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"GMO:" Genetically Modified Organisms or Gigantic Monetary Obligation? The Liability Schemes for GMO Damage in the United State and the European Union

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"GMO:" Genetically Modified Organism or Gigantic Monetary Obligation? The Liability Schemes for GMO Damage in the United States and the European Union

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As with many modern technological developments, the enormous benefits of biotechnology will not come without corresponding social and environmental risks. Although scientists and policymakers have dismissed earlier predictions of pandemics resulting from the release of genetically engineered microorganisms, few maintain that they can predict with certainty the ecological consequences of inserting a gene from one species into another species and releasing the result of that miscegenation into the environment. Past unpleasant experiences with nuclear power, pesticides, and the importation of exotic plant species caution against launching headlong into the development and marketing of a new biotechnology without examining its potential for environmental harm. It may be, as many microbiologists predict, that very few modern biotechnologies pose any risk to humans or the environment; but, almost certainly, there will be one with the potential to cause great damage.[1]

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1. Thomas O. McGarity, *International Regulation of Deliberate Release Biotechnologies*, 26 TEX. INT'L L.J. 423, 425 (1991).

I. INTRODUCTION

A Cornell University study found that pollen from corn genetically modified to produce the toxin Bacillus thuringiensis (Bt) is fatal to monarch butterflies.[2] Environmental groups immediately thereafter filed a petition with the Environmental Protection Agency (EPA) seeking protection for butterflies from the Bt corn pollen.[3] The potential impact on butterflies and other species could be enormous because Bt varieties comprise thirty percent of the U.S. corn crop,[4] which grows on approximately twenty million acres.[5] Considerable resistance to any EPA action is expected from multi-national agra-business giants Novartis, Monsanto, and Pioneer Hi-Bred, whose annual revenues from genetically modified seeds have grown to over a billion dollars each year.[6]

Monsanto, however, continues to maintain the health and environmental benefits of its Bt corn.[7] Claiming the safety of dangerous products, even when science indicates otherwise, is not a new strategy for Monsanto. Three years after Congress mandated a ban on polychlorinated biphenyls (PCBs)[8] (of which Monsanto was the only commercial producer), the company publicly stated that regulation was unnecessary because "PCBs,

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2. *See* John E. Losey et al., *Transgenic Pollen Harms Monarch Larvae*, NATURE, May 20, 1999, at 214; *Genetic Engineering: No Obligation to Report Presence of GMOs If Less than 1%*, EUR. INFO. SERVICE (Brussels, Belg.), June 18, 1999, § 46, *available in* LEXIS, News Library, Eiseng File.

3. *See* Karen L. Werner, *Industry Research to Examine Effect of Bt Corn Pollen on Butterflies in Field*, 22 INT'L ENV'T REP. (BNA) 713, 714 (Sept. 1, 1999). The Environmental Defense Fund petitioned the EPA to require the planting of buffer zones around fields of Bt corn pending a full evaluation of potential risks to other lepidopteran insects. *See* Environmental Defense Fund, *Petition* (visited July 21, 1999) <http://www.edf.org/issues/Btcornpetition.html>.

4. *See* United States Department of Agriculture Economic Research Service, *Genetically Engineered Crops for Pest Management* tbl.4 (visited Nov. 20, 1999) <http://www.econ.ag.gov/whatsnew/issues/biotech>.

5. *See* Online News Hour with Jim Lehrer, *High-Tech Crops* (visited Aug. 12, 1999), <http://www.pbs.org/newshour/bb/environment/July-dec99/seeds_8-12.html>.

6. *See* Scott Kilman, *Once Quick Converts, Farmers Begin to Lose Faith in Biotech Crops*, WALL ST. J., Nov. 19, 1999, at A1.

7. *See* The Monsanto Company, *Environmental Benefits of YieldGard® Corn* (visited Oct. 10, 1999) <http://www.monsanto.com/ag/articles/YieldGardEnvironmentalBenefit.htm> (discussing the results of the independent study commissioned by Monsanto and conducted by Richard S. Fawcett, Ph.D.).

8. *See* Toxic Substance Control Act of 1976, 15 U.S.C. § 2605(e) (1994).

while not harmless, are not carcinogenic and do not have serious long-term health effects."[9] Since that time, corporations using Monsanto's PCBs have spent enormous sums in remediation under the federal Superfund law.[10] Due to the widespread use of genetically modified organisms (GMOs),[11] and the scientific uncertainty of their long-term environmental and health effects, corporate liability could approach Superfund levels in the event of serious GMO damage.

In addition to possibly transferring herbicide-resistant genes via the errant pollen to weeds, pollen from genetically modified crops could cross-pollinate organic crops, thereby stripping organic farmers of their organic status certifications and the accompanying price premiums.[12] Organic tortilla chip processor,

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9. Sandra Sugawara, *EPA Reopening Debate on Effects of PCB*, WASH. POST, May 10, 1982, at A15 (noting that Monsanto was the only firm producing PCBs commercially when Congress passed the 1976 ban and quoting Larry O'Neill, a spokesman for Monsanto).

10. *See* Comprehensive Environmental Response Compensation and Liability Act (Superfund Act), 42 U.S.C. §§ 9601–9675 (1994) (mandating the cleanup of and establishing liability for releasing hazardous substances); 26 U.S.C. § 9507(a) (1994) (creating the "Hazardous Substance Superfund" trust fund). "One of the primary purposes of the Superfund Act is to facilitate government cleanup of hazardous waste discharge and impede future releases in order to prevent, minimize, or mitigate damage to the public health, welfare, or to the environment, which may otherwise result from a release or threat of a release." Charles H. Sarlo, *A Comparative Analysis: The Affirmative Defense of an Innocent Landowner Versus the Prima Facie Case of a Toxic Tort Plaintiff: Can CERCLA'S Innocent Landowner Provision Be Used to Defend a Toxic Tort Suit?*, 16 PACE ENVTL. L. REV. 243, 246 (1999).

11. The most widely accepted definition of a "genetically modified organism" is "an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination." Council Directive 90/220 of 23 April 1990 on the Deliberate Release into the Environment of Genetically Modified Organisms, art. 2(2), 1990 O.J. (L 117) 15, 16 [hereinafter Directive 90/220]. The Directive defines an "organism" as "any biological entity capable of replication or of transferring genetic material." *Id.* art. 2(1). The two most common genetically modified agricultural products include Bt corn (corn modified through genetic manipulation to produce the toxin Bacillus thuringiensis) and Roundup Ready soybeans (soybeans genetically modified to be resistant to the herbicide glyphosate, commonly known as Roundup). *See generally* Janet Carpenter & Leonard Gianessi, *Why U.S. Farmers Are Adopting Genetically Modified Crops*, ECON. PERSP. (U.S. Dep't of State, Office of Int'l Info. Programs) (Oct. 1999) <http://www.usinfo.state.gov/journals/ites/1099/ijee/bio-gianessi2.htm> (providing statistics on U.S. crop acreage planted to GM varieties—in 1998, Bt corn occupied 14.4 million acres (18% of the U.S. total acreage) and Roundup Ready soybeans occupied 19 million acres (26% of the U.S. total acreage)).

12. *See* John Innes Centre, Press Release, *Gene Transfer from Genetically Modified Crops* (June 17, 1999) <http://www.jic.bbsrc.ac.uk/press/990617.htm>. The United Kingdom's Ministry of Agriculture, Fisheries, and Food (MAFF) commissioned the study;

Terra Prima, recalled and destroyed 87,000 units of certified organic tortilla chips from Europe after tests revealed the presence of genetically modified corn.[13] The company traced the corn used to make the recalled chips back to the specific organic farmer who grew the corn.[14] The probable cause of the "positive" test was pollen from genetically modified corn in nearby fields cross-pollinating with the farmer's organically grown corn.[15] A recent study conducted in the United Kingdom identified pollen from genetically modified crops that bees carried 4.5 kilometers away from the test site.[16] The researchers also found airborne genetically modified pollen up to 475 meters away from the test crops.[17]

Many consumers, especially in Europe, oppose genetically modified food because they suspect the food will prove unhealthy in the long run.[18] Such fears are understandable given the recent food scares involving Mad Cow Disease, bacterially contaminated meat, and dioxin in poultry, pork, and beef products.[19] In each of these cases, the affected country's government either suppressed "'inconvenient' scientific data" or directly lied about the food's safety.[20]

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the Centre is an independent world-leading research center in plant and microbial sciences. *See No Scaleback of GMO Trials Despite Study Citing Lack of Cross-Contamination Controls*, 22 INT'L ENV'T REP. (BNA) 535, 535 (June 23, 1999). The study "concluded that 'no system for the field production of seed can guarantee absolute genetic purity of seed samples.'" *Id.*

The premiums organic farmers receive vary according to the particular crop. As a general proposition, "[t]he organic system with organic price premiums had the highest profitability" of any of the farming systems studied over a four year period. Susanne Vaupel, *Advising Producers of Organic Crops*, 2 DRAKE J. AGRIC. L. 137, 151 (1997). *See also generally* Barry Kissoff, *Emergence of U.S. Organic Agriculture—Can We Compete?*, 5 AM. J. ARGIC. ECON. 1130, 1130–1133 (1998) (discussing the price premium for organic products). Once a farmer's crops lose their organic status, the farmer must wait up to three years to obtain re-certification. *See* Francesca Lyman, *'Transgenic' Pollution a New Concern* (visited Nov. 13, 1999) <http://www.msnbc.com/news/309357.asp>.

13. *See* Cheryl Hogue, *Organic Farmers, Greenpeace, Others Ask Court to Pull Bt Crop Registrations*, 22 INT'L ENV'T REP. (BNA) 195, 196 (Mar. 3, 1999).

14. *See id.*

15. *See id. See also* Lyman, *supra* note 11.

16. *See* Friends of the Earth, Press Release, *GM Crops: Genetic Pollution Proved, GM Pollen Found Miles From Trial Site* (Sept. 29, 1999) <http://www.foe.co.uk/pubsinfo/infoteam/pressrel/1999/19990929223031.html>.

17. *See id.*

18. *See Food for Thought*, ECONOMIST, June 19, 1999, at 19, 20.

19. *See id.* at 20.

20. *See id.* The lack of trust in regulatory procedures and institutions is more

In 1996, the *New England Journal of Medicine* published a report identifying possible negative health effects of genetically modified food.[21] The report detailed agra-business giant Pioneer Hi-Bred's efforts to increase amino acid levels in soybeans through genetic modification. The modification transferred to the soybean the same genetic material that occurs naturally in Brazil nuts and causes allergic reactions in some people.[22] Food allergies affect anywhere from two and one half to five million people in the United States, with symptoms ranging from mild discomfort to a severe and even fatal reaction known as anaphylactic shock.[23] Citing fears of potential allergic reactions and antibiotic resistance, the British Medical Association called for a ban on the release of GMOs into the environment.[24]

A United Kingdom survey conducted in June 1999 found that fifty-six percent of those surveyed thought genetically modified foods were unsafe to eat.[25] Sir Paul McCartney, a leading advocate for GMO-free food, publicly criticized the U.K. Government's support of GMO technology.[26] Throughout Europe, larger supermarket chains banned the use of GMOs as ingredients in generic and brand-name labels.[27] Prominent

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significant in Europe than in the United States. *See* George Gaskell et al., *Worlds Apart? The Reception of Genetically Modified Foods in Europe and the U.S.*, 285 SCIENCE 384, 385 (1999). Only four percent of Europeans surveyed place their highest confidence in national political bodies' being truthful about genetically modified crops. *See id.* U.S. citizens, in contrast, expressed 90 and 84 percent confidence in the U.S. Department of Agriculture (USDA) or Food and Drug Administration (FDA) statements on the safety of genetically modified crops. *See id.*

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

22. *See id.* at 691.

23. *See* Environmental Defense Fund, *Gene Altered Food Triggers Allergy* (visited Aug. 23, 1999) <http://www.edf.org/pubs/edf%2Dletter/1996/may/h%5Fbiotec.html>.

24. *See* Maxine Frith & Eileen Murphy, *BMA Calls for Ban on GM Crops and Food*, PRESS ASS'N NEWSFILE, May 17, 1999, *available in* LEXIS, News Library, Wires File.

25. *See* John Willman, *Consumer Power Forces the Food Industry to Modify its Approach*, FIN. TIMES (London), June 9, 1999, at 10.

26. *See* Vivienne Aitken, *Blair Wrong on GM Food, Says Paul*, DAILY REC. (Glasgow, Scot.), June 11, 1999, at 29.

27. *See* Lawrence J. Speer, *Supermarket Coalition to Ban GMOs*, 22 INT'L ENV'T REP. (BNA) 272, 272 (Mar. 31, 1999); *see also Genetic Engineering: Major Companies Reject GM-Food*, EUR. INFO. SERVICE (Brussels, Belg.), June 4, 1999, § 45, *available in* LEXIS, News File, Eiseng File (stating that "[t]o date the four main supermarket chains in the United Kingdom (Tesco, Sainsbury's, Asda, and Safeways) have stopped selling GMO-containing products."); Steve Strecklow, *'Genetically Modified' On the Label Means . . . Well, It's Hard to Say*, WALL ST. J., Oct. 26, 1999, at A1 (describing the reaction of

European food producers Nestle and Unilever quickly adopted a GMO-free policy.[28] Grupo Maseca, Mexico's largest tortilla producer, announced it would no longer purchase genetically modified corn, thereby possibly impacting the $500 million annual U.S. corn export to Mexico.[29] In the United States, Heinz and Gerber, the two largest baby food manufacturers, also announced a GMO-free policy.[30] Gerber's announcement was especially troubling to U.S. farmers because Gerber's parent company, Novartis, is a leader in the biotechnology industry and was the first company to sell genetically modified corn seed.[31] Due to market uncertainties and the potential for "massive liability from damage caused by genetic drift [or cross-pollination],"[32] over thirty farm groups, including the American Corn Growers Association and the National Family Farm Coalition, warned farmers about the dangers of planting genetically engineered crops.[33] Furthermore, Deutsche Bank, a large German bank, withdrew its previously positive projections and issued a report warning investors to "steer clear of companies associated with GMO crops."[34]

On January 21, 1999, in response to growing public skepticism in Europe over possible GMO externalities, the European Parliament's Committee on the Environment, Public Health, and Consumer Protection adopted a proposal advocating a "safety first" principle.[35] The report addresses the European Commission proposal to amend Directive 90/220, the current law

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supermarkets in the United Kingdom to the growing skepticism of GMOs).

28. *See Genetic Engineering: Major Companies Reject GM-Food*, *supra* note 27.

29. *See* Joanna Blythman, *The Seeds of Doubt*, SUNDAY HERALD (Glasgow, Scot.), Sept. 19, 1999, at 9.

30. *See id.*

31. *See NCGA Takes Exception to Novartis/Gerber Actions on GMOs*, SCI. POL'Y REP. (Aces News, Univ. Ill., Urbana Champaign), Sept. 14, 1999 (on file with the *Loyola of Los Angeles International & Comparative Law Review*).

32. William Claiborne, *Biotech Crops Spur Warning*, WASH. POST, Nov. 24, 1999, at A1.

33. *See id. See also Corn Growers Call on Farmers to Consider Alternative to Planting GMOs If Questions are Not Answered*, PR NEWSWIRE (New York, N.Y.), Aug. 25, 1999, *available in* LEXIS, News Library, Prnews File.

34. Sean Poulter, *GM Industry Faces Collapse, Says Bank*, DAILY MAIL (London), Aug. 24, 1999, at 6.

35. *See* Legislative Resolution Embodying Parliament's Opinion on the Proposal for a European Parliament and Council Directive Amending Directive 90/220/EEC on the Deliberate Release into the Environment of Genetically Modified Organisms, 1999 O.J. (C 139) 363 [hereinafter Parliament Resolution].

regulating the deliberate release of GMOs into the environment.[36] The Committee adopted an amendment imposing civil and criminal liability for any damage to human health or the environment resulting from the deliberate release of GMOs.[37] In addition, the Committee recommended a more general environmental liability directive for passage at a future date governing the entire European Union.[38]

In contrast to the European Union's pro-active approach to GMO regulation and liability issues, no single federal statute in the United States regulates GMOs directly.[39] The EPA, Food and Drug Administration (FDA), and U.S. Department of Agriculture (USDA) share minimal and inadequate supervisory responsibilities to regulate only the plant health and pesticide aspects of GMOs, while other characteristics of GMOs remain unregulated.[40] Therefore, recovering damages for injury resulting from the release of GMOs into the environment, such as allergic reactions, cross-pollination of conventional or organic crops, or harm to natural resources, like the Monarch butterfly, must proceed under the common law's difficult burden of proof.

The United States leads the world in the development of genetically modified organisms.[41] A U.S. State Department official testified before the Senate Finance Subcommittee on International Trade that "[w]ithin a few years, virtually one hundred percent of U.S. agricultural commodity exports will be

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36. *See* Commission Proposal for a European Parliament and Council Directive Amending Directive 90/220/EEC on the Deliberate Release into the Environment of Genetically Modified Organisms, 1998 O.J. (C 139) 1 [hereinafter Commission Proposal].

37. *See* Parliament Resolution art. 22(a)(a), *supra* note 35.

38. *See id.* recital 17(a).

39. *See* John H. Barton, *Biotechnology, the Environment, and International Agricultural Trade*, 9 GEO. INT'L ENVTL. L. REV. 95, 108 (1996) (stating that in 1984, the EPA and USDA decided to issue new regulations under a variety of existing laws instead of lobbying for a new comprehensive law dealing with the various biotechnology-related issues).

40. *See* William Allen, *The Current Federal Regulatory Framework for Release of Genetically Altered Organisms into the Environment*, 42 FLA. L. REV. 531, 550 (1990).

41. *See id.* In the year 2000, more than sixty million hectares will be cultivated using GMOs. *See Rapid Growth in GMO Plantings*, AGRA EUR. (London), Nov. 27, 1998, at M/5, *available in* LEXIS News Library, Asapii File. More than eighty percent of the plantings will be in North America, ten percent in Asia, eight percent in South America, and only one percent in Europe. *See id.* A "hectare" is "a metric unit of area equal to . . . 10,000 square meters." WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 1048 (1986).

genetically modified or mixed with GMO products."[42] In contrast, the European Union, which is a major market for U.S. agricultural products, has a "slow and unpredictable process for approving new U.S. agricultural products developed through advanced biotechnology."[43] According to Foreign Agricultural Service Administrator Tim Galvin, who testified before the House Agriculture Subcommittee on Risk Management and Specialty Crops, the United States is "shut out of the E.U. market because of commingling [traditionally grown crops with varieties containing GMOs]."[44] E.U. restrictions on genetically modified corn cost U.S. farmers $200 million in sales in 1998.[45] Meanwhile, the U.S. trade deficit with the European Union continues to rise.[46]

European Union officials claim that the arduous E.U. approval process is based on consumer distrust.[47] According to Congressman Thomas W. Ewing (Rep-Ill.), Chairperson of the House Agricultural Subcommittee on Risk Management and Specialty Crops, the Europeans are "dumb like [foxes]" because they "us[e] this [GMO] issue to keep [U.S. products] out."[48] U.S.

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42. Chad Bowman, *European Union: USTR Working on Draft Retaliation List in Hormone-Raised Beef Spat with E.U.*, INT'L TRADE DAILY (BNA), Mar. 16, 1999, *available in* LEXIS, News Library, Bnaitd File.

43. Prepared Statement of Ambassador David L. Aaron, *Under Secretary of Commerce for International Trade Before the Subcommittee on Trade of the House Committee on Ways and Means*, July 28, 1998, *available in* 1998 WL 12762839 [hereinafter Aaron Statement]. In the United States, Canada, and Japan, nearly 100 products containing GMOs are allowed "general release" while the European Union has approved only fourteen. *See* Philip Clarke, *Europe Takes Hard Line on Genetically Modified Crop Approvals*, FARMER'S WKLY. (Sutton, Surrey, U.K.), Dec. 11, 1998, at 58. Gaining E.U. GMO approval takes much longer than in other states. For example, Novartis' Bt-maize took six months to gain approval in the United States, ten months in Canada and Japan, and over two years in the European Union. *See id.*

44. Jennifer Coderre, *Biotechnology: Agriculture Officials Urge Outreach to Convince Europe of GMOs' Benefits*, INT'L TRADE DAILY (BNA), Mar. 5, 1999, *available in* LEXIS, News Library, Bnaitd File.

45. Stuart E. Eizenstat, *Under Secretary of Commerce, The Future of Our Economic Partnership with Europe, Before the House International Relations Committee*, FED. NEWS SERVICE (Washington, D.C.), June 15, 1999, *available in* LEXIS, News Library, Fednew File.

46. *See* Aaron Statement, *supra* note 43.

47. *See* Daniel Pruzin, *Labeling: United States Reiterates Complaint to WTO on E.U. Labeling of Genetically Modified Foods*, INT'L TRADE DAILY (BNA), Sept. 17, 1998, *available in* LEXIS, News Library, Bnaitd File.

48. Coderre, *supra* note 44, at 2. The rise of international trade arrangements like the WTO, forces nations to use different approaches, such as labeling and strict product "safety" requirements, as opposed to tariffs, to prevent entry of foreign agricultural products. *See* Barton, *supra* note 39, at 95.

farmers already feel the effects of the European Union's resistance to approve imports of GMOs. Two large U.S. food processors, Archer Daniels Midland Company and A.E. Staley Manufacturing Company, announced they intend to reject "any genetically modified corn that is not accepted in European markets."[49] In addition, the European Union rejected several applications for GMO crops, despite the E.U. Scientific Committee on Plants' approval.[50] In response to growing pressure from the agra-business sector, the United States recently voiced concerns to the World Trade Organization (WTO) over E.U. labeling requirements for genetically modified foods[51] and the E.U. approval process for GMO imports.[52]

Although seemingly unrelated, the European Parliament's staunch position on GMO liability plays a major role in the multi-million dollar E.U.-U.S. trade in agricultural products.[53] The current E.U. GMO approval process severely restricts U.S. corn and soybean exports to the European Union.[54] A de facto ban on new GMO approvals is likely to continue until the European Council and Parliament revise the Directive regulating GMOs (Directive 90/220).[55] Parliament insists that any revision to the Directive must include a comprehensive liability scheme for the companies selling GMO products—a position the Council refuses to consider.[56]

In addition to the controversy surrounding application of Directive 90/220, the European Union recently revised Directive 85/374 (Products Liability Directive) to include primary agricultural products within the products liability scheme.[57]

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49. *ADM, Staley to Reject Some Genetically Modified Corn*, NEWS-GAZETTE (Champaign, Ill.), Apr. 15, 1999, at C8.

50. *See European Union: E.U. States Reject GMO Cotton Seeds, Despite Green Light from Science Panel*, INT'L TRADE DAILY (BNA), Feb. 16, 1999, *available in* LEXIS, News Library, Bnaitd File.

51. *See* Pruzin, *supra* note 47.

52. *See U.S. Considers Filing Complaint with WTO over E.U. Barriers to GMO Imports, Aide Says*, 22 INT'L ENV'T REP. 569, 569 (July 7, 1999).

53. Parliament favors imposing strict liability for damage caused by the release of GMOs into the environment; for a detailed discussion of Parliament's standpoint on this issue, see *infra* notes 354–361.

54. *See* Aaron Statement, *supra* note 43.

55. *See* Joe Kirwin, *EU Environment Ministers Strengthen De Facto Ban on GMOs; WTO Fight Looms*, 22 INT'L ENV'T REP. 567, 567–568 (July 7, 1999).

56. *See id.*

57. *See* Council Directive 99/34 of the European Parliament and the Council of 10

Presently, the European Parliament impatiently awaits the long-expected Commission proposal for a directive imposing civil liability for environmental damage. The Commission issued a "Green Paper" in May 1993,[58] promised a final version of the legislation in 1996, but delayed until 2000 to issue a "White Paper" recommending further consultations.[59] The civil liability directive will reportedly address GMO liability as well as other potential causes of environmental damage.[60] Until the E.U. institutions agree on a common GMO liability scheme, E.U.-U.S. trade in virtually all agricultural products will be severely impaired.

As background to the current controversy, Part II of this Article summarizes the legal background of environmental protection in the European Union and its relation to the common market. Part III explores the current E.U. GMO regulatory and liability schemes, specifically those in the United Kingdom, Austria, and Germany. Part IV outlines the U.S. regulatory scheme and analyzes liability for GMO damage under established common law doctrines. Part V examines the approach various international conventions employ to address GMO regulation and liability. Part VI discusses three proposals to modify or create E.U. directives imposing liability for environmental damage resulting from GMOs. Finally, Part VII presents recommendations and predictions for the future scope of environmental liability in the European Union.

May 1999 Amending Council Directive 85/374/EEC on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products art. 2, May 10, 1999, O.J. (L 141) 20 (1999) (amending the Products Liability Directive to remove previous exclusions of "primary agricultural products" from liability by deleting Article 15(1)(a)) [hereinafter Directive 99/34].

58. *See* Communication from the Commission to the Council and Parliament and the Economic and Social Committee: Green Paper on Remedying Environmental Damage, May 14, 1993, COM(93)47 final at 4; Opinion of the Economic and Social Committee on the Communication from the Commission to the Council and Parliament and the Economic and Social Committee: Green Paper on Remedying Environmental Damage, Feb, 23, 1994, 1994 O.J. (C 133) 8 [hereinafter Civil Liability Green Paper].

59. *See Environmental Liability: Commission Still Cagey About Liability for Damage*, EUR. INFO. SERVICE (Brussels, Belg.), Jan. 23, 1996, § 469, *available in* LEXIS, News Library, Eiseng File [hereinafter *Environmental Liability*]; European Commission White Paper on Environmental Liability, COM(2000) 66 final at 4 [hereinafter White Paper].

60. *See Environmental Liability*, *supra* note 59.

II. LEGAL BACKGROUND TO THE EUROPEAN UNION'S ENVIRONMENTAL PROTECTION AND MARKET HARMONIZATION LEGISLATION

The 1957 Treaty of Rome[61] established the European Economic Community, but did not mention environmental protection.[62] During the 1972 Paris Summit, the Community formally stated a need to pay particular attention to environmental protection and improve the general quality of life.[63] Finally, the 1987 Single European Act (SEA)[64] granted environmental protection explicit status within the treaty document.[65]

Prior to the SEA, two treaty provisions served as the basis for environmental legislation.[66] Article 100 of the original Treaty of Rome authorized Community-level legislation to harmonize the laws among the Member States.[67] Article 235 granted the Council authority to enact measures necessary to achieve any objective of the common market in which the Treaty failed to explicitly provide the required power.[68] Both Articles grant broad powers to the Community, practicably limited only by political will.

The Treaty article authorizing the legislation determines whether the legislation will take the form of a "directive" or "regulation" and establishes the specific parliamentary process for approval.[69] Legislation based on both Article 100 and Article 235

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61. TREATY ESTABLISHING THE EUROPEAN ECONOMIC COMMUNITY, Mar. 25, 1957, 298 U.N.T.S. 11 (1958) [hereinafter EEC TREATY].

62. *See* STANLEY P. JOHNSON & GUY CORCELLE, THE ENVIRONMENTAL POLICY OF THE EUROPEAN COMMUNITIES 1 (1989); James E. Pfander, *Environmental Federalism in Europe and the United States: A Comparative Assessment of Regulation Through the Agency Member States*, *in* ENVIRONMENTAL POLICY WITH POLITICAL AND ECONOMIC INTEGRATION: THE EUROPEAN UNION AND THE UNITED STATES 62 (John B. Braden et al. eds., 1996).

63. *See* JOHNSON & CORCELLE, *supra* note 62, at 1–2.

64. SINGLE EUROPEAN ACT, 1987 O.J. (L 169) 1 [hereinafter SEA].

65. *See* Margaret Rosso Grossman, *Agro-Environmental Measures in the Common Agricultural Policy*, 25 U. MEMPHIS L. REV. 929, 941–942 (1995).

66. *See* EEC TREATY arts. 100, 235.

67. *See id.* art. 100.

68. *See* Grossman, *supra* note 65, at 939–940; IAN B. BIRD & MIGUEL A. VEIGA-PESTANA, *European Community Environmental Policy and Law*, *in* EUROPEAN UNION LAW AFTER MAASTRICHT: A PRACTICAL GUIDE FOR LAWYERS OUTSIDE THE COMMON MARKET 209, 223 & n.64 (describing use of Article 235 to protect the environment and European Court cases supporting this interpretation of the Treaty).

69. *See, e.g.*, EEC TREATY art. 100.

requires unanimous action within the Council.[70] While Article 100 legislation is limited to directives, Article 235 applies to both regulations and directives.[71] Directives have been the most popular type of Community legislation because of the flexibility they offer Member States during implementation.[72]

The SEA added three articles to the Treaty relating to environmental protection. Article 130r establishes the general objectives and principles for Community environmental policy.[73] Article 130s dictates the legislative process for community environmental legislation.[74] Although the SEA's purpose was to introduce procedural changes to facilitate Community decision-making and reduce the democratic deficit, Article 130s requires unanimity for environmental legislation and provides Parliament with only an advisory opinion role.[75] Finally, Article 130t allows Member States to maintain more stringent protective measures.[76]

The SEA also added Article 100a, which directs Member States to harmonize legislation impacting the environment and include significant environmental protection.[77] Article 100a also introduced qualified majority voting to the Council[78] and a

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70. *See id.* arts. 100, 235.

71. *See* Grossman, *supra* note 65, at 940.

72. *See id.* at 936.

73. TREATY ON EUROPEAN UNION art. 130r.

74. *See id.* art. 130s.

75. *See id. See also* Grossman, *supra* note 65, at 943; CLIVE ARCHER & FIONA BUTLER, THE EUROPEAN UNION STRUCTURE & PROCESS 53–57 (2d ed. 1996) (describing the consultation, cooperation, and co-decision procedures of adopting legislation).

76. *See* JOHNSON & CORCELLE, *supra* note 62, at 343–344.

77. *See* Grossman, *supra* note 65, at 942; SEA art. 100a(3) (stating that the "Commission, in its proposals . . . concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection.").

78. Member States' votes in the Council roughly correlate to population. There are a total of 87 votes in the Council, with 62 required for a qualified majority. *See* TREATY OF AMSTERDAM AMENDING THE TREATY ON EUROPEAN UNION, THE TREATIES ESTABLISHING THE EUROPEAN COMMUNITIES AND CERTAIN RELATED ACTS art. 148 (as in effect 1997) (now article 205), 1997 O.J. (C 340) 1, 173 [hereinafter TREATY OF AMSTERDAM]. Under qualified majority voting, the "Big Four" Member States of Germany, France, Italy and the United Kingdom do not have enough votes to overrule the unified objections of the smaller states. The votes of the Member States are weighted as follows: Belgium (5), Denmark (3), Germany (10), Greece (5), Spain (8), France (10), Ireland (3), Italy (10), Luxembourg (2), Netherlands (5), Austria (4), Portugal (5), Finland (3), Sweden (4), and United Kingdom (10). *See id.*

cooperation procedure with Parliament,[79] providing them more power to amend or reject proposals.[80]

The 1992 Treaty on European Union (TEU)[81] elevated the importance of environmental protection by placing it "on a par with economic issues."[82] A revised Article 130r established the Precautionary Principle[83] as well as the Polluter Pays Principle.[84] Although Directive 90/220 predates TEU's official inclusion of the Precautionary Principle, the stringent approval process for GMOs the Directive outlined follows precautionary principles. The much older and more established Polluter Pays Principle,[85] however, was omitted from the Directive. Parliament's current efforts to establish liability for GMO accidents fall in line with the Polluter Pays Principle.

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79. *See* Ralph H. Folsom, *The European Union Law-Making Machine*, *in* EUROPEAN UNION LAW AFTER MAASTRICHT A PRACTICAL GUIDE FOR LAWYERS OUTSIDE THE COMMON MARKET 3, 7–8 (Ralph H. Folsom et al. eds., 1996). Under the cooperation procedure, Parliament can reject or offer amendments to the Council's position on the Commission's legislative proposal. *See id.* at 7. If Parliament rejects the Council's position, the Council can adopt the legislation only by unanimous vote. *See id.* Amendments Parliament offers are forwarded to the Commission for consideration. *See id.* at 8. If the Commission adopts the new proposal, it is sent to the Council for adoption by a qualified majority. If the Commission rejects Parliament's amendments, the Council, acting by a qualified majority, may pass the legislation as the Commission proposed. *See id.* The Council may adopt Parliament's amendments over the Commission's objection only with unanimity. *See id.*

80. *See* Grossman, *supra* note 65, at 943; Folsom, *supra* note 79, at 7.

81. TREATY ON EUROPEAN UNION, Feb. 7, 1992, O.J. (C 191) 1 (1992).

82. Grossman, *supra* note 65, at 945. The TEU added to Article 2 the Community's task of "sustainable and non-inflationary growth respecting the environment." TREATY ON EUROPEAN UNION art. 2. In addition, the treaty added to the official "activities of the Community" a "policy in the sphere of the environment." *See id.* art. 3(k).

83. The "Precautionary Principle" means that "where there is a risk of significant damage to human health or the environment[,] lack of scientific certainty should not be used as a reason for not taking or for postponing measures to avoid or minimi[z]e such a risk." Genetically Modified Food and Producer Liability Bill, 1999, § 1(4) (Eng.) (presented to the House of Commons on June 24, 1999) <http://www.parliament.the-stationery-office.co.uk/cgi-bin/empower> [hereinafter Simpson Bill].

84. *See* Grossman, *supra* note 65, at 948. "Community policy on the environment . . . shall be based on the precautionary principle and . . . that the polluter should pay." TREATY ON EUROPEAN UNION art. 130r(2).

85. *See* Organisation for Economic Co-operation and Development: Council Recommendation on the Implementation of the Polluter-Pays Principle, Nov. 14, 1974, 11 I.L.M. 234 (1975) (outlining the definition and guiding principles of the Polluter Pays Principle). *See also generally* Sanford E. Gaines, *The Polluter-Pays Principle: From Economic Equity to Environmental Ethos*, 26 TEX. INT'L L.J. 463, 467–481 (1991) (discussing the evolution of the Polluter Pays Principle).

The TEU significantly revised the legislative process for environmental proposals. For most environmental measures enacted under Article 130s(1), Parliament possesses cooperation powers and the Council must act by a qualified majority.[86] For harmonization legislation under Article 100a, the Treaty requires a qualified majority of the Council and compliance with a co-decision procedure in Parliament, which provides Parliament with power to veto legislation.[87]

The 1997 Treaty of Amsterdam further revised the legislative process for environmental protection.[88] Environmental measures enacted under Article 175(1) (formerly Article 130s(1))[89] now follow the co-decision procedures,[90] elevating Parliament's role in environmental matters to that of Article 95 (formerly Article 100a)[91] legislation on harmonization.[92]

Under the authority that the now-amended Article 100a established, the Council passed Directive 90/220 on April 23, 1990;[93] although the Council could have instead passed the Directive under the Article 130s authority as a general environmental protective measure.[94] Under Article 100a, the Council only needs a qualified majority.[95] Since the ratification of the TEU and Amsterdam Treaties, amendments to the Directive are subject to the more extensive co-decision procedure in Parliament. Parliament is therefore allowed two readings and the opportunity to propose amendments. Furthermore, Parliament

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86. *See* Grossman, *supra* note 65, at 950–951.

87. *See* TREATY ON EUROPEAN UNION art. 189b.

88. TREATY OF AMSTERDAM pmbl.

89. The Treaty of Amsterdam renumbered TEU Article 130s(1) as Article 175(1). *See id.* art. 175(1).

90. *See id.* The Treaty provides for the co-decision procedure in Article 251 (formerly Article 189b). *See id.* art. 251.

91. The Treaty of Amsterdam renumbered TEU Article 100a as Article 95. *See id.* art. 95.

92. *Compare id.* art. 175(1) (environmental protection measures will follow Article 251 co-decision procedures) *and id.* art. 95 (harmonization measures will follow Article 251 co-decision procedures) *with* TREATY ON EUROPEAN UNION art. 100a (harmonization measures will follow Article 189b co-decision procedures) *and* TREATY ON EUROPEAN UNION art. 130s(1) (environmental protection measures will follow Article 189c cooperation procedures).

93. *See* Directive 90/220, *supra* note 11, at 15.

94. *See* TREATY OF AMSTERDAM art. 130s (as in affect 1997) (now article 175).

95. *See id.* art. 100a (as in effect 1997) (now article 95) (referring to the procedures in art. 189b (as in effect 1997) (now article 251)).

also possesses veto power over any attempt by the Council to revise Directive 90/220.[96]

III. THE E.U. GMO REGULATORY AND LIABILITY SCHEMES

Directive 90/220 was the final step in the lengthy building process that the European Union used to establish the necessary consensus for harmonizing its GMO regulatory regimes.[97] Biotechnology companies had demanded E.U. legislation,[98] arguing that the mosaic of regulatory regimes encountered at the Member State level disadvantaged them with respect to United States and Japanese competitors.[99]

The "watchdog"[100] type government agency review the United Kingdom and France employed exemplified this problem by allowing GMO experimentation yet subjecting each project to government agency approval and assessment processes.[101] Denmark and Germany took the opposite approach to GMOs. The Danish Parliament prohibited all GMO experiments for which the Minister of the Environment had not granted explicit permission.[102] Similarly, Germany's Parliament proposed a five-year moratorium on the deliberate release of GMOs.[103] The other Member States did not directly regulate GMOs.[104] The biotechnology industry, however, was willing to accept a more rigorous risk-assessment technique to gain public support and insulate itself from the Green Party.[105] The German Government,

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96. *See* TREATY ON EUROPEAN UNION art. 189b.

97. *See* Michael Balter, *How Europe Regulates Its Genes*, 252 SCIENCE 1366, 1367 (1991). Directive 90/220 required Member States to implement the Directive through national legislation by October 1991. *See* Directive 90/220 art. 23(1), *supra* note 11, at 21.

98. *See* Balter, *supra* note 97, at 1368 (quoting then Director General of the E.C. Environmental Directorate Laurens Jan Brinkhorst: "[i]ndustry often prefers not to be regulated, . . . [b]ut the most important thing is to have predictability, and a standardized process.").

99. *See id.* at 1367; *see also* David Dickson, *Europe Splits Over Gene Regulation*, 238 SCIENCE 18, 18 (1987).

100. Dickson, *supra* note 99, at 18 (quoting Bryan Ager, Secretary of the U.K. Advisory Committee on Genetic Manipulation).

101. *See id.*

102. *See id.*

103. *See id.*

104. *See id.* Clara Frontali, of the Instituto Superior di Sanità in Rome, declared that in Italy, there is "no legislation covering environmental release [of GMOs], and in theory, one is free to take any potentially dangerous organism and spread it around in any amount one wishes." *Id.*

105. *See* Balter, *supra* note 97, at 1368 (explaining the extent of the Green Party's

meanwhile, saw an opportunity to evade public debate over having lifting its moratorium on GMO release.[106] The United Kingdom and France envisioned no real change in their respective procedures other than possibly increased paperwork.[107] The remaining Member States generally approved the notion of the E.U. legislation as a comforting measure designed to calm the public.[108]

A. Approval Procedure in the Eurpoean Union

Directive 90/220 harmonized the approval process for placing GMOs on the market and subsequently deliberately releasing them into the environment.[109] Prior to releasing a GMO, a manufacturer or importer must notify the competent authority of the Member State in which the release is to occur.[110] Notification must include, among other things, a technical dossier and a detailed risk assessment.[111] Within ninety days, the Member State must either (1) forward the dossier to the Commission with a favorable approval or (2) inform the notifier that the proposal is rejected because it does not meet the Directive's requirements.[112] If the Member State's opinion is favorable, the Commission must immediately forward the application to all Member States for review and comment.[113] If no other Member State objects within sixty days, the notifying Member State shall consent to placing the product on the market.[114] To date, however, at least one Member State objects to every GMO consent application.

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influence and its desire to eliminate the biotechnology industry as a whole).

106. *See id.*

107. *See id.*

108. *See* Dickson, *supra* note 99, at 19.

109. The "deliberate release" is "any intentional introduction into the environment of a GMO without provisions for containment" such as physical, chemical and/or biological barriers to limit contact with the general population or the environment. Directive 90/220 art. 2(3), *supra* note 11, at 16. The act of placing the GMO product on the market falls under "deliberate release" regulations. *See id.* art. 2(5). The Directive defines "placing on the market" as "supplying or making available to a third party." *Id.*

110. *See id.* art. 11(1), *supra* note 11, at 18.

111. *See id.* annex II, at 23 (detailing the information required in the notification to the Member State for placing a GMO on the market).

112. *See id.* art. 12(2)(a)–(b), at 19.

113. *See id.* art. 13(1), at 19.

114. *See id.* art. 13(2), at 19.

A Member State's objection triggers a complex dispute resolution process under Article 21 of the Directive.[115] The Commission submits a draft of the Member State's proposed consent to a committee composed of representatives from all the Member States.[116] A qualified majority of the committee members then issue an opinion.[117] If the committee's report supports granting consent for release, the Member State that received the original notification shall give its consent in writing.[118] If the committee's report opposes the release, or the committee cannot reach a qualified majority, the proposal for consent is sent to the Council for a vote by a qualified majority.[119] If a qualified majority of the Council does not vote in favor of or vote to reject the consent within three months, the Commission will approve the proposed consent and notify the Member State to consent to the release.[120]

Once a Member State consents to placing a GMO on the market, the GMO product may be used, without further notification, throughout the Community.[121] As an exception to E.U.-wide consent, a Member State may later provisionally restrict a GMO's deliberate release if it has "justifiable reasons to consider that a product . . . constitutes a risk to human health or the environment."[122] If such a risk arises, the Member State must then notify the Commission, which then takes action in accordance with the above procedures for pre-consent Member State objections.[123]

Since 1990, the Commission issued only fourteen approvals placing GMOs on the market.[124] By comparison, in the United

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115. *See id.* art. 13(3), at 19 (mandating that if a compromise position cannot be reached within the sixty-day notification period, the Commission will make the decision in accordance with Article 21 of the Directive).

116. *See id.* art. 21, at 21.

117. *See id.* The qualified majority required for adopting a position consists of the Member States' weighted votes established in Article 148(2) of the Treaty. *See* TREATY ON EUROPEAN UNION art. 148(2).

118. *See* Directive 90/220 art. 13(4), *supra* note 11, at 20.

119. *See id.* art. 21, at 21.

120. *See id.*

121. *See id.* art. 13(5), at 20. The use must comply with the "specific conditions of use and the environments and/or geographical areas stipulated" to in the written consent. *Id.*

122. *Id.* art. 16, at 20.

123. *See id.*

124. *See, e.g.*, Commission Decision 93/572, 1993 O.J. (L 276) 16 (anti-rabies vaccine for foxes); Commission Decision 94/385, 1994 O.J. (L 176) 23 (herbicide resistant

States, Japan, and Canada, nearly one hundred genetically modified products are allowed "general release."[125] In June 1999, the Member States agreed to implement a de facto ban on future approval of GMO consents.[126] The ban is expected to continue until Parliament and the Council revise Directive 90/220[127]—final approval of which is not expected until 2001.[128]

B. E.U. Member State Implementation of Directive 90/220

1. The United Kingdom

Prior to the European Union's passage of Directive 90/220, GMO regulations in the United Kingdom provided relatively minimal government supervision for most biotechnology activities.[129] Public support for GMOs in the United Kingdom was favorable, with some studies publishing approval rates above seventy-five percent.[130] Lingering skepticism over the safety of the food supply and environmental groups' massive public education efforts, however, changed consumer attitudes about GMOs.[131] As of June 1999, twenty-four of the United Kingdom's

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tobacco); Commission Decision 94/505, 1994 O.J. (L 203) 22 (vaccine Nobi-Provac Aujeszky); Commission Decision 96/158, 1996 O.J. (L 37) 30 (herbicide tolerant swede-rape); Commission Decision 96/281, 1996 O.J. (L 107) 10 (herbicide tolerant soya beans); Commission Decision 96/424, 1996 O.J. (L 175) 25 (herbicide tolerant chicory); Commission Decision 97/98, 1997 O.J. (L 31) 69 (modified maize with insecticidal properties and herbicide tolerance); Commission Decision 97/392, 1997 O.J. (L 164) 38 (genetically modified swede-rape); Commission Decision 97/393, 1997 O.J. (L 164) 40 (genetically modified swede-rape); Commission Decision 97/549, 1997 O.J. (L 225) 34 (Streptococcus test); Commission Decision 98/291, 1998 O.J. (L 131) 26 (genetically modified spring swede-rape); Commission Decision 98/292, 1998 O.J. (L 131) 28 (genetically modified maize); Commission Decision 98/293, 1998 O.J. (L 131) 30 (genetically modified maize); Commission Decision 98/294, 1998 O.J. (L 131) 32 (genetically modified maize).

125. *See* Clarke, *supra* note 43, at 58.

126. *See* Kirwin, *supra* note 55, at 567.

127. *See id.* at 568.

128. *See id.* at 567.

129. *See* Dickson, *supra* note 99, at 18.

130. *See* Rupert Loader & Spencer Henson, *A View of GMOs From the U.K.*, 1 AGBIOFORUM 31, 32 fig.1 (1998)<http://www.agbioforum.missouri.edu> (citing a 1995 Food and Drink Federation study).

131. *See* Jonathan Riley, *Document Leak Hits Monsanto*, FARMERS WKLY. (Sutton, Surrey, U.K.), Nov. 27, 1998, at 8. A leaked document from biotechnology giant Monsanto indicated that despite spending over one million pounds on an advertising campaign promoting GMOs, the number of consumers who found genetically modified food unacceptable rose from thirty-five to fifty-one percent in a twelve-month period. *See id.*

thirty largest food manufacturers[132] and its four most prominent supermarket chains were GMO-free.[133]

Implementation of U.K. legislation for Directive 90/220 constitutes Part VI of the Environmental Protection Act of 1990.[134] The purpose of the Act is to prevent or minimize "any damage to the environment which may arise from the escape or release from human control of genetically modified organisms."[135] Prior to any GMO product's release into the environment or placement on the market, the individual or entity conducting the release must submit a risk assessment to the Secretary of State for the Environment[136] and obtain the Secretary's formal consent.[137]

In addition to following the E.U. consent procedures the Directive 90/220 requires,[138] the Secretary of State must consult with the Advisory Committee on Releases to the Environment (ACRE).[139] The Secretary may revoke consent or attach new limitations thereto at any time.[140] Implied in the Secretary's consent is the requirement that the consent holder: (1) take all reasonable steps to keep informed of any risks of damage,[141] (2) take necessary actions to prevent such damage,[142] and (3) use the "best available techniques not entailing excessive cost" to prevent any damage from occurring.[143]

Offenses under the Act include violating consent limitations, failing to perform proper risk assessment, interfering with an inspector, and filing false documents.[144] The Act imposes civil and criminal liability for offenses.[145] Although the specific maximums

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132. *See id.*

133. *See Genetic Engineering: Major Companies Reject GM-Food*, *supra* note 27.

134. Environmental Protection Act, 1990, ch. 43, pt. VI (Eng.) [hereinafter U.K. EPA].

135. *Id.* pt. VI, § 106.

136. *See id.* pt. VI, § 108(a).

137. *See id.* pt. VI, § 111(1)(b).

138. *See generally* Directive 90/220 arts. 10–18, *supra* note 9, at 18–20 (describing the procedure for obtaining the Commission's consent).

139. *See* U.K. EPA pt. VI, § 124(1)(a). For an organization flow chart of the U.K. GMO-release approval process, see U.K. DEPARTMENT OF TRADE AND INDUSTRY, BIOGUIDE 25 (1996), *available at* (visited Aug. 3, 2000) <www.dti.gov.uk/CB/bioguide/pdf/bioguide.pdf>.

140. *See* U.K. EPA pt. VI, § 111(10).

141. *See id.* pt. VI, § 112(5)(a).

142. *See id.* pt. VI, § 112(5)(b).

143. *Id.* pt. VI, § 112(5)(c).

144. *See generally id.* pt. VI, § 118(1)(a)–(o) (specifying offenses under the Act).

145. *See id.* pt. VI, § 118(3)–(6) (specifying civil and criminal penalties for violations of the Act).

vary for each offense, a magistrate's court generally imposes fines up to £20,000 and prison sentences up to six months.[146] Crown Court convictions carry unlimited fines and up to five years imprisonment.[147] The burden of proof in such proceedings generally shifts to the accused, who, for example, must "prove that there was no better available technique not entailing excessive cost than was in fact used to satisfy the condition or to comply with [the Act]."[148] As a defense for failing to keep informed of any changes in the risk assessment, the accused may "prove that he took all reasonable precautions and exercised all due diligence."[149]

On February 17, 1999, the U.K. Government levied its first fines for violating the Act's GMO provision. After Monsanto and its British subcontractor, Perryfields Holdings, plead guilty, the Government respectively imposed fines of £17,000 and £14,000.[150] An inspector found the companies violated the six-meter border requirement established as a condition of granting consent.[151] The actual border between the GMO crops and the neighboring crops was only "two meters wide—creating a real danger of cross-pollination with the surrounding area."[152] Consequently, the consent holders, Monsanto and Perryfields, were held liable.[153] The third-party grower, however, was not liable because responsibility for following the consent's restrictions is not delegable.[154] In addition to imposing sanctions, the Secretary also listed Monsanto and Perryfields in a public "register" of all those convicted for violating the Act.[155]

Fortunately, in the Monsanto case, the inspector corrected the situation before any harm occurred. If the commission of an offense causes damage, the state may take reasonable action to

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146. *See id.* pt. VI, § 118(3)(a).

147. *See id.* pt. VI, § 118(3)(b).

148. *Id.* pt. VI, § 119(b).

149. *Id.* pt. VI, § 118(2).

150. *See Monsanto, Subcontractor First Fined in U.K. for Breach of Environment Laws in GMO Test*, INT'L ENV'T DAILY (BNA), Mar. 10, 1999, *available in* LEXIS, News Library, Bnaied File.

151. *See id.*

152. *Id.*

153. *See id.* ("[A]s consent holders, "Monasto and Perryfields had a legal responsibility to ensure that a six-meter border was correctly implemented . . .").

154. *See id.*

155. *See* U.K. EPA pt. VI, § 122(1)(g).

remedy the harm caused;[156] costs are recoverable only from those persons convicted.[157] The current Environmental Protection Act contains no liability provisions for environmental or other damage unless there is an "offense," as defined in the statute.[158] On June 24, 1999, Member of Parliament Alan Simpson introduced the Genetically Modified Food and Producer Liability Bill (GMO Bill),[159] which provides that persons holding consent to release or market GMOs in the United Kingdom shall be strictly liable for damage the GMOs cause.[160] Where a corporation holds consent, "any director, manager, secretary or other similar officer . . . shall be similarly liable unless he can show that he did everything in his power to prevent the deliberate release or marketing."[161] The GMO Bill adopts a broad definition of "damage," which includes: personal injury, damage to property, financial loss, and the costs of preventing or rectifying environmental damage.[162] In the event of multiple defendants, a plaintiff need only prove that one or more of the defendants could have caused the damage.[163] Consent holders must secure an insurance policy to pay compensation damages.[164] In the event liability for damage is not attributable to an identifiable defendant, the Secretary of State must compensate the harmed person.[165]

The GMO Bill carefully excludes farmers and consumers from bearing the cost of liability. By assigning liability to consent holders under the Environmental Protection Act, the proposed Bill shifts the risks of planting GMOs "to those who are seeking to introduce alien technology to [the] countryside," not farmers.[166]

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156. *See id.* pt. VI, § 121(1)(a)–(b).

157. *See id.* pt. VI, § 121(1)(b).

158. *See* Friends of the Earth, *supra* note 16. *See also* U.K. EPA pt. VI, § 118 (defining "offenses"); *supra* text accompanying note 144 (discussing offenses under the Act). Neighbors and/or local government may be able to proceed under a theory of nuisance, trespass, or negligence to halt the environmental damage from spreading to adjacent property. *See, e.g.*, U.K. EPA pt. III, §§ 79–82 (statutory nuisance procedures). *Cf.* discussion of these doctrines applied in the United States, *infra* Parts IV.B.1, 3.

159. *See* Simpson Bill, *supra* note 83.

160. *See id.* § 2(1).

161. *See id.* § 2(2).

162. *See id.* § 3(1).

163. *See id.* § 4(2).

164. *See id.* § 6(1).

165. *See id.* § 7.

166. *Legislation Introduced in Britain to Hold Companies Liable for Damage Caused By Genetically Modified Foods, Crops*, FOOD CHEMICAL NEWS (Washington, D.C.), July

Although unlikely to pass the House of Commons, the Bill elevates the liability debate in the United Kingdom to a new level.[167]

2. Austria

Of all E.U. Member States, Austria consistently takes the strongest stance against GMOs. For example, although the use of Bt-maize is approved throughout the European Union, Austria's ban on the product remains intact.[168] In 1997, "more than [twenty] percent of Austrian voters signed a petition calling for a ban on genetically modified foods and plants."[169] On April 16, 1998, Austria approved what biotechnology firm Novartis executives refer to as "the strictest [GMO law] in the world, . . . leav[ing] the biotechnology industry in Austria with little air to breathe."[170]

Although the new Austrian law does not forbid the planting of GMO crops, several aspects of the law essentially accomplish that goal. Previously, only direct neighbors participated in the process of responding to requests to plant GMOs.[171] The revised law permits involvement of not only neighbors, but the also of the mayor of the village, mayors of neighboring villages, and the provincial government.[172] Furthermore, the new law drastically changes the membership of the scientific panel charged with making recommendations to the Minister for Consumer Protection regarding the approval of test-planting GMOs.[173] In the past, the Academy of Sciences selected members based on their genetic expertise.[174] The new law provides that four of the

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12, 1999, at NA, *available in* LEXIS, Education Law Library, Iacnws File (quoting Parliament Member Simpson during a House of Commons debate June 30, 1999).

167. *See id.*

168. *See EU in Disarray Over Policy, Control of Trade in Genetically Modified Organisms*, INT'L TRADE DAILY (BNA), Dec. 14, 1998, *available in* LEXIS, News Library, Bnaitd File.

169. Susan Ladika, *Austria Approves One of Toughest Laws in Europe on Genetically Modified Organisms*, 21 INT'L ENV'T REP. (BNA) 409, 409 (Apr. 29, 1998).

170. *Id.* at 410 (quoting Novaris Austria President Erwin Schillinger, referring to BGB1 Nr. 510/1994 (Aus.)).

171. *See id.* at 409.

172. *See id.*

173. *See id.*

174. *See id.*

members also must be "scientists with expertise in areas such as ecology and entomology."[175]

Liability for illegally releasing GMOs increased from 50,000 to 300,000 schillings.[176] In the event of an accident involving GMOs, the releasing company will be liable for any harm to health, property, or the environment, and must return the property to its "original" state.[177] When a GMO is involved in an "isolated instance," and the damage is "observable," it will be assumed that the GMO caused the damage.[178] The Austrian Parliament delayed the liability provisions' effective date to allow companies time to acquire liability insurance.[179] The amount of insurance required varies with the scale of each operation. Small-scale operations have no statutory minimum amount, but must carry insurance sufficient to meet their liabilities.[180] Large-scale or freestanding operations must carry liability insurance of 9,800,000 schillings.[181] Operations classified as both large-scale and freestanding operations must have insurance of 56,000,000 schillings.[182] In sum, the provisions of the Austrian GMO law create a climate hostile to GMO technology, yet still fall within the broad scope of Directive 90/220.

3. Germany

Germany's approach to GMO technology changes with the daily political climate. Germany initially backed Directive 90/220 to avoid politically damaging public debate between environmental supporters (the Greens) and the biotechnology industry, which saw itself falling behind competitors in other European countries and the United States.[183] The 1990 German Biotechnology Act (*Gesetz zur Regelung der Gentechnik*)[184]

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175. *Id.*

176. *See id.*

177. *See id.*

178. *See* § 79(e) BGB1 510/1994 (Aus.) (as amended April 16, 1999) (establishing strict liability for GMO related damage).

179. *See* Ladika, *supra* note 166, at 409.

180. *See* § 79(j) BGB1 510/1994.

181. *See id.*

182. *See id.*

183. *See* Balter, *supra* notes 98–108; *see also* Steven M. Pepa, *International Trade and Emerging Genetic Regulatory Regimes*, 29 LAW & POL'Y INT'L BUS. 415, 439 (1998) (stating that up until the early 1990s, the German public opposed the basic concepts of genetic research due to the negative memories of the Nazis).

184. *See* Monique P. Nion, *Biotechnology and Environmental Law in Europe*, 34

implemented Directive 90/220 (deliberate release of GMOs) and Directive 90/219 (contained use of GMOs).[185] The highly bureaucratic research regulations constrained domestic investment in biotechnology, resulting in German corporations transferring research activities to the relatively unregulated United States.[186] The German statute was amended in 1993, and again in 1994, to relax research protocols and encourage domestic investment.[187] In another change of attitude, in late 1998, the new coalition government, which includes the Greens, promised a more cautious approach, perhaps modeled on Austria's regulations.[188] The new government criticized its predecessors for monitoring GMO effects from a short-term perspective only and releasing too many GMOs into the environment without sufficient knowledge.[189]

The current German genetic technology law categorizes GMO products according to their potential risk to health and the environment.[190] Relatively relaxed approval standards and simplified procedures for authorization to release or market GMOs are available for "specific organisms if there is no risk for public health or the environment."[191] Furthermore, Germany, without further independent investigation, recognizes permits from other Member States with comparable regulations.[192] As in the other Member States, risk assessments and safety precautions must be undertaken prior to commencing any GMO operation.[193]

German law imposes liability for injury to property or human health "caused by characteristics of an organism created in a biotechnological process."[194] In contrast to Austria's liability scheme, liability under German law does not encompass

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JURIMETRICS J. 317, 325 & n.73 (1994) (citing German Biotechnology Act (GenTG) (F.R.G.)).

185. *See* Council Directive 90/219/EEC of 23 April 1990 on the Contained Use of Genetically Modified Micro-organisms, 1990 O.J. (L 117) 1 [hereinafter Directive 90/219].

186. *See* Pepa, *supra* note 183, at 439.

187. *See id.* at 439 n83.

188. *See Coalition Government to Take More Cautious Approach to Genetically Modified Foodstuffs*, 21 INT'L ENV'T REP. (BNA) 1176, 1176 (Nov. 25, 1998).

189. *See id.*

190. *See* Nion, *supra* note 184, at 325 & n.75 (citing § 7 GenTG (F.R.G.)).

191. *Id.* at 326 & n.83 (citing § 14, Abs. 4 GenTG (F.R.G.)).

192. *See id.* at 356 & n.84 (citing § 14, Abs. 5 GenTG (F.R.G.)).

193. *See id.* at *327* & 89 (citing § 16 GenTG (F.R.G.)).

194. *Id.* at 327 & n.91 (citing §§ 32 *et seq.* GenTG (F.R.G.)).

environmental damage GMOs cause.[195] Regulations place liability for such injuries at the "manager" level of the installation.[196] It is not clear, however, exactly how liability attaches to the GMO's developer or importer. If liability is restricted to the manager level, farmers, as installation managers, may be left with tremendous liability exposures, while the large biotechnology conglomerates remain insulated. In order to relax the burden of proof for plaintiffs, the law presumes that any damage a GMO causes is the result of biotechnology-induced characteristics, and not the organism's "natural" traits.[197] This strict liability scheme assists plaintiffs by recognizing that technology, when released into the environment, entails risk regardless of the amount of testing and precautions undertaken.[198] To protect against liability, operators creating these risks must secure insurance.[199] Plaintiff recovery, however, is limited to DM 160 million.[200]

German Civil law may also provide compensation for damage GMOs cause. The *Umwelthaftungsgesetz*, or Environmental Liability Act of 1990,[201] is "the most important civil law statute for damages caused by environmental pollution."[202] The Act provides liability for harms to the environment caused by certain installations designated in the Act.[203] GMO installations, are not specifically designated in the Act, and therefore fall outside of the Act=s protections.[204] The Act does not preempt imposing liability

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195. *Compare id.* (citing § 32 GenTG (F.R.G.) (imposing liability for "death, personal injury , and damage to property caused by characteristics of an organism created by the biotechnological process)) *with* Ladika, *supra* note 169, at 409 (discussing BGB1 Nr. 510/1994 (Aus.) (imposing liability for damage to "health, property, or the environment")).

196. *See* Nion, *supra* note 184, at 327.

197. *See id.* at 327 & n.92 (citing § 34 GenTG (F.R.G.)).

198. *See* Stephen Kelly Lewis, Comment, *"Attack of the Killer Tomatoes?" Corporate Liability for the International Propagation of Genetically Altered Agricultural Products*, 10 TRANSNAT'L LAW. 153, 192–193 (1997).

199. *See id.* at 193 & n.399 (citing § 36 GenTG (F.R.G.)).

200. *See* Nion, *supra* note 184, at 327 & n.93 (citing § 33 GenTG (F.R.G.)).

201. Gesetz über die Umwelthaftung (Umwelthaftungsgesetz UmweltHG), v. 10.12.1990 (BGB1. I S. 2634) (F.R.G.) [hereinafter UmweltHG], *translated in* GERMAN ENVIRONMENTAL LAW FOR PRACTITIONERS 603 (Horst Schlemminger et al. eds., 1996).

202. ELGA BARTSCH, LIABILITY FOR ENVIRONMENTAL DAMAGES: INCENTIVES FOR PRECAUTION AND RISK ALLOCATION 26 (1998).

203. *See* UmweltHG § 1 (F.R.G.), *translated in* GERMAN ENVIRONMENTAL LAW FOR PRACTITIONERS, *supra* note 201, at 603.

204. *See* UmweltHG app. I (F.R.G.), *translated in* GERMAN ENVIRONMENTAL LAW

for environmental or other damage under other provisions of the German Civil Code.[205]

The general tort and nuisance provisions in the *Bürgerliches Gesetzbuch* (BGB), or German Civil Code, apply to environmental pollution. BGB section 823 imposes tort liability on any person who intentionally or negligently causes harm to "the life, body, health, freedom, property, or other right of another . . . ."[206] Compensation may not be available under Section 823 for purely economic damage GMOs cause, such as cross-pollination of an organic crop. Environmental harm to protected rights raises "difficulties of proof associated with demonstrating causality and fault."[207] The German Supreme Court recently shifted the burden of proof in cases involving tort claims for environmental damage from the plaintiff to the defendant.[208] The defendant now must prove that he or she was not negligent and that he or she took all appropriate precautionary measures.[209] The burden of proof for causation, however, remains on the plaintiff.[210]

The United Kingdom, Austria, and Germany each regulated biotechnology prior to passage of Directive 90/220.[211] Although the Directive attempted to harmonize the various Member States' biotechnology laws, subtle differences, especially with respect to liability, persevere. Variances in imposing liability will continue until the European Union specifically addresses liability via a revised Directive 90/220 or other legislation.

FOR PRACTITIONERS, *supra* note 201, at 618–637 (listing the installations subject to the Act).

205. *See* UmweltHG § 18(1) (F.R.G.), *translated in* GERMAN ENVIRONMENTAL LAW FOR PRACTITIONERS, *supra* note 201, at 613 ("Liability existing on the basis of other provisions shall not be affected by this Act.").

206. § 823 Bürgerliches Gesetzbuch (BGB) (F.R.G.). *See also* BARTSCH, *supra* note 202, at 27–28.

207. GERMAN ENVIRONMENTAL LAW FOR PRACTITIONERS, *supra* note 201, at 176. For a discussion of the problems associated with determining causality and fault, *cf. infra* Part IV.B.1 (describing the problems in the context of U.S. common law liability).

208. *See* BARTSCH, *supra* note 202, at 28.

209. *See id.*

210. *See id.*

211. *See supra* Parts III.B.1–3 (discussing regulation of biotechnology in the United Kingdom, Austria, and Germany prior to Directive 90/220).

IV. GMO REGULATIONS AND LIABILITY IN THE UNITED STATES

A. The U.S. Federal Regulatory Scheme

As genetic engineering expanded in the 1970s, the National Institutes of Health (NIH) assumed supervisory responsibility and developed research guidelines.[212] The NIH originally prohibited all GMO releases, but by 1978, the Director of the NIH began approving GMO field tests.[213] As application of biotechnology expanded outside the laboratory, "federal agencies assumed jurisdiction over the products of genetic engineering that fell within their traditional fields of regulation."[214] In 1985, the Biotechnology Science Coordinating Committee (BSCC) was established "to coordinate the policies of the various agencies having authority to regulate biotechnology products."[215] The following year, the Office of Science and Technology Policy issued the *Coordinated Framework for the Regulation of Biotechnology*.[216] The Reagan administration, following its general policy of providing regulatory relief, concluded that a new law was not necessary to regulate biotechnology and the diversity of biotechnology products justified dividing supervision among multiple government agencies.[217]

The legacy of the Office of Science and Technology Policy's decision to divide GMO supervision responsibility among several government agencies continues. The United States Department of Agriculture (USDA) ensures that GMOs are "safe to grow," the FDA ensures that they are "safe to eat,"[218] and the EPA

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212. *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, 1178 (1992–1993); David J. Earp, *The Regulation of Genetically Engineered Plants: Is Peter Rabbit Safe in Mr. McGregor's Transgenic Vegetable Patch?*, 24 ENVTL. L. 1633, 1640 (1994).

213. *See* Kim, *supra* note 212, at 1178–1179.

214. Earp, *supra* note 212, at 1640.

215. *Id.*

216. *See* Coordinated Framework for the Regulation of Biotechnology, 51 Fed. Reg. 23, 302 (1986).

217. *See* Kim, *supra* note 212, at 1179–1180 (describing the Coordinated Framework Policy's conclusions); Earp, *supra* note 212, at 1641 (describing the same).

218. USDA, Animal & Plant Health Inspection Service, *United States Regulatory Oversight in Biotechnology* (visited Aug. 5, 1999) <http://www.aphis.usda.gov/biotech/OECD/usregs.htm#usdalaw>.

oversees the use of new companion herbicides for GMOs and ensures that the GMOs are "safe for the environment."[219]

The EPA derives its authority to regulate GMOs from the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),[220] the Toxic Substances Control Act (TSCA),[221] and the Federal Food, Drug, and Cosmetic Act (FFDCA).[222] The TSCA's notification requirements apply to nonagricultural uses of biotechnology.[223] The FFDCA regulates pesticide residues in or on food,[224] which may include plants with pesticide properties, such as Bt corn. The FIFRA directly applies to any plants with pesticide properties, or microorganisms intended for use as pesticides.[225] These pesticides must be registered with the EPA,[226] and a permit must be acquired prior to field-testing.[227] In issuing the permit, the EPA must "balance the potential human and environmental risks against the potential benefits to society."[228]

The FDA regulates genetically modified food products under the FFDCA for food safety, but its authority is generally limited to the marketing aspects of GMO products.[229] Currently, there is no U.S. GMO labeling law, but some health-food companies voluntarily label their products "non-GMO."[230] In October 1999, the FDA announced it would conduct hearings to gage public opinion on the issue of labeling all products containing GMOs.[231]

The USDA, under the Federal Plant Pest Act (FPPA)[232] and the Plant Quarantine Act,[233] regulates the release of GMOs in

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219. *Id.*
220. 7 U.S.C. §§ 136–136y (1994).
221. 15 U.S.C. §§ 2601–2629 (1994).
222. 21 U.S.C. §§ 301–392 (1994).
223. *See* Allen, *supra* note 40, at 543.
224. *See* 21 U.S.C. § 231(q)(2).
225. *See* 7 U.S.C. § 136(a).
226. *See id.*
227. *See* Kim, *supra* note 212, at 1180–1181 (citing 40 C.F.R. § 158.170 (1991)).
228. Mary Jane Angelo, *Genetically Engineered Plant Pesticides: Recent Developments in the EPA's Regulation of Biotechnology*, 7 FLA. J.L. & PUB. POL'Y 257, 264 (1996). The required balancing the potential risks against the possible benefits is the basis for the recent Environmental Defense Fund petition to the EPA to reassess the risks associated with Bt corn after publication of the Cornell Monarch butterflies study. *See* Werner, *supra* note 3, at 714.
229. *See* Kim, *supra* note 212, at 1182.
230. *See* Strecklow, *supra* note 27, at A1.
231. *See id.*
232. 7 U.S.C. §§ 150aa–150jj (1994).

agricultural research. The 1987 regulations required a permit prior to the import, or release into the environment, of any genetically modified plant or organism engineered from components of plant pests, including those with pesticide effects.[234] In 1993, the USDA downgraded its regulation to require only "notification" prior to introduction of plants with which the agency had sufficient experience.[235] In addition, the revised 1993 regulations provided that the Administrator of the Animal and Plant Health Inspection Service (APHIS) division of the USDA declare certain GMOs no longer a risk, and thus not subject to regulation.[236] On June 6, 1997, APHIS granted Monsanto's genetically engineered corn line "nonregulated" status.[237] New USDA regulations now also provide for "expedited review" of plants closely related to plants already granted nonregulated status.[238]

B. Liability

Although it is often considered a world leader in biotechnology, the United States has not yet adopted a comprehensive regulatory scheme expressly addressing biotechnology's unique needs. Congress failed to provide for liability in the event of damage resulting from GMO use by allowing agencies to only modify existing regulations to cover biotechnology in a piecemeal fashion.[239] Neither the regulatory

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233. 7 U.S.C. §§ 151–164a, 166–167 (1994).

234. *See* Angelo, *supra* note 228, at 271 & n.71 (citing 52 Fed. Reg. 22,892 (1987) (codified at 7 C.F.R. pts. 330, 340 (proposed June 16, 1987)).

235. *See id.* at 271 & n.77 (citing 58 Fed. Reg. 17,044 (1993) (codified at 7 C.F.R. pt. 340 (proposed Mar. 31, 1993)); Earp, *supra* note 212, at 1662–1663 (describing the 1993 revisions' substantial deregulation of the release of transgenic plants).

236. *See* Angelo, *supra* note 228, at 272.

237. *See Monsanto Corn Line No Longer Regulated Under U.S. Agriculture Department's Laws*, 20 INT'L ENV'T REP. (BNA) 613, 613 (June 25, 1997).

238. *See* 62 Fed. Reg. 19903 (1997).

239. *See* Lewis, *supra* note 198, at 178. When Congress chooses to regulate activities with environmental implications, Congress generally includes specific liability provisions therein. *See, e.g.*, Resource Conservation and Recovery Act (RCRA) § 3013(e), 42 U.S.C. § 6934(a) (1995) (imposing civil penalties up to $5,000 per day for noncompliance); Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) § 107(a), 42 U.S.C. § 9607(a) (1995) (imposing joint and several liability for all cleanup costs); Clean Air Act (CAA) § 113(b), 42 U.S.C. § 7413(b) (1995) (authorizing injunctions and civil penalties up to $25,000 per day for each violation); Clean Water Act (CWA) § 309(d), 33 U.S.C. § 1319(d) (1995) (imposing civil penalties up to $25,000 per day for each violation).

agencies nor citizens may use the various federal laws regulating biotechnology to recover for GMO-caused damage. A few states have enacted statutes, however, to monitor biotechnology activity within their respective jurisdictions.[240] Unfortunately, these state statutes are generally limited to notification and permit requirements and lack liability provisions. As a result, victims must rely on one of three possible common law doctrines for a remedy—negligence, strict liability, or nuisance.

An example of possible damage resulting from the use of a GMO is cross-pollination of an organic crop with genetically modified pollen from an adjacent field. Although many biotechnology experts doubt the likelihood of this scenario occurring, as discussed earlier, for organic tortilla chip processor Terra Prima, this possibility is all too real. Although the Terra Prima contamination could, theoretically, have occurred at several stages of the supply chain, Terra Prima executives determined that the probable cause was pollen from genetically modified corn in "nearby fields."[241]

Recent studies in the United Kingdom conducted by a bee specialist working with the National Pollen Research Unit found airborne genetically modified pollen 475 meters from a genetically modified field, and genetically modified pollen in bee hives up to four and a half kilometers from a genetically modified field.[242] Accordingly, a brief analysis of possible claims under a common law liability scheme from a cross-pollination scenario follows.

1. Negligence

According to the *Restatement (Second) of Torts*, negligence is either:

> (a) an act which the actor as a reasonable man should recognize as involving an unreasonable risk of causing an invasion of an interest of another, or (b) a failure to do an act which is necessary for the protection or assistance of another and which the actor is under a duty to do.[243]

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240. *See, e.g.*, Release of Genetically Engineered Organisms Act, 430 ILL. COMP. STAT. 95/0.01 (West 1999); Genetically Engineered Organisms, MINN. STAT. ANN. § 18F (West 1998); Genetically Modified Organisms, HAW. REV. STAT. § 321-11.6 (1999).

241. Hogue, *supra* note 13, at 196 (quoting Charles Walker, president of Terra Prima).

242. *See* Friends of the Earth, *supra* note 16.

243. RESTATEMENT (SECOND) OF TORTS § 284 (1965).

There are five traditional elements a plaintiff must prove to establish a negligence cause of action: duty, breach, factual causation, proximate causation, and actual injury.[244]

a. Duty

Two possible theories of "duty" apply when damage results from the use of a GMO that pollinates a neighboring farmer's organic crops.[245] A duty may arise from the improper performance of an otherwise lawful act: "anyone who does an affirmative act is under a duty to others to exercise the care of a reasonable man to protect them against an unreasonable risk of harm arising out of the act."[246] An individual, with proper governmental authorization, may plant GMOs. Improper performance of or compliance with this authorization may give rise to a duty even in the absence of statutory liability. This duty arises if the defendant's conduct created a risk of damage and the plaintiff was foreseeable. The existence of federal regulations governing GMO experimentation, as well as scientific reports of cross-pollination, may satisfy the showing of a risk of damage.[247] Furthermore, it is foreseeable that a neighboring field would be affected given the possibility of cross-pollination.

In *Rowland v. Christian*,[248] the California Supreme Court balanced several factors and thereafter recognized that, in the absence of a statutory exemption, the general "duty to exercise reasonable care under the circumstances" should not be departed from "unless clearly supported by public policy."[249] The factors the Court balanced in considering such a departure include:

> the foreseeability of harm to the plaintiff, the degree of certainty that the plaintiff suffered injury, the closeness of the connection between the defendant's conduct and the injury suffered, the moral blame attached to the defendant's conduct, the policy of preventing future harm, the extent of the burden to the defendant and consequences to the community of imposing a duty to exercise care with resulting liability for

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244. *See* W. PAGE KEETON, PROSSER AND KEETON ON TORTS 164–165 (5th ed. 1984).

245. *See supra* note 242–243 and accompanying text describing one possible example of cross-pollination of organic crops. *See* Friends of the Earth, *supra* note 16.

246. RESTATEMENT (SECOND) OF TORTS § 302 cmt. a, *supra* note 243.

247. *See* Lewis, *supra* note 198, at 181.

248. 443 P.2d 561 (Cal. 1968).

249. *Id.* at 564.

> breach, and the availability, cost, and prevalence of insurance for the risk involved.[250]

Although *Rowland* involved the plaintiff's injury sustained while on the defendant's property, other courts have used the *Rowland* factors to establish various duties as a matter of public policy.[251] Accordingly, evaluation of the *Rowland* factors could impose a duty of care upon defendants in the GMO context.

In a case involving cross-pollination of an organic farm with genetically modified pollen from an adjacent field, the harm may be foreseeable for the above-described reasons. The second *Rowland* factor, the certainty of the harm, depends on the likelihood of cross-pollination of the crops and the detection of the "contaminated" organic crops. Once detected, the degree of certainty of injury is absolute because the farmer's crops immediately lose organic status. The degree of closeness of the connection between the defendant's conduct and the injury, the third *Rowland* factor, is essentially the test for proximate cause, as discussed below.[252] A court may find it difficult to blame a defendant for exercising poor judgment if the defendant followed all applicable regulations. Establishing a duty may prevent future harm, because GMO users may take extra precautions. Such precautions could include planting wider buffer zones between genetically modified and non-genetically modified crops, careful cleaning of equipment processing both genetically modified and non-genetically modified foods, and appropriate time lapses before organic crops are grown in fields wherein genetically modified crops previously grew.[253] Only the GMO producers have full knowledge of the possible risks—thus they are best able to structure insurance to guard thereagainst. The biotechnology

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250. *Id.*

251. *See, e.g.*, Slade v. Smith's Mgmt. Corp., 808 P.2d 401, 411 (Idaho 1991) (using the *Rowland* factors to impose a duty on a party host ("[It is] evident that the service of alcoholic beverages to an obviously intoxicated person by one who knows that such intoxicated person intends to drive a motor vehicle creates a *reasonably foreseeable* risk of injury to those on the highway")); Griffith v. Southland Corp., 617 A.2d 598, 604 (Md. 1992) (applying the *Rowland* factors to impose a duty on an employee to allow an individual to use a phone to summon police, which probably would have resulted in a shortened response time and may have prevented a fatal shooting).

252. *See* discussion *infra* Part IV.B.1.d.

253. *See* John Innes Centre, *supra* note 12 (presenting an executive summary of the Centre's report commissioned by the U.K. Ministry of Agriculture Forests and Fisheries).

industry can offset the costs of insurance by passing the costs on to consumers.[254]

An industry entering into biotechnology research for profit should have a minimum duty to protect society from possible damages, even in the face of congressional inaction. Courts may have difficulty, however, extending this duty beyond farmers who plant genetically modified crops in fields adjacent to organic crops. Farmers planting genetically modified crops could face severe pressure from two fronts—the large seed companies selling genetically modified seeds and neighboring farms using organic methods. Unless courts impose a duty on genetically modified seed developers, little incentive exists to re-engineer seeds to eliminate the chances of cross-pollination or conduct field tests to determine effective methods for pollen containment.

An analysis of where the costs and benefits of a potentially negligent action lie may ultimately determine whether a court would impose a duty on farmers who plant genetically modified crops. The Kansas Court of Appeals, in *Krug v. Koriel*,[255] failed to find a common law duty to control volunteer wheat as a means of preventing the spread of the wheat streak mosaic virus.[256] In *Krug*, volunteer wheat from the defendant's field contained the virus, which spread to the plaintiff's wheat field and damaged his crop.[257] Normally, defendants have incentive to take precautionary measures, as they would not otherwise receive economic benefits (e.g., increased yields). The economic benefit, if a court were to establish a duty, would instead fall on the plaintiff. The *Krug* court, however, correctly refused to establish a common law duty to prevent the spread of a virus.[258] In the GMO context, the GMO user/defendant receives the economic benefit from the activity causing the harm. If a duty were established, the non-GMO farmer would receive a portion of the economic benefit the GMO user received from planting genetically modified crops. In *Krug*, the plaintiff would have received an economic benefit from the defendant who, in turn, received nothing. A finding of a duty to control genetically modified pollen would re-establish the pre-GMO allocation of costs and benefits among adjacent farmers.

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254. *See* Lewis, *supra* note 198, at 182.
255. 935 P.2d 1063 (Kan. Ct. App. 1997).
256. *See id.* at 1063.
257. *See id.* at 1064–1065.
258. *See id.* at 1063.

b. Breach

Judge Learned Hand's famous opinion in *United States v. Carroll Towing Co.*[259] balanced the burdens involved in avoiding risk against the magnitude and propensity of risk to determine a breach of duty.[260] In a GMO scenario, the magnitude of risk involved varies from a single cross-pollination to destruction of an entire crop. According to some commentators, the gravity of harm includes the loss of biodiversity and possibly the world food supply.[261] The product's utility, however, may outweigh these concerns because GMOs may reduce pesticide and herbicide use,[262] and by increasing yields, are touted as a potential factor in the cure for world hunger.[263] On balance, to find breach of duty, a court must rely heavily on the possible, yet highly unlikely, possibility that biotechnology will cause grave damage.

c. Factual Causation

Factual causation, or cause-in-fact, is determined by the traditional "but for" test.[264] "But for" the GMO, would there be a destructive cross-pollination? Plaintiffs can prove "but for" causation through analysis of the genetic composition of crops in surrounding fields. There might be difficulty, however, if there are multiple possible pollination sources. For example, if the owners of four surrounding fields each plant the same GMO, and the plaintiff's field contains traces of the GMO, proving which of the surrounding fields' crops actually "caused" the pollination creates complexity.[265] Although in this example, the neighboring farmers might escape liability, the GMOs' developer, as the

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259. 159 F.2d 169 (2d Cir. 1947).

260. *See id.* at 173.

261. *See* Lewis, *supra* note 198, at 182–183.

262. *See Environmental Benefits of YieldGard® Corn*, *supra* note 7; *see also USDA Report Cites Pesticide Reductions and Yield Increases Associated with Biotech Crops*, (visited Oct. 10, 1999) <http://www.monsanto.com/ag/articles/99-07-07ERSStudy.htm> [hereinafter *USDA Report*].

263. *See USDA Report*, *supra* note 262 (stating that biotechnology could contribute to food security in developing countries); *see also* Ismail Serageldin, Viewpoint, *Biotechnology and Food Security in the 21st Century*, 285 SCIENCE 387, 387 (1999) (noting that biotechnology "can contribute to future food security if it benefits sustainable small-farm agriculture in developing countries.").

264. *See* KEETON, *supra* note 244, at 265.

265. An alternative theory, such as market share liability, may apply in such circumstances. *See generally* McCormack v. Abbott Labs., 617 F. Supp. 1521, 1524–1526 (D. Mass 1985) (discussing the history of market share liability).

producer of seeds for all four surrounding fields, ultimately caused the damage. Some proposals for GMO regulations, especially in Europe, call for genetic markers to be placed in all GMO products.[266] This would assist in establishing causation by easing the burden of identifying the GMO's developer and tracing the sale of the GMO seed to a neighboring field.

d. Proximate Cause

Proximate cause turns on the foreseeability of the injury.[267] If the defendant knew or should know, that his or her use of GMOs could result in harm to another, then the injury resulting is foreseeable. In a cross-pollination case, the injury is probably foreseeable because studies found pollen carried, whether by wind or by bees, beyond established buffer zones.[268] Unless the cross-pollination occurred at a very great distance, such injury would be foreseeable.

e. Actual Injury

Proving the actual injury may be the easiest element for the GMO plaintiff to establish. Mere evidence of damaged crops, or traditionally developed crops containing genetically modified DNA, would prove injury. In the Terra Prima tortilla chip case,[269] the injury was the company's lost profits. Although the injury may be relatively obvious, proving the other four elements may be difficult, because there is no judicial precedent for recovery based on a negligence theory in a GMO case.

An injured party faces an arduous, but not impossible, task in recovering damages based on a negligence theory. Hypothetically, a plaintiff's most significant obstacle is convincing a court to impose a duty on farmers planting genetically modified seeds approved by the USDA and/or EPA for general use. Redistributing the economic benefit of planting genetically modified seeds to those the planting harms provides the strongest justification for establishing a duty of care.

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266. *See* Parliament Resolution art. 4(1b), *supra* note 35.

267. *See* KEETON, *supra* note 244, at 273.

268. *See, e.g.*, *supra* text accompanying notes 16–17 (discussing a recent study conducted in the United Kingdom).

269. *See* Friends of the Earth, *supra* note 16; *see also supra* Part IV.B.

2. Strict Liability

Strict liability applies when injury occurs as a result of activities a statute or a court defines as "abnormally dangerous."[270] Under a negligence theory, a plaintiff must prove that the defendant caused the harm and that the defendant's actions were unreasonable. Strict liability, on the other hand, removes the issue of unreasonableness, and imposes liability without fault.[271] The *Restatement (Second) of Torts* provides six factors courts consider in determining if an activity is abnormally dangerous:

> (a) existence of a high degree of risk of some harm to the person, land or chattels of others; (b) likelihood that the harm that results from it will be great; (c) inability to eliminate the risk by the exercise of reasonable care; (d) extent to which the activity is not a matter of common usage; (e) inappropriateness of the activity to the place where it is carried on; and (f) extent to which its value to the community is outweighed by its dangerous attributes.[272]

Although courts consider all six factors, "it is not necessary that each of them be present, especially if others weigh heavily."[273] Evaluation of factors (a), (b), (c) and (f) parallels the analysis for negligence recovery. Therefore, only factors (d) and (e) are discussed below.

The extent to which an activity is a "matter of common usage" may vary with time and location. Five years ago, the idea of using GMOs in commercial agriculture was a relatively novel concept. By 1999, however, half of the United States' seventy-two million acres of soybeans were planted with genetically modified seeds.[274] At the same time, estimates for genetically modified corn ranged from twenty to forty-five percent of the nation's corn plantings.[275] By the year 2000, some estimate that 60 million

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270. KEETON, *supra* note 244, at 545.

271. *See* JAMES A. HENDERSON, JR. ET AL., THE TORTS PROCESS 554 (4th ed. 1994) (describing the difference between recovery under negligence and strict liability).

272. RESTATEMENT (SECOND) OF TORTS § 520(a)–(f), *supra* note 243.

273. *Id.* § 520 cmt. f. "The essential question is whether the risk created is so unusual, either because of its magnitude or because of the circumstances surrounding it, as to justify the imposition of strict liability for the harm that results from it, even though it is carried on with all reasonable care." *Id.*

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

275. *See* David Barboza, *Biotech Companies Take on Critics of Gene-Altered Food*,

hectares worldwide will be cultivated with GMOs.[276] Therefore, in the context of total world agricultural production, although GMOs may not be "common," their acceptance is quickly growing. More importantly, a plaintiff may establish that the use of GMOs is inappropriate or uncommon in a particular location. For example, example, the use of Roundup Ready soybeans in Illinois or Iowa may be common and appropriate for general use on typical farmlands. In contrast, the use of genetically modified crops in portions of California or Oregon that are dominated by organic farms may be inappropriate. Although this may interfere with the landowners' traditional right to use their land as they please, courts have upheld such distinctions in other circumstances.

In *Rylands v. Fletcher*,[277] the court held that altering the natural flow of water to create a reservoir was a strict liability offense if damage occurred to an adjacent landowner's property.[278] In a case with almost identical facts, the Texas Supreme Court rejected *Rylands*, reasoning that creating a reservoir in an area in which water is scarce is common, and is therefore not subject to strict liability.[279] Therefore, using GMOs may only be appropriate after close consideration of the surrounding land use.

The *Rylands* case, however, may stand for a broader principle justifying strict liability not easily distinguished by mere examination of the surrounding land use. The defendant in *Rylands* essentially introduced an alien substance (water) onto his land. Upon the alien substance's escape, the person responsible for its introduction is responsible for the damage caused. The planter of genetically modified seeds unquestionably introduces an alien substance onto his or her land. The substance's escape, in the form of pollen, may cause damage to surrounding lands. Following the reasoning in *Rylands*, U.S. courts could justify imposing strict liability for the substance's release.

Under a strict liability theory, a plaintiff's burden of proof is substantially easier than under a negligence theory. Determining what constitutes abnormally dangerous activities, however,

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N.Y. TIMES, Nov. 12, 1999, at A1.

276. *See Rapid Growth in GMO Plantings*, *supra* note 41, at M/5.

277. [1861–1873] All E.R. Rep. 1 (1866) (Ex. Ch.).

278. *See id.* at 6–7 (Blackburn, J.).

279. *See* Turner v. Big Lake Oil Co., 96 S.W.2d 221, 222–223 (Tex. 1936).

involves a balancing test, which often favors public policy. Similar to negligence, strict liability provides no direct precedent upon which courts can rely for a GMO analysis.[280] Courts could, however, analogize the cross-pollination of genetically modified crops via to wind drift to earlier cases involving crop dusting.

In *Gotreaux v. Gary*,[281] the Louisiana Supreme Court held a landowner strictly liable for damage to a neighboring cotton crop located three and one-quarter miles away.[282] The defendant sprayed his rice field with herbicides.[283] Eight to ten days later, the plaintiff's cotton crop showed chemical damage indicative of the type of chemical the defendant used.[284] In finding that using herbicides is an inherently dangerous activity subject to strict liability, the Court balanced the value of the crop dusting to the farmer against the possible externalities.[285] The benefits accrued to the farmer dusting his crop through increased yields. The increased yields resulting from crop dusting, however, were not sufficient to justify the damage to the adjacent farmer's crops.[286] Likewise, the yield increases genetically modified crops provide may not be sufficient to justify damage to adjacent farmers' crops. A potential defendant, however, could argue a plaintiff's abnormally sensitive activity, especially in the organic farming context, as a defense. The *Restatement (Second) of Torts* contemplates relaxing strict liability standards "if the harm would

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280. Although it should be noted that courts have found strict liability for the transportation or storage of hazardous materials and explosives. *See* James F. Roberts, Note, *Common Carriers and Risk Distribution: Absolute Liability for Transportation of Hazardous Materials*, 67 KY. L.J. 441 (1978–1979) (hazardous materials); *see also* Chavez v. Southern Pac. Transp. Co., 413 F. Supp. 1203 (E.D. Cal. 1976) (explosives).

281. 94 So. 2d 293 (La. 1957).

282. *See id.* at 294–295. *See also* Kennedy v. Clayton, 227 S.W.2d 934, 936, 940 (Ark. 1950) (holding defendant liable for damage to neighboring cotton crop caused by spraying rice field even though the defendant thought the drift was less than 75 feet unless windy, he sprayed on a calm day, and argued he was not sufficiently put on notice); *see also* Binder v. Perkins, 516 P.2d 1012, 1015–1016 (Kan. 1973) (holding defendant wheat field sprayer liable for damage to neighboring alfalfa crop because the defendant knew or should have known fumes could escape for two days following application, knew of the alfalfa field's existence, and knew of the possibility of a wind shift).

283. *See Gotreaux*, 94 So. 2d at 293.

284. *See id.* at 294.

285. *See id.* at 294–295 (discussing the applicability of strict liability).

286. *See id.* at 295–296 ("Although the use of the spraying operation was lawful, it was carried out in such a manner as to unreasonably inconvenience plaintiff and deprive him of the liberty of enjoying his farm.").

not have resulted but for the abnormally sensitive character of the plaintiff's activity."[287]

The concept of nonreciprocal risk may also justify imposing strict liability in the GMO context.[288] Nonreciprocal risk is a risk a defendant creates "that exceeds those to which he is reciprocally subject."[289] When a defendant plants genetically modified crops, he subjects his neighbors to risks to which he is not subjected. Genetically modified crops may contain traces of non-genetically modified pollen, while organic or traditionally grown crops may not. In order to correct the imbalance of risks genetically modified pollen creates, courts could apply a strict liability theory to damaged crops.

3. Public and Private Nuisance

Under negligence and strict liability theories, claims are limited to those plaintiffs who are damaged by the GMO activities. Public nuisance theories allow the government, and possibly private individuals, to enjoin activities[290] and recover damages[291] for "unreasonable interference with a right common to the general public."[292] Private nuisance rights provide private parties with the power to enforce injunctions and receive damages for unreasonable interference with their use and enjoyment of their property.[293]

a. Public Nuisance

The public nuisance doctrine provides local governments with the power to protect their jurisdictions' environments, as long as federal and state regulations do not preempt such action.[294] In the

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287. RESTATEMENT (SECOND) OF TORTS § 524A, *supra* note 243.

288. *See* George P. Fletcher, *Fairness and Utility in Tort Theory*, 85 HARV. L. REV. 537, 547–548 (1972) (qualifying the concept of nonreciprocal risk as especially relevant in justifying strict liability).

289. *See id.*

290. *See* RESTATEMENT (SECOND) OF TORTS § 821C(2), *supra* note 243.

291. *See id.* § 821C(1).

292. *Id.* § 821B.

293. *See id.* § 821D.

294. *See generally* ROBERT V. PERCIVAL ET AL., ENVIRONMENTAL REGULATION: LAW, SCIENCE AND POLICY 87–102 (2d ed. 1996) (describing the evolution of public nuisance theory in protecting the environment). In *Georgia v. Tennessee Copper Co.*, 206 U.S. 230, 239 (1907), the U.S. Supreme Court enjoined the operation of a copper smelter in Tennessee that destroyed forests, orchards, and crops in Georgia.

GMO context, this includes the cross-pollination of local resources with GMOs from neighboring fields. The *Restatement (Second) of Torts* limits the public nuisance doctrine's application to those interferences that are "unreasonable."[295] Courts should consider whether the conduct (a) significantly inters with public health, safety, peace, or comfort; (b) is illegal; or (c) "whether the conduct is of a continuing nature or has produced a permanent or long-lasting effect, and, as the actor knows or has reason to know, has a significant effect upon the public right."[296] Private individuals may maintain a public nuisance action only if they "have suffered harm of a kind different from that suffered by other members of the public . . . ."[297] In a simple cross-pollination scenario, the general public does not suffer interference with health, safety, peace, or comfort—only the farmer with the contaminated crops suffers injury. Therefore, the doctrine of public nuisance may not provide adequate relief to those individuals whose crops genetically modified pollen affects.

b. Private Nuisance

A defendant's actions interfering with a plaintiff's private use and enjoyment of his or her own land may be considered a private nuisance.[298] Genetically modified pollen drifting onto an organic or traditionally planted field may be an unreasonable interference in a plaintiff landowner's use and enjoyment of his or her land. In *Regina v. Secretary of the State for the Environment, Transport and the Regions, Ex parte Watson*,[299] Lord Justice Buxton described an organic farmer's request to enjoin the government from approving a trial planting of genetically modified corn in an adjacent field as "one of private nuisance."[300]

Although actions giving rise to nuisance culpability vary, a number of courts impose liability in the absence of intent. In *Jost v. Dairyland Power Cooperative*,[301] the Wisconsin Supreme Court held a coal-burning electric-generating plant liable for creating a

295. RESTATEMENT (SECOND) OF TORTS § 821B(2), *supra* note 243.
296. *Id.* § 821B(2)(a)–(c).
297. *Id.* § 821C(1).
298. *See id.* § 821D.
299. [1999] Env. L. Rep. 310 (Eng. C.A. July 21, 1998), *available in* 1998 WL 1042193.
300. *Id.* judgment 3 (Buxton, L.J.).
301. 172 N.W.2d 647 (Wis. 1969).

nuisance that injured nearby crops.[302] The Court found it irrelevant that the defendant exercised due care in operating the plant.[303] The Court refused to balance the power plant's social and economic utility against the damage to the nearby farmers' fields.[304] Other courts have held that a "knowing" infliction of injury constitutes intent for nuisance liability purposes.[305] In fact, Missouri courts have completely abandoned investigation into defendants' negligence or intent in nuisance suits.[306] "Nuisance is a condition, not an act or failure to act, and it is therefore immaterial in determining liability to inquire whether the defendant was negligent and what his intention, design or motive may have been."[307]

An action for nuisance, therefore, may provide plaintiffs whose crops are damaged by genetically modified pollen the best chance for recovery. A plaintiff may not need to demonstrate that the defendant intended to allow pollen from genetically modified crops to cross-pollinate. More importantly, courts may refuse to balance the genetically modified crop's social and economic utility against its harm to the organic farmer's crops. The difficulty in securing prospective injunctions under a nuisance theory, however, fails to prevent the harm, and thereby provides only post hoc compensation.

The United States' piecemeal approach to biotechnology regulation creates a system with overlapping agency jurisdictions and a recovery scheme in which it is difficult for plaintiffs litigating the common law doctrines to prevail. As a historical note, Congress indirectly regulated water pollution through the Rivers and Harbors Act of 1899.[308] It was not until water quality in the United States became a crisis in the early 1970s that Congress

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302. *See id.* at 653–654.

303. *See id.* at 651–652.

304. *See id.* at 653 ("It will not be said that, because a great and socially useful enterprise will be liable in damages, an injury small by comparison should go unredressed.").

305. *See* HENDERSON, *supra* note 253, at 519 (citing Bradley v. American Smelting & Refining Co., 709 P.2d 782, 785 (Wash. 1985) (adopting the *Restatement (Second) of Torts* § 8A definition of intent ("'[I]ntent' is used . . . to denote that the actor desires to cause consequences of his act, or that he believes that the consequences are substantially certain to result from it.")); *see also* Morgan v. Quailbrook Condo. Co., 704 P.2d 573, 576 (Utah 1985) (adopting the *Restatement (Second)* definition of intent).

306. *See* Davis v. J.C. Nichols Co., 714 S.W.2d 679, 684 (Mo. Ct. App. 1986).

307. *Id.*

308. 33 U.S.C. §§ 401–467 (1994).

passed the Clean Water Act.[309] The U.S. Government's failure to enact a specific statute addressing water pollution and relying instead on existing laws tangentially related to the actual problem, appears strikingly similar to its approach under the Coordinated Framework for Regulation of Biotechnology.[310] Perhaps it will take a crisis caused by biotechnology before Congress takes direct action to control GMOs. Furthermore, recent attempts to internationally standardize supervisory programs and liability schemes have met with intense U.S. opposition.[311]

V. INTERNATIONAL CONVENTIONS

Several international conventions address the liability aspects of damage resulting from GMOs. None of these conventions are binding on the United States or the European Union, although some E.U. Member States are signatories. Although several commentators acknowledge the need for unified GMO regulation and liability standards to facilitate trade,[312] international standardization does not appear likely in the foreseeable future.

A. Council of Europe Conventions

The Council of Europe is a Pan-European organization consisting of forty members, including all fifteen E.U. countries. The United States is not a member. The Council is independent of the European Union, and even if all fifteen E.U. Member States sign Council conventions, the conventions are not legally binding on the European Union.

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309. 33 U.S.C §§ 1251–1387 (1994).

310. *See* Coordinated Framework for the Regulation of Biotechnology, 51 Fed. Reg. 23,302 (1986).

311. *See EU Accuses U.S., Others of 'Extreme' Positions that Will Block Biosafety Protocol*, INT'L ENV'T DAILY (BNA), Feb. 16, 1999, *available in* LEXIS, News Library, Bnaied File [hereinafter *Extreme Positions*].

312. *See* McGarity, *supra* note 1, at 437–462 (discussing the elements of an adequate international legal regime for managing the risks posed by the deliberate release of GMOs); *see also* Richard B. Stewart, *Environmental Regulation and International Competitiveness*, 102 YALE L.J. 2039, 2097–2106 (1993) (examining the justifications for international harmonization); Barton, *supra* note 39, at 113–117 (discussing the structure and need for a biosafety protocol); Thomas P. Redick, *Biotechnology, Biosafety and Sustainable Development*, 12 NAT. RESOURCES & ENV'T 114, 114 (1997) (proposing a voluntary management program).

1. Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment

On June 21, 1993, seven members of the Council of Europe signed the Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment.[313] E.U. Member States Italy, Luxembourg, the Netherlands, Greece, and Finland (although not an E.U. Member at the time) were original signatories.[314] Portugal signed the Convention in 1997.[315] The Convention attempts to ensure adequate compensation for victims of environmental harm via a strict liability regime based on the Polluter Pays Principle.[316] In addition, the Convention compels signatories to either require individuals carry adequate liability insurance or make payments into national compensation funds.[317]

Article 2 of the Convention defines dangerous activities as including the "production, handling, storage, use or discharge . . . of genetically modified organisms."[318] Similarly, the Convention broadly defines the scope of damage as including health, property, impairment of the environment (including property, which forms part of the cultural heritage and characteristic aspects of the landscape), and the costs of preventive measures.[319] The operator, defined as the person exercising control over the dangerous activity,[320] is liable for any damages.[321] Unfortunately, the Convention places the liability burden on the individual

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313. *See* Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment ch. II, art. 12, June 21, 1993, Europ. T.S. No. 150, at 7 [hereinafter Civil Liability Convention]. *See also Council of Europe: Seven States Sign Civil Liability Convention*, EUR. ENV'T (Brussels, Belg.), July 6, 1993, *available in* LEXIS, News Library, Eurnvf File [hereinafter *Seven States*].

314. *See Seven States*, *supra* note 313.

315. *See* Council of Europe Treaty Office, *Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment; Chart of Signatures and Ratifications* (status as of Aug. 19, 2000) <http://conventions.coe.int/treaty/EN/cadreprincipal.htm>.

316. *See* Civil Liability Convention preamble, *supra* note 313, at 2. *See also* Leonard R. Olsen, Jr., *Assessing Environmental Damage in Western Europe*, GLOBAL TRADE & TRANSP., Nov. 1994, at 40.

317. *See* Civil Liability Convention ch. II, art. 12, *supra* note 313, at 7. *See also* Arthur Rogers & Jon Reeds, *Environmental Insurance—Civil Liability*, REUTER TEXTLINE SURVEYOR, Mar. 25, 1993, at 6.

318. Civil Liability Convention ch. I, art. 2, *supra* note 313, at 3.

319. *See id.* ch. I, art. 7, at 4 (establishing and defining the scope of damage).

320. *See id.* ch. I, art. 5, at 4 (defining "operator").

321. *See id.* ch. II, art. 6, at 6.

farmers, not the GMOs' developers or importers.[322] The Convention provides for joint and several liability when multiple installations are involved,[323] but it is unclear from the text if this includes the laboratories developing GMOs.

The Convention establishes a three-year statute of limitations, which begins running on the date of discovery or the date on which the damage reasonably should have been discovered, with a maximum time period of thirty years from the date on which the incident causing the damage occurred.[324] Acts of nature, intentional damage by third parties, and contributory negligence are the Convention's only exemptions from liability.[325]

The Council of Europe's Convention presented a comprehensive starting point for adopting civil liability provisions in European nations. Unfortunately, the European Union and other multi-national organizations have failed to follow the Council's leadership and adopt civil liability provisions accordingly.[326]

2. Convention on the Protection of the Environment Through Criminal Law

The Council of Europe's Convention on the Protection of the Environment Through Criminal Law[327] is the first international law to protect the environment by criminalizing pollution.[328] On November 16, 1998, seven nations signed the Convention, including E.U. Member States Denmark, Finland, France, Germany, Greece, and Sweden.[329] Austria, Belgium, and Luxembourg signed in 1999.[330] In addition to criminalizing

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322. *See id.* (placing liability on the individual with "control" over the activity). In the GMO context, this would place liability on the farmer exercising control over his field.

323. *See id.*

324. *See id.* ch. IV, art. 17, at 9.

325. *See id.* ch. II, art. 8, at 7.

326. The E.U. Commission 2000 White Paper on Environment Liability acknowledged the Convention's value but reiterated the Commission's preference to address liability through a comprehensive directive and not accession to the Convention. *See* White Paper, *supra* note 59, at 25.

327. Convention on the Protection of the Environment Through Criminal Law pmbl., Nov. 4, 1998, EUROP. T.S. No. 172 (1998).

328. *See Council of Europe Draft Calls for Use of Criminal Law to Protect Environment*, 18 INT'L ENV'T REP. (BNA) 500, 500 (June 28, 1995).

329. *See* Arthur Rogers, *Seven Nations Sign Council of Europe Treaty Criminalizing Acts Harmful to Environment*, 21 INT'L ENV'T REP. (BNA) 1155, 1155 (Nov. 25, 1998).

330. Council of Europe Treaty Office, *Convention on the Protection of the Environment*

pollution, the Convention takes a proactive approach and punishes acts that create "a significant risk" of harming the environment.[331] Possible penalties include: prison, fines, restoration of the environment, confiscation of profits, and corporate liability.[332]

By establishing the possibility of imprisonment for corporate executives, criminalization aims to prevent pollution through company business decisions. According to Council of Europe Attorney Peter Csonka, although the issue was not discussed in detail during the negotiations, the Convention's provisions are "sufficiently broad" to cover GMO damage.[333] Until the European Union harmonizes criminal law, however, this Convention must be adopted only at the Member State level.

B. United Nations

In 1992, the United Nations Conference on Environment and Development convened in Rio de Janeiro to reaffirm the Stockholm Declaration of the United Nations Conference on the Human Environment.[334] Principle 13 of the Rio Declaration, which the United States signed, proclaims that "[s]tates shall develop national law regarding liability and compensation for the victims of pollution and other environmental damage."[335] With respect to GMOs, victims in the United States do not have a statutory basis for relief and therefore must rely upon the common law for compensation.[336] This scheme may be unable to satisfy Principle 13, and as discussed earlier in Part IV, may inadequately address victims' needs.

The United Nations Industrial and Development Organization (UNIDO) produced voluntary guidelines for the

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Through Criminal Law; Chart of Signatures and Ratifications (status as of Aug. 20, 2000) http://conventions.coe.int/treaty/EN/cadreprincipal.htm>.

331. *See* Convention on the Protection of the Environment Through Criminal Law § II, art. 2(1)(a)(ii), *supra* note 327, at 3. *See also* Rogers, *supra* note 329, at 1156 (quoting Council of Europe attorney Peter Csonka ("[T]he idea is to criminalize acts which create a significant risk, so that the problem is tackled before damage is actually caused . . .")).

332. *See* Rogers, *supra* note 329, at 1156. *See also* Convention on the Protection of the Environment Through Criminal Law § II, arts. 6, 7, 9, *supra* note 327, at 5–6.

333. Rogers, *supra* note 329, at 1157.

334. Rio Declaration on Environment and Development, June 14, 1992, UN Doc. A/Conf. 151/26 (vol. I) (1992), *reprinted in* 31 I.L.M. 874 (1992).

335. *Id.* princ. 13, at 878.

336. *See supra* Part IV.B.

release of GMOs.[337] The guidelines outline a series of voluntary reporting procedures through which users report to their respective national governments, which, in the event of GMO damage, then report to international organizations.[338] The guidelines, however, are silent as to liability issues.

C. 1992 Convention on Biological Diversity/Biosafety Protocol

The Convention on Biological Diversity[339] was the second major international agreement drafted at the 1992 United Nations conference in Rio de Janeiro. The Convention called for the development of a Biosafety Protocol to "set international standards for the handling of genetically engineered organisms."[340] The European Union approved the Convention in 1993.[341] Although President Clinton signed the Convention, the Senate refused to ratify it.[342] In January 2000, after five years of negotiating, the parties to the Convention, and observers such as the United States, agreed to the Cartagena Protocol on Biosafety.[343]

Several liability and compensation issues were at the center of U.S. efforts to dismantle the Protocol, including (1) requiring that either export or import companies be bonded, (2) establishing an international liability fund, and (3) fixing liability on either importing or exporting countries.[344] As the largest producer of genetically modified products, the United States lobbied for bonding import companies and fixing liability on the importing, not the exporting, country.[345] Additionally, the United States

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337. *See* U.N. Industrial and Developmental Organization, *Voluntary Code of Conduct for the Release of Organisms into the Environment* (visited Nov. 24, 1999) <http://www.binas.unido.org/binas/Regulations/unido/codes.html>.

338. *See id.* § II-C-1, princ. 6.

339. United Nations Conference on Environment and Development: Convention on Biological Diversity, June 5, 1992, 31 I.L.M. 818 (1992).

340. *See id.* art. 19, at 830. *See also* Cheryl Hogue, *Debate at Biosafety Protocol Talks to Center on Advance Agreement Regime*, 21 INT'L ENV'T REP. (BNA) 807, 807 (Aug. 19, 1998).

341. Council Decision 93/626 of October 25, 1993 Concerning the Conclusion of the Convention of Biological Diversity, 1993 O.J. (L 309) 1.

342. *See* Hogue, *supra* note 340, at 808.

343. *See* Convention on Biological Diversity, *Global Treaty Adopted on Genetically Modified Organisms* (Jan. 29. 2000) <http://www.biodiv.org/press/pr-2000-01-28-biosafety.html>.

344. *See* Hogue, *supra* note 341, at 808.

345. *See Extreme Positions*, *supra* note 311.

opposed the establishment of an international liability fund.[346] Finally, the United States favored eliminating all agricultural commodities from the scope of the Protocol.[347] The European Commission labeled the United States' position on agricultural commodities as "extreme" because it effectively excluded ninety-nine percent of the GMOs the Protocol supposedly covered.[348] Furthermore, the Europe Union criticized the United States for attempting to place "all responsibility when it comes to liability on the country to which a particular genetically modified crop will be exported."[349]

The compromised Protocol to which the United States finally agreed failed to resolve the liability issues. The Protocol merely requires that GMO exporters, through "Advanced Informed Agreement Procedures,"[350] ensure that recipient countries have the opportunity and capacity to assess the technology's risks prior to its importation.

VI. PROPOSED CHANGES IN E.U. LAW TO ENSURE LIABILITY FOR ENVIRONMENTAL DAMAGE

Proposed changes to Directive 90/220 and a proposed new directive on civil liability may include provisions establishing liability for damage resulting from GMOs within the European Union. Each proposal adopts the Polluter Pays Principle, which places the financial burden on GMO users, and not on a national or E.U.-wide compensation scheme. Elements of each proposal also invoke the use of the Precautionary Principle. In addition, the recently revised Products Liability Directive may provide an alternate means to address some damage GMOs cause, although it may not necessarily address environmental damage.

A. Modification of Directive 90/220

In February 1998, the European Commission proposed extensive revisions to Directive 90/220 on the issue of deliberate release of GMOs into the environment.[351] The impetus for the

346. *See id.*
347. *See id.*
348. *See id.*
349. *Id.*
350. *See* Protocol on Biosafety art. 19, pt. 3, *supra* note 343, at 830.
351. *See generally* Commission Proposal, *supra* note 36.

Commission's revisions was to simplify and accelerate the approval process.[352] The European Parliament, acting through the Committee on the Environment, Public Health and Consumer Protection, rejected the Commission's proposal and instead adopted several substantive amendments.[353]

The European Parliament may be taking an especially firm stance against the revisions because of the passage of revised Directive 90/219 on the contained use of GMOs'.[354] Under cooperation procedures with the Council, Parliament could propose amendments but could not block the legislation.[355] Current proposals to revise Directive 90/220 fall under the harmonization procedures of Article 95 (formerly Article 100a), which provides Parliament with a veto power.[356] Many of Parliament's concerns that Directive 90/219 failed to address were added as amendments to Directive 90/220.

The most controversial amendment Parliament proposed involves imposing full civil and criminal liability for any damage to health or the environment caused by a GMO release.[357] The Commission's revised proposal, submitted March 25, 1999, does not include Parliament's amendments establishing liability.[358] The Commission firmly opposes including liability provisions in the GMO Directive, preferring instead to generally address liability in a separate directive,[359] for which Parliament has been waiting since 1996.[360] In addition to facing civil and criminal liability, the parliamentary amendments also require each entity to have

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352. *See* Parliament Resolution recital 12 (amend. 6), *supra* note 35.

353. *See generally id.*

354. *See* Directive 98/81 of 26 October 1998 Amending Directive 90/219 on the Contained Use of Genetically Modified Micro-organisms, 1998 O.J. (L 330) 13.

355. *See Biotech Industry Should Bear Full Responsibility for Accidental "Escapes" of GMOs*, INT'L ENV'T DAILY (BNA), June 18, 1998, *available in* LEXIS, News Library, Bnaied File [hereinafter *Full Responsibility*]. For a discussion of the various legislative procedures between the Commission, Parliament, and Council, see *supra* notes 86–96 and accompanying text.

356. *See* TREATY ON EUROPEAN UNION art. 189b (co-decision procedures).

357. *See* Parliament Resolution art. 1(12) (amend. 95), *supra* note 35.

358. *See* Amended Proposal for a European Parliament and Council Directive Amending Directive 90/220/EEC on the Deliberate Release into the Environment of Genetically Modified Organisms, Mar. 26, 1999, O.J. (C 139) 7 (1999).

359. *See Full Responsibility*, *supra* note 355. *See also* White Paper, *supra* note 59, at 26.

360. *See Commission's Long-Awaited Communication on Civil Liability Expected in Coming Months*, 19 INT'L ENV'T REP. (BNA) 723, 723 (Aug. 21, 1996) [hereinafter *Long-Awaited Report*].

sufficient liability insurance to cover any potential losses.[361] Given the intense political climate surrounding GMO safety, Parliament may veto any revision of Directive 90/220 rather than sacrifice its proposed liability and insurance amendments.

B. Proposed Directive on Civil Liability for Environmental Damage

In 1994, the Commission first proposed a comprehensive directive establishing civil liability for damage to the environment.[362] The 1994 proposal identified four reasons for Community action: (1) to recognize public demand for systems of accountability; (2) pledge to take action; (3) establish uniform liability for environmental damage throughout the Community; and (4) eliminate distortions in competition resulting from differing civil liability systems.[363] In addition to these four reasons, there is a danger that environmental liability will be implemented in a piecemeal fashion through product-specific GMO and products liability directives. The initial 1993 proposal included the civil law tradition of enforcing the principle that a person should rectify damage that he or she causes[364]—this concept is in line with the general Polluter Pays Principle, which the European Union adopted in the TEU.[365]

In February 2000, the Commission issued a White Paper on Environmental Liability,[366] which proposes a liability regime implementing the Polluter Pays Principle.[367] Strict liability would apply for all damage to health, property, and the environment caused by activities the European Community designates as "dangerous"[368] and traditional fault-based liability would apply for environmental damage caused by non-dangerous activities.[369] In addition, the Commission recommended liability not apply

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361. *See* Parliament Resolution art. 1(12) (amend. 95), *supra* note 35.

362. *See* Civil Liability Green Paper, *supra* note 58.

363. *See id.* pt. 2.

364. *See id.* pt. 1.4.

365. *See* TREATY ON EUROPEAN UNION art. 130r(2) (adopting the Polluter Pays Principle).

366. *See* White Paper, *supra* note 59.

367. *See id.* at 11–13.

368. *See id.* at 31.

369. *See id.* For a thorough discussion of the benefits of a strict liability regime for dangerous goods and a fault-based regime for non-dangerous goods, see Lucas Bergkamp, *A Future Environmental Liability Regime*, 7 EUR. ENVTL. L. REV. 200 (1998).

retroactively.[370] Finally, the Commission recommended legislation allowing interests groups to take action against either the state or the polluter to restore the environment.[371] Despite the issuance of the White Paper, the Commission has not yet indicated when it will actually submit proposed legislation to the Council and Parliament.

C. Products Liability Directive

Recent revisions to the Products Liability Directive specifically include primary agricultural products.[372] "The producer of any raw material"[373] and "any person who imports into the Community a product . . . in the course of his business"[374] is subject to liability. Liability for any defective product containing a GMO is therefore traced to the farmer-producer. Austria has recently come under the Commission's fire for exempting farmers from the scope of the Products Liability Directive.[375] The Commission objected to Austria's amendment of the Directive by adding other exemptions.[376] It is unclear whether Austria will appeal the decision to the European Court of Justice or amend its national legislation.[377]

Under the Products Liability Directive, an injured person must prove actual damage, such as personal injury or damage to property.[378] This injury definition may exclude purely economic damage, such as the organic farmer's lost profits due to cross-pollinated crops and ownerless environmental damage. A claimant must also establish the existence of a defect in the product itself.[379] Member States, however, could pass legislation deeming a GMO defective in the event it causes damage.[380]

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370. *See* White Paper, *supra* note 59, at 16.

371. *See id.* at 22–23.

372. *See* Directive 99/34 pt. 6, *supra* note 57, at 20.

373. Council Directive on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products No. 85/374, art. 3(1), July, 25, 1985 O.J. (L 210) 29, 31 (1985) [hereinafter Directive 85/374].

374. *Id.* art. 3(2), at 31.

375. *See Austrian GM Liability Exemption Challenged*, AGRA EUR. (London), July 30, 1999, at EP/8, *available in* LEXIS, News Library, Asapii File.

376. *See* Directive 85/374 art. 3(2), *supra* note 373, at 31.

377. *See id.*

378. *See id.* art. 9, at 31.

379. *See id.* art. 4, at 31.

380. *See* Nion, *supra* note 184, at 327.

Finally, an injured person must prove the existence of a causal relationship between the defect and the damage.[381] Genetic markers placed inside GMOs could greatly aid in establishing causation. Potentially liable parties may invoke a "state-of-the-art defense," as long as "the state of scientific or technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered."[382]

Although the Products Liability Directive is a potentially useful liability scheme for injured plaintiffs, it fails to provide adequate relief for farmers whose crops are cross-pollinated by genetically modified pollen. Defendants probably could not avail themselves to the state-of-the-art defense because scientific studies document the risks of cross-pollination. Even seed companies recommend planting buffer zones around genetically modified fields. The Directive's critical flaw lies in its damage definition, which only includes economic injury or injury to property not intended for private use or consumption.[383] Therefore, individuals harmed by cross-pollination probably could not recover under a products liability theory.

VII. CONCLUSION

Although several factors influence the final results, it is predictable that pressure from within the European Union to reach a common position, coupled with outside pressure to limit trade distortions, will force the European Union to pass legislation containing GMO liability provisions in the near future. Professor Michel Petit identified four primary political and economic forces shaping E.U. agricultural policy: (1) pressure to reach a common decision; (2) the need to accommodate budget constraints; (3) the downward rigidity of price supports; and (4) outside pressures to limit trade distortions.[384] With respect to the European Union's GMO policy, only the first and fourth factors appear relevant—the budget constraints and price supports are not implicated.

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381. *See* Directive 85/374 art. 4, *supra* note 373, at 31.

382. *Id.* art. 7(e), at 31.

383. *See id.* art. 9, at 31 (providing the Directive's definition of damage).

384. *See* MICHEL PETIT, THE WORLD BANK, PRESSURES ON, AND TRENDS IN, THE EVOLUTION OF THE COMMON AGRICULTURAL POLICY: IMPACT OF WTO COMMITMENTS 1 (1998).

Revision of Directive 90/220 is subject to extensive outside pressure, specifically from the United States and the WTO.[385] U.S. corporations are eager to export their biotechnology advances. U.S. farmers, searching for additional markets in a period of historically low commodity prices, anxiously await the revised directive and subsequent product approvals. The recent WTO decisions holding in favor of the United States with respect to trade disputes over bananas and hormone-fed beef established precedents against the European Union's attempts to impose non-science based trade barriers.[386] Revision of the GMO directive may forestall formal WTO complaints about the European Union's inconsistent approval process. Parliament's disappointment with the revisions of Directive 90/219 and the absence of a civil liability directive addressing environmental damage may provide the necessary impetus for Parliament to continue blocking attempts to revise Directive 90/220 until its demands are met. Therefore, if the Council and Parliament agree to a revised GMO directive's terms this year, it probably will contain liability provisions.

In the absence of a GMO directive, the revised Products Liability Directive may adequately cover damage defective GMOs cause to health and personal property. Member States could increase the liability scheme's effectiveness by implementing a presumption of defect in the event of GMO-caused damage.[387] Although environmental and economic damage will be unrecoverable, the Directive's strict liability provisions will benefit plaintiffs in the Member States that have no existing liability schemes. International agreements, such as the Council of Europe's Convention or the Biosafety Protocol, may push Member States to adopt liability legislation independent of the European Union. Without additional legislation establishing a comprehensive liability scheme directly addressing GMOs (like Austria's), plaintiffs in common law countries, such as the United

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385. *See U.S. Considers Filing Complaint with WTO over EU Barriers to GMO Imports, Aide Says*, 22 INT'L ENV'T REP. (BNA) 569, 569 (July 7, 1999); Aaron Statement, *supra* note 43; Eizenstat, *supra* note 45.

386. *See* UNITED STATES TRADE REPRESENTATIVE, 2000 NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS 90, 95, *available at* (visited Aug. 26, 2000) <http://www.ustr.gov/reports/nte/2000/nte2000.pdf>.

387. *Cf. supra* text accompanying note 197 (explaining German laws' use of the defect presumption with regard to GMO-caused damage).

States and the United Kingdom, as well as in civil law countries, such as Germany, will only recover damages if they meet very difficult standards of proof. Furthermore, liability would be imposed on individual farmers and not biotechnology companies, which are more likely able to afford the costs of such an imposition than are farmers.

An E.U. Directive modeled on the U.K. proposed Simpson Bill may be the optimal solution. Under such a model, plaintiffs would enjoy the benefits of a strict liability recovery regime and mandatory insurance for satisfying damage awards. Damage to the environment, as well as purely economic damage, would fall within the Directive's purview. Liability payments could be capped at a level sufficient to cover most damages, as they are in Austria and Germany, thereby providing the biotechnology industry with a degree of certainty. Finally, under a Simpson-type Directive, consent holders, and not individual farmers, would be liable for damage caused by the deliberate release of GMOs. General tort theories, such as negligence, could apply in rare cases wherein farmers or individual users fail to properly use the valuable, yet possibly risky, GMO technology.