that drew U.S. objections, the technology transfer provisions proved particularly irksome to U.S. policymakers and those sectors of industry with a stake in the outcome. *See id.* at 517. Particularly, the biotechnology industry urged the United States not to sign a Convention that contained such broad technology transfer provisions, as they would undermine related intellectual property rights. *See id.* at 518. However, one normative question that arises is whether we should continue to allow patenting of living organisms — is this really the type of innovation we want to encourage by granting intellectual property rights? Industry argues that honoring intellectual property rights actually acts as an incentive for companies to develop technologies that might preserve biodiversity. *See id.* This argument, however, raises another question. Does such a system encourage preservation of only those resources that have a monetary value while discouraging preservation of resources that might not have a developmental potential?

diversity reducing activities.[181] Article 8(g) of the Convention specifically requires nations "to regulate 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."[182] In addition to the language of Article 8(g), Article 19, paragraph 3 of the Convention states:

> The parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.[183]

The United States felt that, of the many activities that could adversely impact the environment, the Convention unfairly singled out biotechnology for further regulation, and that the biotechnology industry was already adequately regulated under existing domestic regulations.[184]

With the Convention closed to negotiation and because it allowed for no reservations to its terms, the Bush administration refused to sign.[185] However, on June 4, 1993, after working to clarify the official U.S. interpretation of the troublesome provisions, President Clinton reversed the U.S. position and signed the treaty.[186] After receiving a favorable recommendation from the Senate Committee on Foreign Relations, the treaty was submitted to the Senate body for advice and consent ratification, where it remains.[187] The treaty has gone no further since 1993, and the United States remains a nonparty to the Convention.[188] However, that has not prevented the United States from participating in negotiations of the Biosafety Protocol.

B. HISTORY OF THE BIOSAFETY PROTOCOL NEGOTIATIONS

The three year's worth of negotiations that led to adoption of the final Biosafety Protocol[189] ("Protocol") were both divisive and contentious, with

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181. *See id.* at 525.

182. *See* Convention, *supra* note 12, art. 8(g).

183. *See id.* art. 19(3).

184. *See* Bell, *supra* note 170, at 525-26. It is these provisions regarding the regulation of biotechnology that eventually required creation of the Biosafety Protocol. Chapter 16 of the U.N. Convention report, entitled *Environmentally Sound Management of Biotechnology*, further elucidates the ideas outlined in the Convention. *See Report of the United Nations Conference on Environment and Development, Agenda 21*, U.N. Doc. A/CONF.151/26 (vol. II) (1992) [hereinafter *Biotechnology Report*].

185. Voicing concerns similar to those expressed by the United States, France very reluctantly signed the Convention. *See* Bell, *supra* note 170, at 508.

186. *See* FLETCHER, *supra* note 171.

187. *See id.* President Clinton signed a statement of understanding on certain provisions even though no formal reservations are allowed. *See* Redick, *supra* note 30, at 17.

188. *See* Redick, *supra* note 30, at 17.

189. For official reports from all of the Protocol negotiations, see *Convention on Biological Diversity Clearing-House Mechanism* (visited Apr. 1, 2000) <http://www.biodiv.org/biosafe/biosafe-meetings.html>.

early adversarial factions generally following the global North/South split that had emerged in international biotechnology regulation.[190] For the most part, the developing South had pushed for a binding protocol that would have included strict labeling, advance notification, risk assessment and risk management, and liability provisions. The North, characterized by countries more experienced with biotechnology, pressed for a voluntary and less-restrictive guideline, implementing individual countries' domestic regulations.[191]

The successful adoption of a Protocol came almost a year after it had initially been planned. The sixth Biosafety Working Group meeting, BSWG-6, was to have culminated on February 19, 1999, with a final Protocol to be voted on for adoption at the Conference of Parties three days later.[192] Ultimately, no vote took place because the negotiators were unable to reach a consensus on a finalized Protocol by the end of the meeting.[193] It was not until January 29, 2000, that the finalized Biosafety Protocol was adopted.

1. Rio de Janiero, Brazil: June 5-14, 1992

Shortly after opening the Convention for signing at the Rio Conference, the UNEP began to assess which provisions of the Convention needed immediate implementation.[194] It established four expert panels to help parties to the Convention identify those areas that were urgently in need of attention.[195] Finding a system of outdated, inapplicable, or nonexistent regulations regarding genetically modified organisms (GMOs), the UNEP Experts Panel IV, which was assigned to deal with GMOs, determined that biosafety was a priority area for further regulation, and the Panel began to discuss the creation of a Biosafety Protocol pursuant to Article 19 of the Convention.[196] A matter of particular concern to the Panel was the absence of regulations regarding the safety of transgenic organisms transferred from countries with knowledge and experience in biotechnology issues to countries without.[197] Although not a party to the Convention, the United States expressed its belief that there was no need for such a protocol, contending that the internal, domestic regulations of each country would suffice.[198] Nonetheless, a regular meeting schedule was established for the

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190. For a discussion of the dissention between the North and the South, see discussion *infra* Part V.C of the dissention between the North and the South.

191. *See* Redick, *supra* note 30, at 7-8.

192. *See* Draft Report of the Extraordinary Meeting of the Conference of the Parties for the Adoption of the Protocol on Biosafety to the Convention on Biological Diversity, Conference of the Parties to the Convention on Biological Diversity, 1st mtg., paras. 3, 4, U.N. Doc. UNEP/CBD/ExCOP/1/L.2/Rev.1 [hereinafter BSWG-6].

193. *See id.* para. 36.

194. *See* THIRD WORLD NETWORK, BIOSAFETY: SCIENTIFIC FINDINGS AND ELEMENTS OF A PROTOCOL, Pt. I (on file with GEO. INT'L ENVTL. L. REV.).

195. *See id.*

196. *See* Graziano, *supra* note 89, at 196.

197. *See Biotechnology Report*, *supra* note 184, § 16.29.

198. *See* Melinda Chandler, *The Biodiversity Convention: Selected Issues of Interest to the International Lawyer*, 4 COLO. J. INT'L ENVTL. L. & POL'Y 141, 168 (1993).

member states of the Convention ("Conference of the Parties" or "COP"), one purpose of which was to begin work on biosafety regulations.

2. Nassau, The Bahamas: November 28-December 9, 1994

The first COP meeting was held in Nassau, the Bahamas, in the winter of 1994,[199] and an ad hoc group of government nominated experts was established to prepare a background document and begin preparations for the negotiation of a protocol.[200] Some NGOs called for an export moratorium of transgenic organisms until an international protocol could be adopted, but such a moratorium never materialized.[201] In November of 1995, at the second COP meeting held in Jakarta, Indonesia, the parties engaged in heated debate and finally agreed to negotiate a formal and binding protocol to ensure compliance with the biosafety provisions of the Convention.[202] It was determined that the international agreement should cover "the safe transfer, handling, and use of living modified organisms, . . . specifically focusing on transboundary movement, of any [LMO] resulting from modern biotechnology that may have adverse effect [sic] on the conservation and sustainable use of biological diversity . . . ."[203] The Open-Ended Ad-Hoc Working Group on Biosafety ("BSWG") was created to work on the Protocol and a timeline was established for completing an international protocol. The group's first meeting was scheduled to be held in Aarhus, Denmark in July of 1996,[204] and the deadline to complete the protocol was initially set for the end of 1998.[205]

3. Aarhus, Denmark: July 22-26, 1996

The first meeting of the BSWG was held as an open forum to encourage participation from all sectors, not just governments.[206] Representatives from over ninety countries, twenty eight non-governmental organizations, and assorted other intergovernmental organizations presented opinions and proposals, many of which focused on Advanced Informed Agreement ("AIA") provisions and the development of a network for information exchange amongst parties.[207]

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199. The full text of the official report from this meeting is available at <http://www.biodiv.org/cop1/index.html>.

200. *See* THIRD WORLD NETWORK, *supra* note 194, Pt. I.

201. *See* Graziano, *supra* note 89, at 199.

202. *See Biodiversity Meeting Adopts Ministerial Statement and Launches New Initiative on Coastal and Marine Areas* (visited Feb. 8, 2000) <http://www.unep.ch/bio/pr11-17>.

203. *See* BSWG-6, *supra* note 192, para. 27.

204. *See* Redick, *supra* note 30, at 42.

205. *See Report of the First Meeting of the Subsidiary Body on Scientific, Technical, and Technological Advice* (visited Apr. 14, 2000) <http://www.biodiv.org/cop2/cop2_decisions_e.pdf>.

206. *See A Brief Analysis of the Meeting* (visited June 7, 1999) <http://www.iisd.ca/linkages/vol09/0948014e.html> [hereinafter *BSWG-1 Analysis*].

207. *See Report of the First Meeting of the Open-ended Ad Hoc Working Group on Biosafety*, UNEP

Although the Aarhus meeting was utilized more as a forum for defining important issues, there were still indications of the divergent negotiating blocs that would later develop. Characterized by nations with a larger stake in biotechnology (for example, the United States, Japan, Germany, and the United Kingdom), one bloc articulated the desire for a less restrictive protocol that confined regulation to issues of transboundary movement of LMOs and that would exempt entire classes of LMOs from regulation.[208] Characterized by lesser developed nations and nations suspicious of biotechnology (for example, China and the countries of the European Union),[209] and backed by the G-77,[210] another bloc pushed for a strict protocol that would take into account socioeconomic impacts as well as potential environmental impacts of LMOs.[211] However, the G-77 position was far from unified, with particular disagreement arising over a proposed inclusion of liability and compensation provisions in the Protocol.[212] Finally, in a surprising move, Argentina broke ranks with the G-77, instead endorsing a position similar to that of the U.S. bloc.[213]

4. Montreal, Canada: BSWG 2 to 5

After the pre-negotiation phase was completed in Aarhus, a draft Protocol was created during the next two meetings held in Montreal, Canada.[214] Over the course of the BSWG 2 to 5, various provisions of the draft were debated and negotiations began in earnest.[215] One main change was the emergence and

Open-ended Ad Hoc Working Group on Biosafety, 1st mtg., para. 65, U.N. Doc. UNEP/CBD/BSWG/1/4 (1996) [hereinafter *BSWG-1*].

208. *See* Chee Yoke Ling, *Concerted Moves to Undermine a Strong Biosafety Agreement* (visited Mar. 27, 1999) <http://www.southside.org.sg/souths/twn/title/chee-cn.htm>.

209. It is not surprising that the European Union aligned itself with the southern position, considering the EU history of state and consumer distrust of transgenics. *See, e.g.*, Beef Hormones, *supra* note 9.

210. The Group of 77 (G-77) is a group of less-developed nations who frequently negotiate and vote as a block on matters of international importance.

211. *See BSWG-1 Analysis*, *supra* note 206.

212. For an overview of the split between the countries of the G-77, see *id.*

213. *See* Ling, *supra* note 208. Considering Argentina's ties to multinational biotechnology companies and its own development of such technology, perhaps it isn't surprising after all that Argentina took a more trade-oriented approach to negotiations of the Protocol.

214. Although an in-depth discussion of each meeting is not relevant to this paper, it is interesting to note the gradual evolution of the Protocol. For example, the official report of the BSWG-2 included an annex containing a summary draft of Protocol elements raised by delegates to the meeting. As the draft condensed the divergent views of many parties, the provisions frequently expressed opposite viewpoints. Thus, Annex II, paragraph 10 states, "There should be a time limit for a response by importing country," (sic) while paragraph 11 states, "There should be no time-limit for a response by the importing country." *Report of the Second Meeting of the Open-ended Working Group on Biosafety*, UNEP Open-ended Ad Hoc Working Group on Biosafety, 1st mtg., U.N. Doc. UNEP/CBD/BSWG/2/6, Annex II [hereinafter *BSWG-2*].

215. While these debates are not discussed here, full text of the meeting reports can be found at Convention on Biological Diversity, Clearing-House Mechanism, *Meetings of the Open-ended Ad Hoc Working Group on Biosafety and First Extraordinary Meeting of the COP to Finalize and Adopt a Protocol on Biosafety* (visited Apr. 1, 2000) <http://www.biodiv.org/biosafe/biosafe-meetings.html>.

solidification of three different negotiating groups that remained intact through the negotiations that eventually led to the adoption of the Protocol.

Throughout negotiations, the "Miami Group" included the United States, Argentina, Australia, Canada, Chile, and Paraguay, and advocated a narrow Protocol that recognized intellectual property rights and limited regulation to products with a scientifically demonstrated ability to affect biodiversity.[216] This stance directly conflicted with that of the "Like-Minded Countries," which included China, most members of the G-77, and (for the most part) the European Union.[217] This group advocated a strong, broad, binding Protocol that followed the Precautionary Principle, included liability and compensation for any LMO-caused damages, exclusion of trade with non-parties, and consideration of socioeconomic impact as part of risk assessment procedures.[218]

The "Compromise Group" included Switzerland, Norway, Korea, and Japan, and advocated a middle ground between the "Miami" and "Like-Minded" stances.[219] However, on some issues the "Compromise" countries eventually sided with the "Like-Minded" countries in a futile attempt to force consensus and an end to the negotiations in Cartagena, as discussed below.[220]

5. Cartagena, Colombia: February 14-24, 1999

The sixth BSWG meeting, BSWG-6, was to have culminated on February 19, 1999 with a final Protocol to be voted on for adoption at the Conference of Parties three days later.[221] When the Conference of Parties was convened on February 22, 1999, the President of the Conference, Mr. Laszlo Miklos, exhorted the parties to show their commitment to the promotion of biodiversity by finalizing a Protocol.[222] Despite the fact that the Protocol was not yet finished, the Conference adopted an agenda centered on adoption of a Protocol.[223] However, the parties agreed to temporarily suspend the Conference to allow further negotiations within the BSWG in the hope that the Protocol could be completed.[224]

Many issues prevented the BSWG-6 from reaching a consensus during negotiations. However, many blamed the U.S.-influenced Miami Group for the stalemate, accusing the group of blatant protectionism of the biotechnology

216. *See* Christopher S. Zalewski & Paul F. McQuade, *A Stalemate on Biosafety Pact*, NAT'L L.J., Mar. 24, 1999, at C1.

217. *See id.*

218. *See* Tewolde Berhan Gebre Egziabher, *Outstanding Issues of the Biosafety Negotiations* (visited June 8, 1999) <http://www.capside.org.sg/souths/twn/title/tewolde-cn.htm>.

219. *See* Zalewski & McQuade, *supra* note 216.

220. *See id.*

221. *See* BSWG-6, *supra* note 192, paras. 3, 4.

222. *See id.* para. 12.

223. *See id.* para. 21.

224. *See id.* para. 22.

industry.[225] During earlier meetings, it became clear that the Protocol would regulate the transboundary movements of all LMOs; therefore much debate centered on which materials would be excluded from the definition.[226] Additionally, other areas of contention included the scope of the Advance Informed Agreement (AIA) provisions that would require notification to an importing country of the shipment of LMOs and attendant risks, liability provisions, protection of intellectual property rights, and whether application of the "precautionary principle"[227] would result in a virtual moratorium on LMOs.[228]

One problem throughout the negotiations was that many nations' official representatives had little understanding of the issues being discussed. The Brief Analysis of the [Aarhus] meeting[229] relates that:

> One African delegate, representing a country without a biotechnology industry, cautioned that modern biotechnology was capable of reviving ancient bacteria extinct for millions of years. This prompted a correction from a Latin American molecular biologist, who reminded the delegate that such feats are only accomplished in Hollywood movies.[230]

At the Cartegena meeting, Rodrigo Artunduaga, Colombian scientist and delegate to the negotiations, told reporters of his concern that "many of the official delegations negotiating the protocol lack scientific knowledge."[231]

Another interesting aspect of the Cartagena meeting was the amount of influence the United States had over negotiations, despite an inability to vote on the final Protocol. Throughout the years of negotiations, the strong U.S. presence had caused a backlash from many of the parties, and the United States shrewdly let the Canadian delegation act as the spokesperson for the Miami Group.[232] Additionally, because the Cartagena negotiating sessions were supposed to have resulted in the adoption of a binding Protocol, they saw a notable increase in the presence of biotechnology industry representatives, particularly from U.S. companies.[233] Essentially, the "observers" representing the United States were

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225. *See* Zalewski & McQuade, *supra* note 216, at C1.

226. *See id.*

227. For a discussion of the U.S objection to the precautionary principle, see discussion *infra* Part VI.C.1.

228. *Cf.* Zalewski & McQuade, *supra* note 216.

229. For further discussion of the Aarhus meeting, see discussion *infra* Part VI.B.3.

230. Earth Negotiations Bulletin, *A Brief Analysis of the Meeting* (visited June 7, 1999) <http://www.iisd.ca/linkages/vol09/094801e.html> [hereinafter *BSWG-1 Analysis*].

231. Angela Sanchez, *North and South Split Over Genetic Engineering*, INTER PRESS SERVICE, Feb. 16, 1999, *available in* 1999 WL 5947070.

232. *See* Chee Yoke Ling, *U.S. Behind Collapse of Cartagena Biosafety Talks* (visited Feb. 8, 2000) <http://www.capside.org.sg/souths/twn/title/cheey-cn.htm>.

233. Compare the list of non-governmental organizations present, see *BSWG-6*, *supra* note 192, para. 19, with attendance at earlier BSWG meetings. Also, it is interesting to note that the U.S. delegation to the Aarhus meeting was comprised of U.S. representatives who were in consultation with U.S. biotechnology industry representatives, where the U.S. "delegation" to Cartagena actually included industry representatives. *See* Ling, *supra* note 208.

lobbyists and delegates from approximately twenty agrochemical companies and biotechnology associations who attended the negotiating sessions in Colombia to push for less restrictive regulations.[234]

That the U.S. biotechnology industry attended these negotiations en masse underscores the impact the Protocol could have on these companies. Globally, agricultural biotechnology is currently estimated to be a U.S.$ two billion industry and is projected to climb to U.S.$ twenty billion by 2005.[235] Of that market, the United States controls a significantly large market share,[236] a balance the corporations feared would be affected by the adoption of a strict Protocol.

Thus, it was less than a shock when the U.S. biotechnology industry-led force, finding some provisions of the binding protocol objectionable, managed to temporarily derail adoption of the Protocol in Cartagena.[237] The delegates failed to reach an agreement at the last negotiations meeting held in February 1999.[238] Thus, the biotechnology industry had time to prepare its strategy to weaken the Protocol, and the opposing parties had time to clarify their goals and bargaining positions for the January 29, 2000 Protocol negotiations.

6. Montreal, Canada: January 24-29, 2000

After years of strife, the Cartagena Protocol on Biosafety[239] was finally adopted on January 29, 2000, and will be implemented after ratification by fifty countries, a process that could take two to three years.[240] Although the United States is not an official party to the Protocol because it has not ratified the Convention on Biodiversity, it has expressed an intention to abide by Protocol terms.[241] However, Secretary of State Madeleine Albright has come under strong scrutiny from Senator John Ashcroft (R-Mo.) and others for making this concession, as it is unclear to what extent the Protocol will impact the U.S. trade in agricultural biotechnologies.[242] What is clear is that regardless of whether or not

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234. *See* Jeremy Lennard, *Western Union: Global Politics*, GUARDIAN (London), Feb. 24, 1999, *available in* 1999 WL 12072187.

235. *See* Angela Sanchez, *Debate Over Transgenics Heats Up*, INTER PRESS SERVICE, Feb. 23, 1999, *available in* 1999 WL 5947186.

236. It is estimated that after two pending mergers are completed, just five firms involved in agricultural biotechnology control 68% of the global agrochemical market and over 20% of the global commercial seed trade. Of these five firms, three are based in the United States. *See* RAFI, *AgBiotech's Five Jumbo Gene Giants* (last updated Jan. 7, 2000) <http://www.rafi.org/web/docus/pdfs/jumbogia.pdf>.

237. *See* Ling, *U.S. Behind Collapse*, *supra* note 232.

238. *See id.*

239. The Protocol is named after the Colombian city in which negotiations stalled in February of 1999. *See* Biosafety Protocol, *supra* note 11.

240. Danielle Knight, *Biotechnology: Critics Fear New Treaty Could Be Weakened*, INTER PRESS SERVICE, Feb. 1, 2000, *available in* 2000 WL 4089686.

241. *See* Bill Lambrecht, *In a Hearing, Ashcroft Assails New Accord on Gene-Altered Food; He Says Biosafety Protocol Gives Europe Too Much Clout on Trade Restrictions*, ST. LOUIS POST-DISPATCH, Feb. 9, 2000, at A1.

242. *See id.*

the U.S. expressly agrees with the final terms of the Protocol, it will be constructively bound to follow them when it engages in trade with parties to the Protocol. Thus, the actual terms of the Protocol will prove vitally important to U.S. trade issues in the coming years.

C. DISCUSSION OF U.S. OBJECTIONS TO THE PROTOCOL

Throughout the years of negotiations, the United States consistently voiced six different objections to the Protocol. The United States (1) opposed the application of the Precautionary Principle to biotechnology, (2) believed the scope of the Protocol was too broad, and (3) believed that the AIA and (4) labeling provisions were too burdensome, (5) opposed the inclusion of information sharing provisions, and (6) opposed provisions that allowed importing countries to consider socio-economic issues before allowing importation of LMOs.

1. The Precautionary Principle

Throughout the years of negotiations, the United States advocated against the inclusion of the Precautionary Principle, one of the main features of the new Protocol. When applied to international environmental law, the Precautionary Principle "ensures that a substance or activity posing a threat to the environment is prevented from adversely affecting the environment, even if there is no conclusive scientific proof linking that particular substance or activity to environmental damage."[243] Under the Protocol, this principle will allow parties to (a) exclude an LMO if there is evidence that it is dangerous or (b) exclude it and subject it to testing until a determination can be made as to the risks posed by that product.[244]

Thus, one argument of the biotechnology industry has consistently been that the inclusion of the Precautionary Principle was really a trade barrier in disguise, and therefore is in conflict with the World Trade Organization (WTO) principles.[245] Industry fears that the precautionary principle could be used superficially or pretextually to delay trade in LMOs.[246] However, the Protocol contains a "savings" clause emphasizing that the Protocol does not preempt rights and obligations under other international agreements and organizations.[247] This may mediate the effect of the Precautionary Principle by allowing countries to

243. James Cameron & Juli Abouchar, *The Precautionary Principle: A Fundamental Principle of Law and Policy for the Protection of the Environment*, 14 B.C. INT'L & COMP. L. REV. 1, 2 (1991).

244. *See* Knight, *supra* note 65.

245. For an interesting discussion of the WTO as it might interact with an international biosafety protocol, see Barton, *supra* note 139, at 113-17.

246. *See* Zalewski & McQuade, *supra* note 216.

247. *See* Knight, *supra* note 65.

challenge decisions of excluding countries under other international agreements or organizations such as the WTO.[248]

2. Scope of the Protocol

One large part of the debate centered on finding an appropriate definition of LMO, as that definition delineates the body of products that will be regulated under the Protocol. Arguing for a narrower definition, the United States contended that only genetically engineered organisms that are going to be released (e.g., planted, tested, etc.) should fall within the regulatory definition.[249] This argument highlighted the administrative headache that would be involved in the compilation of a globally comprehensive list of exemptions. For example, the United States feared that an all-inclusive definition would automatically bring things such as enzymatic cleaners and fabrics made from transgenic cotton within the purview of the Protocol.[250]

However, most other countries, including the members of the European Union, wanted initial inclusion of all LMOs and products derived from LMOs in the scope of the regulations, with the later addition of an annex listing exceptions to the regulations.[251] This approach avoided the dangers of granting automatic exemptions for entire classes of LMOs, thus allowing a cautious approach to regulation with flexibility to amend the scope to accommodate increased knowledge and development of future agricultural biotechnologies.

The actual Protocol text offers a compromise between these two approaches. Article 4 of the Protocol includes virtually all LMOs within the scope of the Protocol.[252] However, when taken in light of the limits imposed by the other provisions, the breadth of Article 4 is not quite so sweeping. For example, in response to early and continued criticisms that pharmaceuticals posed little danger to biodiversity and that unreasonably strict regulation would result in deaths caused by delays in shipments of medications, a per se exclusion was made for pharmaceuticals.[253]

3. Advanced Informed Agreement

When the AIA provisions were originally proposed, the United States argued that they were unfair and burdensome because they were to include all products of biotechnology.[254] However, the original provisions were considerably watered

248. *See id.*

249. *See* Lisa Seachrist, *Biosafety Protocol Fails to Pass Muster in Colombia*, 46 BIOWORLD TODAY (Mar. 10, 1999).

250. *See id.*

251. *See* Ling, *U.S. Behind Collapse*, *supra* note 232.

252. *See* Biosafety Protocol, *supra* note 11, art. 4.

253. *See id.* art. 5; Zalewski & McQuade, *supra* note 216.

254. *See BSWG-2*, *supra* note 214, Annex II; U.S. Dep't of State, Bureau of Oceans and Int'l Envtl. and Sci. Affairs, Fact Sheet on Biodiversity and the Convention on Biological Diversity, Jan. 5, 1999.

down in the final Protocol text. The original provisions required that government approval be obtained prior to any exchange of transgenic material, whether an exchange between scientists or a commercial exchange of grain to a customer.[255] In contrast, the final Protocol mainly requires notice for LMOs meant for release into the environment[256] and generally does not include products meant for direct consumption or processing.[257] In addition to the notification provisions, the Protocol provides a mechanism via the world wide web for recipient countries to give or deny consent for a shipment of LMOs.[258]

The final structure of the AIA provisions reflects the U.S. influence on the negotiations. At the Cartagena meeting, the United States conceded that it was willing to have companies obtain approval from recipient countries prior to the release of any LMO but opposed extension of the notification requirement for subsequent shipments or for exchanges of nonliving biotechnology products.[259] Under the Protocol text, these weakened AIA provisions require little in the way of pre-shipment notification. However, the impact of these weakened AIA provisions could be mediated by the effective use of the Biosafety Clearing-House[260] and application of the Precautionary Principle by recipient countries. Under the precautionary principle, the recipient country could deny entry of an LMO shipment.

While inclusion of even a weak AIA is commendable, it could ultimately prove useless unless educational efforts are seriously pursued under the Biosafety Clearing-House provisions of the Protocol. To make AIA meaningful, there must also be a corresponding effort to build biotechnology infrastructure in countries that have little or no knowledge, experience, or resources with which to address biosafety issues. There can be no informed consent if there is no knowledge with which to assess the risks associated with biotechnology products.[261]

4. Labeling Requirements

Another controversial provision requires that shipments of genetically altered products such as soybeans or corn be specially labeled.[262] Throughout negotiations, the United States has opposed any requirement that placed special labeling

255. *See Agricultural Biotechnology: Hearings Before the House Comm. on Agric.*, 106th Cong. 59-61 (1999) (statement by Roger Pine, President of the National Corn Growers Association).

256. *See* Biosafety Protocol, *supra* note 11, art. 7.

257. *See id.* art 11.

258. *See* Knight, *supra* note 240. For a discussion of the Biosafety Clearing-House, see discussion *infra* Part VI.C.5.

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

260. For a discussion of the Biosafety Clearing-House provisions, see discussion *infra* Part VI.C.5.

261. The Protocol also provides guidelines for Risk Assessment (Article 15) and Risk Management (Article 16) for receiving countries. *See* Biosafety Protocol, *supra* note 11, arts. 15, 16.

262. *See* Biosafety Protocol, *supra* note 11, art. 18.

requirements on transgenic products, even while such products were in transit.[263] Again, the final Protocol provisions reflect U.S. influence. The European Union and other Like-Minded countries lobbied for precise labeling of all LMO shipments, including the specific variety of LMO being shipped.[264] The United States argued that segregation of LMO and non-LMO products would be economically and technically infeasible, thus rendering it virtually impossible to comply with the strict labeling provisions.[265] As a result, the actual Protocol labeling requirements are very mild, only requiring that shipments bear a label stating that the shipment "may contain" LMOs.[266]

Although the practical and economic realities of the international agricultural trade may make more extensive labeling difficult, the "may contain" language presents other difficulties. For example, if there were an accidental release of LMOs in transit,[267] local authorities would have a difficult time identifying and managing the release and its attendant risks.[268] Further, the backlash against LMO products in many countries may have its own economic impact if consumers refuse to purchase products that cannot be certified as LMO-free. Labeling requirements instituted domestically in other countries are based on the consumer's right to know,[269] and any such regulations have the potential to force U.S. companies to engage in a more extensive separation and labeling of LMO products. In the end, the labeling issue might be decided through consumer and political pressures rather than on the basis of the Protocol.

5. Information Sharing

One of the most intriguing aspects of the Protocol is the establishment of the Biosafety Clearing-House under Article 20[270] on the world wide web.[271] The

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263. *See* BSWG-6, *supra* note 192, Annex II.

264. *See* Bill Lambrecht, *The Deal Has Been Struck on Gene-Altered Foods, and More than One Side is Claiming Victory*, ST. LOUIS POST-DISPATCH, Feb. 6, 2000, at A14.

265. *See* Griffin Shea, *High Price of Bio-Labels Stews Farmers; Fear Consumers Won't Pay for Proof of Unaltered Food*, WASH. TIMES, Feb. 7, 2000, at A10.

266. *See* Biosafety Protocol, *supra* note 11, art. 18(2)(a).

267. Article 17 of the Protocol discusses emergencies and unintended releases of LMO's. *See id.* art. 17.

268. *See* Egziabher, *supra* note 218. A related provision that had met with strong resistance from the United States was the proposed liability and compensation scheme. Despite the popularity with the Southern countries of provisions creating a new liability and compensation scheme, the United States had strongly opposed such provisions, arguing that current domestic and international liability schemes are adequate. Under early proposals, the United States could be held liable for any damages caused by LMOs exported by U.S. companies, potentially a huge liability risk considering the global dominance of U.S. biotechnology firms. However, while Article 27 is entitled "Liability and Redress," it simply institutes a four-year time period during which the COP must adopt a liability scheme. *See* Biosafety Protocol, *supra* note 11, art. 27.

269. *See Biosafety Protocol Could Impede Biotech Trade, Analyst Warns*, 27 PESTICIDE & TOXIC CHEMICAL NEWS, Nov. 12, 1998, *available in* 1998 WL 11009297.

270. *See* Biosafety Protocol, *supra* note 11, art. 20.

271. *Talk of the Nation / Science Friday: Controversy Surrounding Bioengineered Food Products and Genetically Modified Organisms Used in Agriculture* (NPR radio broadcast, Feb. 4, 2000).

purpose of the Clearing-House is to "[f]acilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms,"[272] and to assist parties with Protocol implementation.[273] Educational efforts are particularly aimed at increasing the biosafety knowledge of developing countries and countries rich in biodiversity.[274]

The United States feared that information-sharing provisions would abridge private intellectual property rights by forcing disclosure of proprietary knowledge and materials, and was criticized at earlier meetings[275] for insisting on the addition of a companion article that allows for nondisclosure of confidential information.[276] However, information-sharing provisions are a small step towards educating entities that have little knowledge of biosafety. While a delicate balance must be struck between education of others and a legitimate protection of intellectual property rights, a serious implementation of Article 20 would help alleviate concerns about whether implementation of the AIA provisions achieves truly informed consent.

6. Socioeconomic Considerations

Over U.S. protest, many countries successfully argued for the inclusion of a provision regarding socioeconomic considerations of the importing country.[277] This provision allows countries to institute import restrictions on LMOs not only for scientific reasons, but also to prevent harm "arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities."[278]

As discussed earlier, indigenous cultures and subsistence farmers are an important means of *in situ* conservation.[279] Allowing countries to consider factors that have a potentially large impact on biodiversity when making important decisions could be an effective way to encourage conservation of biodiversity and slow genetic erosion. However, implementation of Article 26 will have to be approached carefully, so as to allow legitimate protection of a country's citizens, while avoiding institution of exclusionary trade practices.

VII. CONCLUSIONS

At this point, it is impossible to predict where the regulation of biotechnologies will go next. In the United States, questions remain as to whether existing

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272. *See* Biosafety Protocol, *supra* note 11, art. 20(1)(a).
273. *Id.* art. 20(1)(b).
274. *Id.*
275. *See* Egziabher, *supra* note 218.
276. *See* Biosafety Protocol, *supra* note 11, art. 21.
277. *See id.* art. 26.
278. *Id.* art. 20(1).
279. For a discussion of genetic erosion, see discussion *supra* Part IV.A.

regulatory agencies are adequate to track and regulate the recent proliferation of transgenics in the marketplace. Internationally, questions remain as to whether the Protocol will provide sufficient guidance to individual countries as well as the international community. In each case, the harmonization of law that could occur under a thoughtfully implemented Protocol could help minimize the possible environmental and health risks currently posed by the disparity between regulated and unregulated countries, and may also protect legitimate trade interests by facilitating the building of infrastructure to support trade in LMOs.

To fulfill this potential, the global community must be willing to educate itself about both the benefits and the risks agricultural biotechnologies pose, then work to implement the Protocol in such a way as to encourage development of the beneficial aspects of such biotechnology while minimizing the attendant risks. It is certain that resolution of these conflicts will require a great deal more of the flexibility and compromise demonstrated by all involved in the final Protocol negotiations. Only then can the challenges posed by agricultural biotechnology be addressed for the greater good.