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# From the Test Tube to the Dinner Table in Record Time: Liberalizing Effects on Domestic and International Regulatory Frameworks for Controlled Environmental Introduction of Genetically Engineered Agricultural Organisms

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# FROM THE TEST TUBE TO THE DINNER TABLE IN RECORD TIME: LIBERALIZING EFFECTS ON DOMESTIC AND INTERNATIONAL REGULATORY FRAMEWORKS FOR CONTROLLED ENVIRONMENTAL INTRODUCTION OF GENETICALLY ENGINEERED AGRICULTURAL ORGANISMS

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## I. Introduction

The exploitation of naturally occurring biological processes in the production of useful consumer products and commodities has been known since biblical times.[1] In the intervening millennia many of these traditional bioprocesses have been refined and optimized to efficiently produce a number of useful consumer and industrial products.[2]

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1. Biblical references to bioprocesses typically relate to traditional fermentation and coagulation processes for the production of foodstuffs. These processes include the use of leaven in the production of bread, the fermentation of fruit juice into wine, and the curdling of milk into cheese. Some references tend to be purely literary. For example, in discussing the physical afflictions and infirmities of his old age with God, Job expostulated that he was "poured . . . out as milk, and curdled . like cheese." *Job* 10:10.

In contrast, other references describe bioprocessed foodstuffs by reference to the day-to-day activities of the Hebrews. An early biblical reference (by implication) to the existence of leavened bread is found in the book of *Genesis*. "And there came two angels to . . . Lot . . . [A]nd he made them a feast, and did bake unleavened bread, and they did eat." *Genesis* 19:1-3. More commonly, implied biblical references to leavened bread derive from the Hebrew dietary requirement for unleavened bread during the seven days of the Passover. *See, e.g., Exodus* 12:17-20.

The early passages of the Bible also teach that the Hebrews were skilled vintners and viticulturists who readily partook of the products of their labor without moderation, and experienced the predictable consequences. "Noah began *to be* an husbandman, and he planted a vineyard: And he drank of the wine, and was drunken . . . ." *Genesis* 9:20-21.

Later passages of the Bible expand from the social and subsistence aspects of biologically processed foodstuffs, and discuss the medicinal aspects of such materials. Some references discuss the medicinal effects of wine. See, for example, the first epistle of Paul the apostle, to Timothy, where Paul advises Timothy to "[d]rink no longer water, but use a little wine for thy stomach's sake and thine often infirmities." 1 *Timothy* 5:23. But, see also, the proverbs of Solomon, where Solomon advises to "[l]ook not thou upon the wine when it is red, when it giveth his color in the cup, *when* it moveth itself aright. At the last it biteth like a serpent, and stingeth like an adder." *Proverbs* 23:31-32.

The most notorious biblical reference to biological processing or alchemical transformation of foodstuffs is presumably the miraculous changing of water into wine by Jesus of Galilee, at a wedding celebration in Cana. *John* 2:1-11.

2. Some optimized bioprocesses are able to produce chemical intermediates at conversion efficiencies competitive with purely synthetic processes. For example, the solvent and elixir ethanol may be produced by a biological fermentation process at a conversion efficiency comparable to various synthetic means. *See* FREDERICK A. LOWENHEIM

Notwithstanding the viability of these traditional bioprocesses, the field of biology has rapidly diversified over the last several decades. The impetus for this diversification was the discovery of genetic engineering techniques in the early 1970's.[3] Examples of areas into which biology has diversified pursuant to genetic engineering include biocomputing,[4] eugenics,[5]

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& MARGUERITE K. MORAN, FAITH, KEYES, AND CLARK'S INDUSTRIAL CHEMICALS 355-59 (4th ed. 1975).

Notwithstanding the comparable chemical conversion efficiencies, the choice of industrial process for ethanol production is strongly influenced by the cost and availability of feedstock materials. *Id.* at 363. In this regard, the cost and availability of agricultural feedstocks typically makes the biological fermentation process economically unattractive. *Id.*

Recent legislative initiatives have provided various credits and incentives (economic and non-economic) in an attempt to make the biological fermentation process economically more attractive, while simultaneously providing for cleaner ambient air and reduced dependence on imported petroleum products. *See* Clean Air Act §§ 241-50, 42 U.S.C. §§ 7581-90 (Supp. II 1990); Alternative Motor Fuels Act of 1988, Pub. L. No. 100-494, 102 Stat. 2441 (codified at 15 U.S.C §§ 2001-02, 2006, 2013, 2512 (1988); 42 U.S.C §§ 6201, 6374, 6374a-d (1988)); National Energy Security Act of 1992, §§ 301-514, Pub. L. No. 102-486, 106 Stat. 2776, 2866-2899.

Other significant industrial chemicals that can alternatively be produced through either biological fermentations or purely synthetic means include acetone, butanol, and citric acid. *See* Herman J. Phoff, *Industrial Microorganisms*, SCI. AM., Sept. 1981, at 77, 88.

3. Genetic engineering technology is alternately known as recombinant DNA technology, transgenic DNA technology, or genetic splicing technology. Genetic engineering technology allows for introduction of genetic material from the cells of one organism (i.e., the donor) into the cells of another organism (i.e., the host). As a consequence of the transfer of genetic material the host organism will exhibit characteristics indigenous to the donor species. Prior to the transfer of such genetic material the host would have been unable to exhibit those characteristics. *See* STEVE OLSON, BIOTECHNOLOGY: AN INDUSTRY COMES OF AGE 15-18 (1986). *See generally* DAVID M. GLOVER, GENETIC ENGINEERING CLONING DNA (1980).

Although genetic engineering technology has been used to produce novel and unexpected traits in various organisms, the scientific principles exploited in genetic engineering are similar to the artificial insemination and cross pollination techniques traditionally used for species enhancement. In some instances the use of genetic engineering techniques simply accelerates a result that could be achieved using traditional techniques. In other cases the use of genetic engineering techniques accelerates a result that would most likely be achieved only through mutation. *See generally* LAWRENCE E. METTLER & THOMAS G. GREGG, POPULATION GENETICS AND EVOLUTION (1969).

Much of the pioneering work in genetic engineering technology was undertaken at Stanford University in early 1972. *See generally* JOHN LEAR, RECOMBINANT DNA: THE UNTOLD STORY (1978). Many of the initial technical advances were reported at the 1973 Gordon Research Conference on Nucleic Acids. *See* Maxine Singer & Dieter Soll, *Potential Biohazards of Recombinant DNA Molecules*, 181 SCI. 1114 (1973).

Not all areas of biotechnology rely upon genetic engineering processes. *See, e.g., infra* notes 4, 10. However, genetic engineering technology has, in general, provided the foundation for many of the recent exceptional advances in various biotechnology fields.

4. Biocomputing involves the use of computer electronics to facilitate the measurement and control of biological processes that occur through electrical impulses. *See generally* BIOCOMPUTERS: THE NEXT GENERATION FROM JAPAN (Tsuguchika Kaminuma & Gen Matsumoto eds., Norman D. Cook trans. 1991).

Recent increases in microelectronic circuit integration have yielded biocompatible implantable silicon semiconductor chips suitable for both neurologic sensing and stimulus applications. *See* David H. Liang et al., *A Method for Evaluating the Selectivity of Electrodes Implanted for Nerve Stimulation*, 38 IEEE TRANSACTIONS ON BIOMEDICAL ENGINEERING 443 (1991); Jin Ji & Kensall D. Wise, *An Implantable CMOS Circuit Interface for Multiplexed Microelectrode Recording Arrays*, 27 IEEE JOURNAL OF SOLID-STATE CIRCUITS 433 (1992).

5. Although the medical and biochemical aspects of modern eugenics are fairly straightforward, the moral and ethical implications of human eugenics are profound. *See supra* note 3; Paul A. Lombardo, *Three Generations, No Imbeciles: New Light on Buck v. Bell*, 60 N.Y.U. L. REV. 30 (1985) (historical perspective on traditional human eugenics through involuntary sterilization). In Buck v. Bell, 274 U.S. 200 (1927), the Court upheld a Virginia law that

biomedical forensics,[6] human tissue transplantation,[7] bioagriculture,[8] bio-assisted environmental pollution remediation,[9] and bio-assisted natural resource development.[10]

Although genetic engineering clearly has implications in a variety of applications, this paper will focus specifically on the agricultural aspects of that technology.[11] Within the limited

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provided for involuntary sterilization of persons committed to state run institutions for the epileptic and feebleminded. *Id.* at 205-07.

Predictably, the legal debate surrounding human eugenics pertains to a competition between an individual's constitutional right of free choice and a state's interest in providing for the general social welfare. Lombardo, *supra*, at 33.

6. Some of the techniques used in biomedical forensics are derived from the same scientific principles that are used in genetic engineering. *See supra* note 3. Currently, the most controversial area in forensic medical diagnostics is the use of DNA typing as an evidentiary tool in judicial proceedings. *See generally* Sally E. Renskers, *Trial by Certainty: Implications of Genetic "DNA Fingerprints "D"*, 39 EMORY L.J. 309 (1990).

7. In addition to the traditional surgical transplants of whole human organs, the area of human tissue transplantation has recently evolved to include selective implantation of individual cells obtained from human fetuses. Recent reports indicate substantial medical successes in this area. *See* Gina Kolata, *Success Reported Using Fetal Tissue to Repair a Brain*, N.Y. TIMES, Nov. 26, 1992, at A1.

The legal debate surrounding human tissue transplantation includes commercial and ethical considerations pertaining to individual property rights in fetal tissues and cells. *See* Jenn S. Bregman, *Conceiving to Abort and Donate Fetal Tissue: New Ethical Strains in the Transplantation Field -- A Survey of Existing Law and a Proposal for Change*, 36 UCLA L. REV. 1167 (1989); Beverly R. Burlingame, *Commercialization in Fetal-Tissue Transplantation: Steering Medical Progress to Ethical Cures*, 68 TEX. L. REV. 213 (1989).

8. The field of bioagriculture seeks to achieve enhanced agricultural yields through the application of both traditional microbiological techniques and advanced genetic engineering techniques. *See* Winston J. Brill, *Agricultural Microbiology*, SCI. AM., Sept. 1981, at 199.

Legal concerns in this area pertain to the extent and type of regulatory control that is appropriate to ensure minimal environmental risk while simultaneously assuring a wholesome food supply. *See* Daniel D. Jones, *Commercialization of Gene Transfer in Food Organisms: A Science-Based Regulatory Model*, 40 FOOD DRUG COSM. L.J. 477 (1985); Peter Mostow, *Reassessing the Scope of Federal Biotechnology Oversight*, 10 PACE ENVTL. L. REV. 227 (1992).

9. *See* Diamond v. Chakrabarty, 447 U.S. 303 (1980). *Chakrabarty* is a seminal case relating to both biotechnology and intellectual property law. In *Chakrabarty*, the Court first held that certain genetically modified micro-organisms are patentable subject matter under § 101 of the Patent Statute, 35 U.S.C. § 101 (1988). Chakrabarty, 447 U.S. at 308-10.

Chakrabarty, a microbiologist employed with General Electric Company, discovered a method whereby he could stably introduce plasmids capable of degrading oil components into a *Pseudomonas* bacterium which otherwise had no capacity for oil degradation. *Id.* at 305.

10. *See* Arnold L. Demain & Nadine A. Solomon, *Industrial Microbiology*, SCI. AM., Sept. 1981, at 67, 74-75.

The authors describe a biologically enhanced process to extract copper from low grade ores. The process uses catalytic amounts of a *Thiobacillus* bacteria, presumably as a mediator in the air oxidation of catalytic amounts of iron containing compounds. The resulting ferric ion solutions are recycled through low grade copper ore dumps where copper and sulfur are extracted in the form of acidic copper sulfate. Copper is recovered from this acidic leachate. *Id.*

A similar process can be used to extract uranium. The processes may have historic basis in the Roman empire. *Id.* at 74.

11. *See supra* note 8.

scope of agriculture this paper will further focus on domestic and international regulatory frameworks for environmental introduction of genetically engineered agricultural organisms.

Environmental introductions of such organisms normally occur during research, development, and field testing of genetically engineered products or processes related to food production.[12] In turn, food production may routinely involve exposure of many acres of land under varying meteorologic conditions providing limited environmental control. Thus, introductions of genetically engineered agricultural organisms have been perceived as riskier than analogous experiments involving genetically engineered organisms under physically confined laboratory conditions.[13] To provide a complete history of genetic engineering regulation Part II of this paper will introduce the domestic regulatory constraints on genetic engineering research under physically confined laboratory conditions. By analogy, Part III of this paper will introduce the domestic regulatory scheme for controlled environmental introduction of genetically engineered agricultural organisms. Part III will also introduce the federal policies governing genetic engineering, as well as the statutes and federal agencies through which such policies are implemented.

Part IV of this paper will discuss the extent of federal judicial review of controlled environmental introductions of genetically engineered agricultural organisms.

Part V will introduce two intergovernmental initiatives for regulation of environmental introductions of genetically engineered organisms. The first initiative is a European Economic Community Directive. The second initiative is contained within a United Nations committee report prepared for the United Nations Conference on Environment and Development (UNCED).[14]

The final part of this paper will discuss and contrast the various regulatory approaches and reconcile their differences within the context of political priorities and preferences of the institutions through which they were promulgated.

## II. Regulation of Genetic Engineering Laboratory Research

Shortly after the discovery of genetic engineering techniques in the early 1970's[15] several scientific researchers expressed concern that uncontrolled exploitation of such techniques might lead to unexpected, unpredictable, and irremediable consequences.[16] As a result of these concerns the researchers requested the National Academy of Sciences (NAS) to study the implications of genetic engineering technology and to recommend specific actions or guidelines to assure laboratory safety.[17]

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12. *See* Jones, *supra* note 8, at 478.

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

14. *See infra* notes 89-91 and accompanying text.

15. *See* LEAR, *supra* note 3.

16. *See* Singer & Soll, *supra* note 3.

17. *See* Singer & Soll, *supra* note 3.

In response, the NAS requested the scientific community to impose a voluntary moratorium on certain types of genetic engineering experiments, pending further government action.[18] Simultaneously, the NAS also requested the National Institutes of Health (NIH) to establish an advisory oversight committee to develop procedures and guidelines for genetic engineering research.[19]

The initial NIH guidelines were issued in 1976.[20] The most recent update to those guidelines was promulgated in 1986.[21] The guidelines are quite comprehensive.[22] They establish a Recombinant DNA Advisory Committee (RAC) within the NIH and they establish Institutional Biosafety Committees (IBCs) within organizations funded for genetic engineering research by the NIH.[23] Substantively the guidelines provide four different categories for review of genetic engineering experiments[24] and several types of containment and control procedures.[25] The guidelines then assign the appropriate category of review and the relevant containment and control procedures to specific types of genetic engineering research

18. Paul Berg et al., *Potential Biohazards of Recombinant DNA Molecules*, 185 SCI. 303 (1974). The types of experiments that were covered by the moratorium included: 1) experiments where certain types of bacteria were modified to provide antibiotic resistance or toxin formation characteristics; and 2) experiments where certain types of bacteria or viruses were modified to incorporate tumor causing or other viral characteristics. *Id.*

19. *Id.*

20. Recombinant DNA Research Guidelines, 41 Fed. Reg. 27,902 (1976); U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, OTA-BA-494, BIOTECHNOLOGY IN A GLOBAL ECONOMY 173 (1991) [hereinafter BIOTECHNOLOGY IN A GLOBAL ECONOMY].

The guidelines were issued through the NIH Director's authority to undertake or fund research in health related fields. *See* 42 U.S.C. § 284(b)(2) (1988).

21. Guidelines for Research Involving Recombinant DNA Molecules, 51 Fed. Reg. 16,958 (1986).

22. Although the guidelines are comprehensive they are, as noted above, only guidelines and not rules. *See supra* note 20. They are enforceable only through the contracting authority of the NIH. 51 Fed. Reg. at 16,959. However, private organizations and other political jurisdictions have generally adopted the guidelines as standard industry practice. BIOTECHNOLOGY IN A GLOBAL ECONOMY, *supra* note 20, at 173-74.

23. 51 Fed. Reg. at 16,959.

24. The four categories are: 1) experiments that require RAC and IBC approval prior to initiation; 2) experiments that require only IBC approval prior to initiation; 3) experiments that require IBC notice simultaneous with initiation; and 4) exempt experiments. *Id.*

25. *Id.* at 16,959, 16,972-78. The most common containment and control procedures are based upon laboratory controls and physical containment. These procedures include laboratory operating practices, laboratory design, and laboratory safety equipment. *Id.*

The 1986 guidelines also contemplated the use of biological barriers to limit the spread of genetically engineered organisms. The biological barriers included the use of DNA carrier organisms of limited infectivity and the use of DNA carrier organisms of limited environmental viability. *Id.* at 16,959, 16,980-81.

activities.[26]

## III. Regulation of Genetically Engineered Agricultural Organisms

### *A. The Federal Statutes and Regulatory Agencies*

The overriding feature of federal genetic engineering regulation is the absence of a statutory mandate specific to that area. Instead, federal genetic engineering regulation is accomplished through existing statutes and agencies as a consequence of non-genetic characteristics possessed by genetically engineered products or processes. Thus, as genetically engineered products and processes progress to the marketplace from the laboratory they are frequently, based upon the nature and scope of their non-genetic characteristics and intended uses, subject to regulations other than the guidelines promulgated by the NIH.[27]

At first glance there may appear to be a bewildering array of rules, regulations, and agency directives with which emerging genetically engineered products or processes might need to comply. However, since this paper is focused only on agricultural introductions of genetically engineered products, the relevant statutory and regulatory scope is actually substantially reduced.[28] Within this reduced scope, introductions of genetically engineered agricultural products and processes are regulated by the Environmental Protection Agency (EPA),[29] the Department of Agriculture (USDA),[30] the Food and Drug Administration (FDA),[31]

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26. For example, the most stringent level of control and approval is required for genetic engineering experiments involving synthesis of toxic materials such as diphtheria virus or tetanus toxin. 51 Fed. Reg. at 16,960. The least restrictive level of control is applied, among other categories, to experiments that do not involve viruses or other living organisms. *Id.* at 16,961.

27. BIOTECHNOLOGY IN A GLOBAL ECONOMY, *supra* note 20, at 173.

28. A matrix of federal statutes and rules generally applicable to biotechnology is given in Coordinated Framework for Regulation of Biotechnology; Establishment of the Biotechnology Science Coordinating Committee, 50 Fed. Reg. 47,174, 47,178-95 (1985).

29. The EPA derives its regulatory authority primarily from the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136-136y (1988), and the Toxic Substances Control Act (TSCA), 15 U.S.C. §§ 2601-2671 (1988).

Section 3 of FIFRA provides for registration of all pesticides that are distributed, sold, or used within the United States unless the pesticide is subject to an experimental use permit under section 5 of the Act or an emergency exemption under section 18 of the Act. 7 U.S.C. §§ 136a, 136c, 136p.

TSCA is a gap filling statute that provides for regulation of chemical substances in both interstate and intrastate commerce to assure that there is no "unreasonable risk of injury to health or the environment." TSCA § 2, 15 U.S.C § 2601.

30. The USDA exercises its authority, in part, through the Virus-Serum-Toxin Act (VSTA), 21 U.S.C. §§ 151-59 (1988), the Federal Plant Pest Act (PPA), 7 U.S.C. §§ 150aa-jj (1988), the Plant Quarantine Act (PQA), 7 U.S.C. §§ 151-67 (1988), the Federal Meat Inspection Act (MIA), 21 U.S.C. §§ 601-95 (1988), and the Poultry Products Inspection Act (PPIA), 21 U.S.C. §§ 451-70 (1988). The PPA and PQA are administered by the Animal and Plant Health Inspection Service (APHIS) of the USDA. The MIA and PPIA are administered by the Food Safety and Inspection Service (FSIS) of the USDA.

The VSTA regulates animal vaccines and other biologics. 21 U.S.C. § 151. The PPA and PQA provide for regulation and quarantine of plant products and pests that may threaten U.S. agriculture. 7 U.S.C. §§ 150bb, 154. The

and, to a lesser extent, the Occupational Safety and Health Administration (OSHA).[32]

*B. Federal Oversight and Policy Guidance*

In order to coordinate the regulatory activities of the various federal agencies, the Office of Science and Technology Policy (OSTP) established a Biotechnology Sciences Coordinating Committee (BSCC) in 1985.[33] Shortly after establishing the BSCC, the OSTP also issued a policy document, known as the Coordinated Framework,[34] to guide federal oversight of genetic engineering. Accompanying the Coordinated Framework document were individual policy statements of the FDA, EPA, USDA, OSHA, and NIH.[35]

The Coordinated Framework document provided two fundamental policies to guide individual agencies in regulating genetically engineered products and processes. The first policy was that the existing regulatory frameworks of the individual federal agencies should be adequate for the continuing regulation of genetically engineered products and processes.[36] The second policy was that introductions of genetically engineered products and processes into the environment should proceed on a case-by-case basis subject to risk assessment principles.[37]

In the intervening several years since issuance of the Coordinated Framework document

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MIA and PPIA provide for inspection of livestock and poultry products to ensure safety, wholesomeness, and proper labelling. 21 U.S.C. §§ 452, 603.

At present there exists no regulation of genetically engineered fish under federal law. BIOTECHNOLOGY IN A GLOBAL ECONOMY, *supra* note 20, at 184.

31. The FDA, within the Department of Health and Human Services (HHS), exercises its authority through the Federal Food, Drug, and Cosmetics Act (FFDCA), 21 U.S.C. §§ 301-393 (1988). The Act provides the FDA with authority to regulate food and food additives which are subject to interstate commerce. 21 U.S.C. §§ 331, 341-50a.

32. OSHA exercises its authority through the Occupational Safety and Health Act (OSH), 29 U.S.C. §§ 651-78 (1988). The Act provides the Secretary of Labor with authority to promulgate standards to assure that employers' workplaces "are free from recognized hazards that are causing or are likely to cause death or serious physical harm to . . . employees." OSH §§ 5-6, 29 U.S.C. §§ 654-55.

33. Coordinated Framework for Regulation of Biotechnology; Establishment of the Biotechnology Sciences Coordinating Committee, 50 Fed. Reg. 47,174, 47,175-76 (1985); BIOTECHNOLOGY IN A GLOBAL ECONOMY, *supra* note 20, at 176-77.

In 1990, the BSCC was replaced with the Biotechnology Research Subcommittee (BRS) of the Committee on Life and Health Sciences. BIOTECHNOLOGY IN A GLOBAL ECONOMY, *supra* note 20, at 176-77.

The authority and mandate of the OSTP is found in 42 U.S.C §§ 6611-17 (1988 & Supp. II 1990). "The primary function of the [OSTP] director is to provide . . . advice on the scientific, engineering, and technological aspects of issues that require attention at the highest level of Government." 42 U.S.C. § 6613(a) (1988).

34. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (1986) [hereinafter Coordinated Framework].

35. *Id.* at 23,309 (statement of FDA policy); *Id.* at 23,313 (statement of EPA policy); *Id.* at 23,336 (statement of USDA policy); *Id.* at 23,347 (statement of OSHA policy); 51 Fed. Reg. at 23,349 (statement of NIH policy).

36. *Id.* at 23,303.

37. *Id.* at 23,308-09.

federal genetic engineering policy has continued to evolve. The evolution has been influenced by several non-regulatory organizations of the federal government. These organizations include the National Research Council (NRC), the National Academy of Sciences (NAS), the Office of Technology Assessment (OTA), and The President's Council on Competitiveness.[38] In February 1992 the OSTP issued a revised policy statement for federal oversight of introduction of genetically engineered biotechnology products into the environment.[39] The revised policy statement affirmed the policy directives of the Coordinated Framework.[40] However, it also refined those directives in two important ways.[41] The first refinement quantified the risk assessment principles initially outlined in the Coordinated Framework. This refinement provided that "federal agencies shall exercise oversight of planned introductions of biotechnology products into the environment only upon evidence that the risk posed by the introduction is unreasonable."[42] The second refinement addressed the nature of organisms that should be subject to federal oversight. This refinement provided that "[f]ederal government regulatory oversight should focus on the characteristics and risks of the biotechnology product -- not the process by which it [wa]s created."[43] Although the refinements and the underlying policies are neither new nor unpredictable, both have been subject to varied degrees of analysis and commentary.[44]

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38. *See, e.g.*, NATIONAL RESEARCH COUNCIL, FIELD TESTING GENETICALLY MODIFIED ORGANISMS: A FRAMEWORK FOR DECISIONS (1989); COMMITTEE ON THE INTRODUCTION OF GENETICALLY ENGINEERED ORGANISMS INTO THE ENVIRONMENT, COUNCIL OF THE NATIONAL ACADEMY OF SCIENCES, INTRODUCTION OF RECOMBINANT DNA-ENGINEERED ORGANISMS INTO THE ENVIRONMENT: KEY ISSUES (1987); U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, OTA-BA-350, NEW DEVELOPMENTS IN BIOTECHNOLOGY - FIELD TESTING ENGINEERED ORGANISMS: GENETIC AND ECOLOGIC ISSUES (1988); THE PRESIDENT'S COUNCIL ON COMPETITIVENESS, REPORT ON NATIONAL BIOTECHNOLOGY POLICY (1991).

39. Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment, 57 Fed. Reg. 6,753 (1992). The OSTP initially proposed its federal oversight principles in July 1990. Principles for Federal Oversight of Biotechnology: Planned Introduction Into the Environment of Organisms With Modified Hereditary Traits, 55 Fed. Reg. 31,118 (1990).

40. 57 Fed. Reg. at 6,753.

41. *Id.* at 6,756.

42. *Id.* The policy statement further defines unreasonable risk in terms of a cost-value analysis. "A risk is unreasonable where the full value of the reduction in risk obtained by oversight exceeds the full cost of the oversight measure." *Id.*

43. 57 Fed. Reg. at 6,756. This criteria is commonly referred to as the "product over process" formulation. The policy document further states that "[p]roducts developed through biotechnology processes do not *per se* pose risks to human health and the environment; risk depends instead on the characteristics and use of individual products." *Id.* (emphasis in original).

The product over process formulation presumably derives from the presumption that modern genetic engineering techniques are not fundamentally dissimilar from traditional breeding and cross pollination techniques used for species enhancement and diversification. Rather, genetic engineering techniques accelerate the probability of achieving desirable traits in species variants that would not otherwise be readily accessible. *See supra* note 3.

44. *See infra* notes 98-120 and accompanying text.

### *C. Agency Compliance With Federal Policy*

#### *1. The Environmental Protection Agency*

As noted above, the EPA's regulatory authority over genetically engineered agricultural product introductions derives from either FIFRA or TSCA.[45] Although the EPA requested comments in 1989 for revisions to its policy pertaining to genetically engineered microbial pesticides,[46] the current EPA biotechnology policies for both FIFRA and TSCA date from the EPA's 1986 policy statement that accompanied the Coordinated Framework document.[47] However, the current EPA regulatory agenda indicates proposed rulemaking activities designed to codify and align EPA biotechnology regulation with federal directives.[48]

#### *2. The United States Department of Agriculture*

Of the agencies having regulatory authority over genetically engineered agricultural product introductions, the USDA probably has the most experience and will presumably continue to see the highest level of activity.[49] In addition to the policy statement issued by the USDA simultaneously with the Coordinated Framework,[50] the USDA has: 1) established a permitting system for introduction of genetically engineered plant organisms into the environment;[51] and 2) proposed a set of guidelines for research involving genetically

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45. *See supra* note 29.

46. Microbial Pesticides; Request for Comment on Regulatory Approach, 54 Fed. Reg. 7,026 (1989).

47. *See* Coordinated Framework, *supra* note 34. The current procedure for experimental field introductions of microbial pesticides relies upon a notice and comment rulemaking process initially outlined in the EPA policy statement that accompanied the Coordinated Framework document. Coordinated Framework, *supra* note 34, at 23,320-24. *See, e.g.*, Receipt of Notification of Intent to Conduct Small-Scale Field Testing; Genetically Altered Microbial Pesticide, 57 Fed. Reg. 18,144 (1992).

48. *See* Environmental Protection Agency Regulatory Agenda, 57 Fed. Reg. 52,024, 52,038, 52,046 (1992).

A proposed FIFRA rule is designed to clarify situations involving small scale testing of certain microbial products where an experimental use permit is not required. *Id.* at 52,038. The proposed rule has recently been issued by the EPA. *See* Microbial Pesticides; Experimental Use Permits and Notifications, 58 Fed. Reg. 5878 (1993).

A proposed TSCA rule may discuss exceptions and expedited notification procedures for microbial products at both the research and commercial stages of development. 57 Fed. Reg. at 52,046.

49. *See* Genetically Engineered Organisms and Products; Notification Procedures for the Introduction of Certain Regulated Articles; and Petition for Nonregulated Status, 57 Fed. Reg. 53,036, 53,037 (1992). The Animal and Plant Health Inspection Service (APHIS) of the USDA has issued over 300 permits for field tests of genetically engineered products and over 1000 permits for movement of regulated genetically engineered articles. *Id.*

50. *See supra* note 34.

51. Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which are Plant Pests or Which There is Reason to Believe are Plant Pests, 52 Fed. Reg. 22,892 (1987) (codified at 7 C.F.R. §§ 330, 340 (1992)). The permitting system requires a minimum 120 day notice and public comment review period prior to environmental introduction of a regulated genetically engineered plant organism. 7 C.F.R. § 340.3(b) (1992).

Authority for these rules derives, in part, from the Plant Pest Act & the Plant Quarantine Act. *See supra* note

engineered products.[52] The former of these two activities is more relevant to this topic.

In November 1992 the USDA proposed two revisions to the permitting system noted above.[53] The first revision proposes a simplified notification procedure for environmental introduction of some genetically engineered organisms that are currently subject to environmental introduction only through a permit.[54] The second revision proposes a procedure to allow interested parties to petition the USDA for complete deregulation of some genetically engineered bioproducts.[55] The notice of proposed rulemaking for these revisions explicitly acknowledged the recent federal policy directives.[56]

*3. The Food and Drug Administration*

In addition to the policy statement it issued simultaneously with the Coordinated Framework in 1986,[57] the FDA recently issued a revised policy statement pertaining to foods derived from genetic engineering processes.[58] Consistent with existing policy, the FDA reiterated that "foods . . . derived from plant varieties developed by the new methods of genetic modification are [to be] regulated within the existing framework of the [Food, Drug and Cosmetic A]ct."[59]

To support this policy the FDA discussed the relationship between scientific issues and public policy.[60] Within this discussion the FDA acknowledged that: 1) "[r]ecombinant DNA

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52. Proposed USDA Guidelines for Research Involving the Planned Introduction Into the Environment of Organisms With Deliberately Modified Hereditary Traits, 56 Fed. Reg. 4,134 (1991).

53. *See supra* note 51 and accompanying text; Genetically Engineered Organisms and Products; Notification Procedures for the Introduction of Certain Regulated Articles; and Petition for Nonregulated Status, 57 Fed. Reg. 53,036 (1992).

54. 57 Fed. Reg. at 53,036-39. Although it is limited by additional criteria, the proposed notification procedure is generally applicable to common varieties of corn, cotton, potato, soybean, tobacco, and tomato plants into which new genetic material has been stably introduced, presuming that the new genetic variant does not exhibit toxic or infectious characteristics. *Id.* at 53,037.

55. *Id.* at 53,039-40. This proposed revision formalizes a process that was already established under the existing regulations. *See* 7 C.F.R. § 340.2 (1992).

56. 57 Fed. Reg. at 53,036.

57. *See* Coordinated Framework, *supra* note 34.

58. Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984 (1992).

59. *Id.* at 22,985-88. FFDCA §§ 301, 402(a)(1), 21 U.S.C. §§ 331, 342(a)(1) (1988), currently provides the Secretary of Health and Human Services with the authority to control adulterated and misbranded food in interstate commerce. The authority of the Secretary is executed largely in an aftermarket fashion through: 1) food inspections; and 2) investigations of consumer complaints of tainted and misbranded food products. There is no ongoing program for preliminary permits for field testing of newly developed food products. *Id.*

60. 57 Fed. Reg. at 22,985-88.

techniques are used to produce the same types of goals as traditional [plant breeding] techniques,"[61] and 2) "[p]lants are known to produce naturally a number of toxicants."[62]

*4. The Occupational Health and Safety Administration*

In the policy statement that it issued with the Coordinated Framework in 1986,[63] OSHA expressed the policy that the occupational safety and health aspects of genetically engineered products and processes could be addressed through existing standards and statutory mandates.[64] That policy has not changed.

## IV. Judicial Review

Although the number of environmental introductions of genetically engineered agricultural products has increased substantially within the last several years, there has been comparatively little federal judicial intervention into this area. In the limited number of situations where judicial action has been initiated,[65] the Foundation on Economic Trends (the Foundation)[66] has proceeded as a plaintiff.

While an overriding theme of the litigation initiated by the Foundation may be difficult to define, it is nonetheless instructive to analyze the judicial responses to the Foundation's actions. To assist in this analysis a review of the first and last cases litigated by the Foundation is helpful.

The first case litigated by the Foundation involved the first controlled environmental

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61. *Id.* at 22,986.

62. *Id.* at 22,987.

63. *See* Coordinated Framework, *supra* note 34.

64. *See* Coordinated Framework, *supra* note 34, at 23,348.

65. *See* Foundation on Economic Trends v. Heckler, 756 F.2d 143 (D.C. Cir. 1985), *aff'g in part and vacating in part* 587 F. Supp. 753 (D.D.C. 1984) (successful challenge, under the National Environmental Policy Act (NEPA), 42 U.S.C. §§ 4321-70(a) (1988), to a deliberate release experiment involving bacteria) [hereinafter Foundation on Economic Trends I]; Foundation on Economic Trends v. Thomas, 637 F. Supp. 25 (D.D.C. 1986) (unsuccessful challenge, under NEPA, FIFRA & Administrative Procedure Act (APA), 5 U.S.C. §§ 702-706 (1988), to EPA's issuance of an experimental use permit (EUP) for a genetically engineered microbial pesticide) [hereinafter Foundation on Economic Trends II]; Foundation on Economic Trends v. Johnson, 661 F. Supp. 107 (D.D.C. 1986) (unsuccessful challenge to the validity of the Coordinated Framework document) [hereinafter Foundation on Economic Trends III]; Foundation on Economic Trends v. Lyng, 680 F. Supp. 10 (D.D.C. 1988) (unsuccessful challenge, under VSTA, NEPA & APA, to the marketing of a genetically engineered pseudorabies vaccine) [hereinafter Foundation on Economic Trends IV]; Foundation on Economic Trends v. Bowen, 722 F. Supp. 787 (D.D.C. 1989) (unsuccessful challenge, under NEPA, to NIH funding of biotechnology research involving genetics, AIDS, and cancer) [hereinafter Foundation on Economic Trends V]; Foundation on Economic Trends v. Lyng, 943 F.2d 79 (D.C. Cir. 1991) (unsuccessful challenge, under NEPA, to USDA participation in a national germplasm preservation program) [hereinafter Foundation on Economic Trends VI].

66. The Foundation on Economic Trends is a watchdog organization headed by Jeremy Rifkin. The organization's charter calls for oversight of biotechnology activities since the organization feels that the development and exploitation of biotechnology will compromise the traditional American lifestyle. *See generally* JEREMY RIFKIN, ALGENY (1983).

introduction of genetically engineered agricultural organisms.[67] In that case the Foundation argued that the NIH did not comply with the National Environmental Policy Act (NEPA)[68] requirement of an adequate Environmental Impact Statement (EIS) prior to initiation of the environmental introduction.[69] In that instance, the court agreed with the Foundation and found that the NIH's activities pursuant to an EIS were inadequate[70] due to the NIH's failure to fully consider the potential dispersive effects of the genetically engineered organisms.[71] Thus, the appellate court sustained the district court's injunction prohibiting the environmental introduction experiment.[72]

The most recent case litigated by the Foundation also involved compliance with NEPA.[73] In that case the Foundation challenged the USDA's ongoing participation in a national germplasm[74] preservation program due to the USDA's failure to prepare an EIS. In this instance the court found that the Foundation lacked standing to challenge the activities of the USDA since the Foundation had failed to identify a final agency action for which judicial review could be sought.[75] In its decision the appellate court reconciled its holding with a recent

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67. Foundation on Economic Trends I, 756 F.2d at 146. The experiment at issue was proposed by two researchers at the University of California at Berkeley, and approved by the NIH. Recombinant DNA Research; Actions Under Guidelines, 48 Fed. Reg. 24,548, 24,549-50 (1983). The experiment involved the use of genetically engineered bacteria to displace naturally occurring bacteria in a number of food crops. The bacteria were genetically engineered to provide frost resistance to the food crops. *Id.* at 24,549.

68. 42 U.S.C. §§ 4321-70a (1988).

69. At the time the case was initiated the Coordinated Framework document for federal oversight had not yet emerged. Environmental releases of biotechnological organisms were regulated by the NIH under a 1983 revision to NIH Guidelines initially issued in 1976. *See supra* note 20 and accompanying text; Foundation on Economic Trends I, 756 F.2d at 148-50; Guidelines for Research Involving Recombinant DNA Molecules; June 1983, 48 Fed. Reg. 24,556, 24,580 (1983).

70. Foundation on Economic Trends I, 756 F.2d at 153-55.

71. *Id.*

72. *Id.* at 160.

73. Foundation on Economic Trends VI, 943 F.2d 79 (D.C. Cir. 1991).

74. "'Germplasm' consists of plants, seeds and plant parts maintained for the purposes of study, breeding or genetic research." *Id.* at 80. The USDA participates with various other federal, state and private agencies in a number of activities pertaining to germplasm. *Id.* at 81. At present, the national germplasm "'collections contain more than 380,000 different accessions of some 8,700 species, including virtually all of the crops of interest to U.S. agriculture.'" *Id.* (quoting NATIONAL RESEARCH COUNCIL, MANAGING GLOBAL GENETIC RESOURCES: THE U.S. NATIONAL PLANT GERMPLASM SYSTEM 3 (1991)).

75. Foundation on Economic Trends VI, 943 F.2d at 86.

In its analysis the court reviewed the relationship between citizen environmental group standing and final governmental agency action in NEPA cases. The court acknowledged that the Foundation suffered an injury in fact due to the USDA's failure to prepare an EIS. *Id.* at 85. The court concluded that the Foundation was a membership organization dedicated to information dissemination and that the USDA's failure to prepare an EIS "informationally injured" the Foundation. *Id.*

However, the court also held that a mere "informational injury" was not by itself adequate to confer standing

Supreme Court decision which analogously limited standing of another environmental group that had also challenged the actions of a federal agency.[76]

Thus, from these two cases it appears that notwithstanding expected increases in environmental introductions of genetically engineered agricultural organisms, the opportunity for judicial review of those activities is likely to be limited unless the complaining party is able to clearly articulate a final agency action for which judicial review is appropriate. Given the stringent requirements for such agency actions under NEPA cases, and the current trend towards complete deregulation of some genetically engineered agricultural product introductions,[77] many future introductions may not, in fact, provide a final agency action appropriate for review.

## V. Intergovernmental Initiatives

### *A. European Economic Community Directive*

In addition to a directive addressing the contained use of genetically modified micro-organisms,[78] the Council of the European Economic Community (EEC) has issued a directive pertaining to deliberate environmental release of genetically modified organisms.[79]

The latter directive differentiates environmental releases which are purely for research and development purposes[80] from releases that are part of a program to market products containing genetically modified organisms.[81] Introductions that fall into the latter category have additional data reporting requirements.[82]

In general, the EEC directive for environmental release of genetically modified organisms follows the framework established by other EEC directives pertaining to environmental

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to citizen environmental groups challenging NEPA actions under § 702 of the APA, 5 U.S.C. § 702 (1988). *Id.* at 86. On the basis of precedent the court held that in order to have standing under such circumstances the environmental group "must show . . . [a] particular agency action -- in addition to the agency's refusal to prepare an impact statement -- that . . . caused the injury." *Id.* at 87.

76. *Id.* at 85-87. The case in point was Lujan v. National Wildlife Fed'n, 110 S. Ct. 3177 (1990), *rev'g* National Wildlife Fed'n v. Burford, 878 F.2d 422 (D.C. Cir. 1989). In *Lujan* the plaintiff public interest group argued that it had standing to challenge a Department of Interior land withdrawal program relating to mining and timber ventures. The Court held that the plaintiff did not have standing since the plaintiff failed to delineate with particularity the nature of the injury that the plaintiff was suffering. *Id.* at 3182.

77. *See supra* notes 54-56, 75 and accompanying text.

78. Council Directive of 23 April 1990 on the Contained Use of Genetically Modified Micro-Organisms, 90/219/EEC, 1990 O.J. (L 117) 1.

79. Council Directive of 23 April 1990 on the Deliberate Release Into the Environment of Genetically Modified Organisms, 90/220/EEC, 1990 O.J. (L 117) 15 [hereinafter EEC Directive].

80. *Id.* at 17-18.

81. *Id.* at 18-20.

82. *Id.* at 27.

regulation.[83] Specifically, the EEC directive provides that parties wishing to deliberately introduce genetically modified organisms into the environment must first notify the competent authority[84] within the member state in which they reside.[85] Along with that notification the applicant must supply a comprehensive technical dossier containing the prescribed details of the proposed introduction.[86] Upon receipt of the notification and dossier the competent authority then undertakes a risk assessment and negotiates further details of the introduction with the applicant party.[87] In comparison with the U.S. domestic regulatory schemes for environmental introduction of genetically engineered organisms the reporting requirements of the EEC are much more stringent and comprehensive.[88]

*B. United Nations Committee Report*

One of the topics that was on the agenda of the United Nations Conference on Environment and Development (UNCED)[89] was the environmentally sound management of biotechnology.[90] A preparatory document describing this topic was compiled and published in

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83. *See, e.g.*, Council of European Communities Directive on Classification, Packaging, and Labelling of Dangerous Substances, 67/548/EEC, 1967 O.J. (L 196) 1 (last amended by 91/632/EEC, 1991 O.J. (L 338) 23). This directive is the EEC counterpart to the domestic regulation of hazardous chemicals through TSCA. *See also* Turner T. Smith, Jr. and Roszell D. Hunter, *The European Community Environmental Legal System*, 22 Envtl. L. Rep. (Envtl. L. Inst.) 10,106 (Feb. 1992) (review of the structure and function of the EEC governing system).

84. "Competent authority" is a term of art designating the regulatory agency within each individual EEC member country that has authority to address specific EEC directives.

For example, if the United States were an EEC member country the competent authority within the United States to address EEC directives pertaining to hazardous chemicals would be the EPA. Similarly, the competent authority within the United States to address EEC directives pertaining to regulation of genetically engineered organisms might be the NIH, EPA, USDA, or the FDA, depending on the nature and scope of the EEC directive.

85. EEC Directive, *supra* note 79, at 17, 18.

86. EEC Directive, *supra* note 79, at 17, 18, 23-27.

87. EEC Directive, *supra* note 79, at 17, 18.

88. For example, the EEC directive provides little discretion to the competent authority for defining the criteria through which to regulate biotechnology introductions. EEC Directive, *supra* note 79, at 23-27. In comparison, the domestic frameworks and policy guidance are designed to provide federal agencies with freedom of action within their existing statutory mandates. *See supra* notes 33-43 and accompanying text.

89. The Conference, held in Rio de Janeiro, Brazil from June 3-14, 1992, was commonly referred to as the Earth Summit.

90. The environmentally sound management of biotechnology should not be confused with the maintenance of biodiversity. There is some overlap between the two topics and they were both on the UNCED agenda. However, the maintenance of biodiversity relates primarily to preservation of existing species and wildlife populations in the face of activities such as global deforestation. In contrast, the environmentally sound management of biotechnology relates, as noted herein, to regulatory considerations for controlled introduction of genetically engineered organisms into the environment such that unexpected and detrimental consequences may be minimized.

The maintenance of biodiversity received a substantial amount of publicity at the UNCED meeting when then President Bush refused to allow the American delegation, headed by then EPA Administrator William Reilly, to sign

1991.[91]

The preparatory document notes that there is little commonality in the world-wide regulation of environmental introductions of genetically engineered biotechnology products.[92] Thus, it suggests that the transfer of such products to third world countries, and the testing therein, be addressed on a case-by-case basis.[93] Due to the divergent national and intergovernmental regulatory schemes the document further suggests the need for internationally developed biotechnology safety methodologies concurrent with efforts to further harmonize existing regulations.[94] Finally, the document proposes five fundamental principles for safety in environmental release of genetically engineered organisms.[95]

Since the preparatory document was compiled from various national and intergovernmental documents currently used for regulation of genetic engineering in the U.S. and several other jurisdictions,[96] some of the principles enunciated in the document are analogous to the domestic policy directives discussed above.[97]

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a treaty aimed at preserving global biodiversity. The impediment to approval of the biodiversity treaty related to loss of intellectual property rights that might be experienced by domestic biotechnology businesses as they expand into third world ventures. *See Bush Leaves U.S. on the Sidelines at the Earth Summit*, PUB. UTIL. FORT., July 15, 1992, at 9.

In comparison with the biodiversity issues, the environmentally sound management of biotechnology has received relatively little media attention.

91. *Environmentally Sound Management of Biotechnology: Background and Issues*, U.N. GAOR Preparatory Comm. for the United Nations Conference on Environment and Development, 3d Sess., U.N. Doc. A/CONF.151/PC/67 (1991) [hereinafter *UNCED Document*].

Subsequent official comments and revisions to this document are found in *Environmentally Sound Management of Biotechnology: Report of the Secretary General of the Conference*, U.N. GAOR Preparatory Comm. for the United Nations Conference on Environment and Development, 4th Sess., U.N. Doc. A/CONF.151/PC/100/Add.27 (1992), and *Compilation of Views on the Environmentally Sound Management of Biotechnology*, U.N. GAOR Preparatory Comm. for the United Nations Conference on Environment and Development, 4th Sess., U.N. Doc. A/CONF.151/PC/109 (1992). These latter two documents are reprinted in 2 AGENDA 21 AND THE UNCED PROCEEDINGS 649-76, 949-53 (Nicholas A. Robinson, ed. 1992).

92. *UNCED Document*, *supra* note 91, at 12.

93. *UNCED Document*, *supra* note 91, at 12.

94. *UNCED Document*, *supra* note 91, at 14.

95. *UNCED Document*, *supra* note 91, at 14-16. The five principles are: 1) biotechnology introductions should focus on the organism, not the process by which it was produced; 2) biotechnology releases should be undertaken in a step-by-step fashion, progressing along a cycle from the laboratory, to the greenhouse, to the field test, and finally to the product introduction; 3) the principles of risk assessment and risk management should be used to establish biotechnology product introduction and monitoring protocols; 4) a distinction should be made between confined uses of biotechnology products and environmental releases of biotechnology products; and 5) safety in biotechnology should be addressed through a rigorous framework. *UNCED Document*, *supra* note 91, at 14-16.

96. *UNCED Document*, *supra* note 91, at 18-19. The source documents included directives from the Organization for Economic Cooperation and Development (OECD), the EEC, Great Britain, Australia and the United States. *UNCED Document*, *supra* note 91, at 18-19.

97. *See supra* notes 36-43 and accompanying text.

## VI. Discussion

### *A. Risk Analysis and Decentralized Regulation*

A criterion that pervades the domestic and international regulatory frameworks for controlled environmental introduction of genetically engineered agricultural organisms is the requirement that such introductions proceed through risk assessment and risk management principles.[98] Since risk can liberally be defined in terms of chance or uncertainty,[99] it is clear that risk assessment and risk management are not designed to assure a total absence of harm. Rather, vis-a-vis genetically engineered agricultural organisms, risk assessment and risk management are designed to optimize the benefit of environmental introductions of such products while simultaneously minimizing any detrimental consequences.

In pursuit of this goal, the regulatory frameworks discussed above provide varying degrees of guidance to entities responsible for undertaking genetic engineering risk assessments.[100] In this regard the U.S. federal oversight documents provide comparatively liberal guidance to domestic regulatory agencies.[101]

Due in part to this liberal character, the domestic framework has fostered considerable debate and criticism.[102] Within this debate some commentators have sought to equate genetic engineering risks with risks from other technologies wherein small errors in judgment may result in devastating consequences.[103] The analogy to nuclear power risks is unavoidable.[104] Based upon this analogy some commentators further suggest the need for additional domestic regulatory means specifically designed for genetic engineering.[105] Notwithstanding its appeal, the analogy between genetic engineering and nuclear power risks is probably flawed due to fundamental differences in the types of risks those technologies present.

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98. *See supra* notes 37, 42, 87, 95 and accompanying text.

99. WEBSTER'S NEW COLLEGIATE DICTIONARY 992 (1981).

100. Compare, for example, the Coordinated Framework document (which provides broad policy mandates to domestic regulatory agencies) with the EEC Directive (which provides for specific data requirements pursuant to environmental introductions of genetically engineered organisms). *See supra* notes 36-37, 41-43, 84-87 and accompanying text.

101. *See supra* notes 36-37, 41-43, 84-87 and accompanying text. Although the domestic framework provides liberal guidance regarding the level of authority of regulatory agencies, the agencies must still comply with the congressional directives pursuant to the underlying statutes. These directives may be considerably more conservative. For example, the FIFRA directives for registration of pesticides require substantial data submissions. *See supra* note 29.

102. *See, e.g.*, Thomas O. McGarity, *International Regulation of Deliberate Release Biotechnologies*, 26 TEX. INT'L L.J. 423 (1991); Robert Saperstein, Comment, *The Monkey's Paw: Regulating the Deliberate Environmental Release of Genetically Engineered Organisms*, 66 WASH. L. REV. 247 (1991); Mostow, *supra* note 8.

103. *See* McGarity, *supra* note 102, at 434; Saperstein, *supra* note 102, at 250; Mostow, *supra* note 8 at, 248.

104. *See* McGarity, *supra* note 102, at 434; Saperstein, *supra* note 102, at 250; Mostow, *supra* note 8 at, 248.

105. *See* Mostow, *supra* note 8, at 266-72.

An understanding of the analytical basis for risk analysis helps differentiate genetic engineering risks from risks associated with other technologies such as nuclear power. Within this understanding it is important to recognize that although risk analyses for different technologies need not proceed in similar fashions,[106] similar risk analysis factors may nonetheless apply to those different types of technologies. Within this vein two common risk analysis factors generally applicable to many technologies are: 1) the gravity of the potential detrimental occurrence sought to be avoided, and 2) the probability that the detrimental occurrence will occur.[107]

Analysis of genetic engineering and nuclear power risks within the context of these two factors differentiates the risks posed by those two technologies. Specifically, the gravity component of nuclear power risks is very well understood and quite substantial, while the probability component has proven to be exceedingly small and unpredictable. In contrast, analysis of the same two factors for genetic engineering risks yields the converse result. For agricultural introductions of genetically engineered products the history of product introductions suggests that the gravity component of risk, although not entirely well understood, is typically small. On the other hand the probability component is very high due to the limited containment available for agricultural introductions.

When evaluated in this fashion the validity of a decentralized statutory framework for regulation of genetically engineered agricultural product introductions is more easily justified. Since the consequences of such introductions lack a singular or predictable significance, individually tailored regulatory approaches are likely to be more appropriate. In contrast, decentralized regulatory control over nuclear power, where risks are well known and significant, is inappropriate.

Correlating with this federal policy of decentralized risk based regulation of genetically engineered biotechnology introductions is the continuing judicial deference to regulatory agencies that exercise their authority within congressionally defined bounds.[108] However, Congress has not yet issued any statutory boundaries pertaining to genetic engineering. Thus, agency actions that fall within the existing federal genetic engineering oversight policies are likely to receive substantial judicial deference.

### *B. Policy Analysis of the Product Over Process Formulation*

A second feature common to contemporary regulation of genetic engineering is the maxim that such regulation should be biotechnology product specific, not biotechnology process

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106. *See, e.g.*, Stephen L. Brown, *Harmonizing Chemical and Radiation Risk Management*, 26 ENVTL. SCI. & TECH. 2336 (1992) (contrasting the risk-benefit balancing approach for management of radiation risks and the protectionist approach for management of chemical risks).

107. *See* Paul Slovic, *Perception of Risk*, 236 SCI. 280, 282 (1987). The author treats these two factors as the observable and the controllable factors of risk. *Id.*

108. *See* Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc. 467 U.S. 837 (1984). In *Chevron* the Court held that federal agencies must comply with statutory congressional mandates that are unambiguous. However, if a congressional mandate is either statutorily ambiguous or non-existent an agency's interpretation of congressional intent is given judicial deference. *Id.* at 842-45.

specific.[109] In different terms this maxim states that genetic engineering processes are not per se risky.[110] Although this maxim is less pervasive than the risk analysis precept discussed above, it nonetheless strongly permeates domestic policy.[111]

Analogous to the commentary on applicability of risk assessments to genetically engineered biotechnology products,[112] there exists commentary pertaining to the viability of the product over process formulation as a regulatory criteria for such genetically engineered products.[113] The commentary does not suggest that the product over process formulation is invalid.[114] Rather, it suggests that regulation of genetic engineering should be a political process and that the product over process formulation should not be overextended in the political sphere.[115]

We undoubtedly exist in a political society. However, the federal government functions not only through politics and long term policymaking, but also through intricate daily implementation of policy directives.[116] To facilitate the latter activity, the legislative branch of the government typically delegates these day-to-day activities to administrative agencies.[117]

Although agencies are not immune from the political process, they are, as noted above, afforded substantial judicial deference provided that they operate within statutory directives.[118] In the absence of statutory guidance, agencies are afforded judicial deference if their interpretation of legislative intent is reasonable.[119] Thus, analogously to the discussion of genetic engineering regulation through risk assessment,[120] Congress has also, by its silence, acquiesced in regulation of genetic engineering through executive and agency policy, not through legislative policy. Although Congress may certainly incorporate genetic engineering and biotechnology into a legislative policy agenda, it has not yet chosen to do so.

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109. *See supra* note 43 and accompanying text.

110. *See supra* note 43 and accompanying text.

111. *See supra* note 43 and accompanying text.

112. *See supra* notes 98-108 and accompanying text.

113. *See* Mostow, *supra* note 8, at 238-42.

114. *See* Mostow, *supra* note 8, at 242.

115. *See* Mostow, *supra* note 8, at 242.

116. WILLIAM F. FOX, JR., UNDERSTANDING ADMINISTRATIVE LAW 1 (1986).

117. *Id.*

118. *See supra* note 108 and accompanying text.

119. *See supra* note 108 and accompanying text.

120. *See supra* notes 98-108 and accompanying text.

*C. Availability of Alternate Remedies*

Although genetically engineered agricultural product introductions may be regulated through the statutes noted above,[121] the statutes themselves do not necessarily provide a remedy for a party injured by such an introduction. Fortunately, however, none of the statutes precludes an injured party from pursuing remedies based upon traditional contract or tort causes of action.

Although some commentary in this area suggests the need for additional regulation of genetically engineered bioproducts,[122] other commentary explicitly discusses the applicability of tort remedies.[123] Although the latter commentary acknowledges limitations pertaining to causation, standards of liability, and opportunities for recovery,[124] it also suggests modifications to traditional tort concepts to specifically accommodate biotechnology claims.[125] The comment concludes that such modifications are likely to prove more cost effective than additional regulatory oversight.[126]

Within the context of the above comparison between genetic engineering and nuclear power,[127] it is interesting to note that one obvious example where traditional tort remedies have been modified by federal statutory directives is in the area of nuclear power plant accidents. Through the Price-Anderson Act[128] Congress has specifically defined the maximum compensation level for nuclear accidents.[129] The impetus behind the Price-Anderson mandate was Congress' desire to assuage the electric power industry's perception that the risks of

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121. *See supra* notes 29-32 and accompanying text.

122. *See generally supra* note 105 and accompanying text.

123. Note, *Designer Genes That Don't Fit: A Tort Regime for Commercial Releases of Genetic Engineering Products*, 100 HARV. L. REV. 1086, 1092-1104 (1987) [hereinafter *Designer Genes*]; Barry R. Furrow, *Governing Science: Public Risks and Private Remedies*, 131 U. PA. L. REV. 1403, 1404-06 (1983).

124. *See, e.g., Designer Genes, supra* note 123, at 1094.

125. The modifications include: 1) rebuttable presumptions of causation for biotechnology injuries; 2) minimum requirements for adequate financial resources for biotechnology ventures; and 3) joint and several liability. *Designer Genes, supra* note 123, at 1096-1103.

126. *Designer Genes, supra* note 123, at 1104-05.

127. *See supra* notes 102-104 and accompanying text.

128. Pub. L. No. 85-256, 71 Stat. 576 (1957) (codified as amended in scattered sections of 42 U.S.C.).

129. As initially enacted the Price-Anderson Act provided a maximum of 560 million dollars reparations for any one nuclear accident. The 560 million dollars was comprised of sixty million dollars that electric utilities could raise through available insurance coverage and 500 million dollars that was guaranteed by the federal government. *See* JOSEPH P. TOMAIN ET. AL, ENERGY LAW AND POLICY 392-93 (1989).

More recently, the level of compensation available for nuclear accidents has been increased to approximately seven billion dollars. *See* Keith Kendrick, *Nuclear Claims Changes Envisioned; Panel's Call for Catastrophic Compensation Omits Source of Funds*, WASH. POST, Aug. 21, 1990, at A4.

nuclear power outweighed the economic incentives.[130]

Although other factors may contribute to the analysis, the absence of Price-Anderson incentives for genetically engineered products suggests that neither private industry nor the federal government views genetic engineering risks as economically inordinate.

*D. Organizational Priorities*

As a final commentary this subsection provides a brief review and comparison of the institutional goals and priorities underlying the various regulatory frameworks for environmental introductions of genetically engineered products. Of the regulatory frameworks discussed in this paper the policies of the United States are clearly the most liberal.[131] The EEC directive is the most conservative and cumbersome.[132] The United Nations' activities fall between those of the United States and the EEC. However, they tend to be liberal due to their derivation from United States' policies.[133]

One might generally expect a broad range of national and intergovernmental policies for the regulation of environmental introductions of genetically engineered products. A diversity of such policies does in fact exist. For simplicity, such policies can be divided into three jurisdictional categories based upon the stringency of regulation.[134] The three categories are: 1) jurisdictions which have no regulations directed towards genetically engineered products; 2) jurisdictions which have stringent regulations specifically directed towards genetically engineered products; and 3) jurisdictions having limited regulations where genetically engineered products are controlled through existing legislation or amendments thereof.[135]

Jurisdictions in the first category include some rapidly industrializing third world countries where the primary national goals of economic development and growth often exclude social and environmental policies.[136] Jurisdictions in the second category primarily include some conservative European countries and the EEC.[137] These jurisdictions have highly refined political systems and the regulation of genetic engineering is addressed directly through those

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130. *See* Tomain, *supra* note 129.

131. *See supra* notes 36-37, 39-43 and accompanying text.

132. *See supra* notes 84-87 and accompanying text.

133. *See supra* notes 95-97 and accompanying text.

134. BIOTECHNOLOGY IN A GLOBAL ECONOMY, supra note 20, at 188-89.

135. BIOTECHNOLOGY IN A GLOBAL ECONOMY, supra note 20, at 188-89.

136. BIOTECHNOLOGY IN A GLOBAL ECONOMY, supra note 20, at 189. Jurisdictions in this category include the Pacific Rim countries of South Korea, Singapore, and Taiwan. Presumably, many other third world countries also lack biotechnology regulations (ie: African and South American countries). However, these other countries are distinguished from the Pacific Rim countries since these other countries are not actively engaged in genetic engineering product development, manufacturing, or export.

137. BIOTECHNOLOGY IN A GLOBAL ECONOMY, supra note 20, at 189-94. The countries include Denmark and Germany.

systems as a political issue.[138] Jurisdictions in the last category include many industrialized countries.[139] The distinguishing feature of biotechnology regulation within these jurisdictions is the attempt to base such regulation upon rational scientific and technical principles.[140]

The policies of the United States and the United Nations fit within the last category. The United States' policy of scientifically based genetic engineering regulation comports with federal directives for cost-value based regulations having minimal impact on industrial competitiveness.[141] For the United Nations this regulatory approach comports with institutional interests in providing global society with the benefits of genetically engineered products while simultaneously providing minimal environmental risk.[142]

## VII. Conclusion

Regulation of environmental introductions of genetically engineered agricultural products and processes is an area of internationally diverse policies and priorities. The U.S. domestic policy in this area decentralizes such regulation among existing federal agencies and statutes. Federal policy oversight further provides for cost-value risk based regulation of the nature of the genetically engineered products themselves, not the processes by which the products are produced.

This domestic policy provides a valid and reasoned technical basis for genetically engineered agricultural product regulation. It isolates such products from: 1) over-zealous regulation which might result if biotechnology policies were derived from a purely political process; and 2) inadequate regulation which might result if domestic economic growth and development were emphasized to the exclusion of environmental concerns.

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138. BIOTECHNOLOGY IN A GLOBAL ECONOMY, supra note 20, at 189-91.

139. The countries include Australia, Belgium, Brazil, Canada, France, Japan, The Netherlands, Switzerland, and the United States. BIOTECHNOLOGY IN A GLOBAL ECONOMY, supra note 20, at 194. Also included in this category are the OECD and the United Nations. BIOTECHNOLOGY IN A GLOBAL ECONOMY, supra note 20, at 194; *see supra* notes 96-97 and accompanying text.

140. BIOTECHNOLOGY IN A GLOBAL SOCIETY, *supra* note 20 at 194.

141. *See supra* note 42 and accompanying text.

142. *See UNCED Document, supra* note 91, at 2-3.