Washington Law Review

Volume 66 | Number 1

1-1-1991

The Monkey's Paw: Regulating the Deliberate Environmental Release of Genetically Engineered Organisms

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THE MONKEY'S PAW: REGULATING THE DELIBERATE ENVIRONMENTAL RELEASE OF GENETICALLY ENGINEERED ORGANISMS

Abstract: The deliberate release of genetically engineered organisms poses uncertain but potentially grave risks to the environment. The governing federal and state environmental regulations are inefficient and do not protect environmental integrity. This Comment examines the deliberate release of genetically engineered organisms in the context of federal and state environmental laws. It concludes that the current regulatory schemes are inadequate and proposes changes to meet the goals of effective environmental regulation.

[A]n English working couple comes into possession of a talisman, a monkey's paw said to have been endowed by an Indian holy man with the virtue of granting its owner three wishes. The couple first wish for [a thousand dollars]; shortly thereafter a messenger arrives to inform them that their son has been killed in a factory accident and that his employer has offered [a thousand dollars] out of sympathy. Their second wish is that their son return; it is answered by a strange knocking at the door that the parents somehow know to be their son—but not in the flesh. The tale ends with the couple's third wish, that the ghost go away. The moral . . . from this tale is that all magic . . . "is singularly literal-minded, that if it grants you anything at all it grants what you ask for, not what you should have asked for or what you intend[ed]." The risk is that the resulting flaw in what you get may be less obvious than it was in the case of the monkey's paw—until it is too late.[1]

Genetic engineering is a tool used to manipulate living systems at the molecular level. Technicians now have the power to alter the genetic material of life forms to enhance "beneficial" characteristics, delete "undesirable" characteristics, and even supplement an organism with altogether new characteristics.[2] As applications of this new technology develop commercially, the manipulated organisms are being moved from the laboratory into the environment for testing and assessment. The potential environmental impact is not yet well understood. Now, when commercial development is in its infancy, is a criti-

1. Tribe, *Policy Science: Analysis or Ideology,* 2 PHIL. & PUB. AFF. 66, 102–03 (1972) (citing N. WIENER, GOD & GOLEM, INC., 58–59 (1964) (footnotes omitted)). Technological development has much the same character as the magic of the monkey's paw. If it grants anything at all, it grants what is asked for, not what should have been asked for or what was intended.

2. Applications of genetic engineering techniques stretch into every industrial sector: agriculture, chemicals, pharmaceuticals, hazardous waste clean-up, disease control, animal husbandry, and more. *See infra* notes 7–9 and accompanying text.

cal time to anticipate and to attempt to control the environmental consequences of genetic engineering.

Part I of this Comment discusses genetic engineering and the current regulatory schemes governing the environmental release of genetically engineered organisms. Part II examines these regulatory schemes in the context of three important goals of environmental regulations: protecting the environment, guiding the commercial development of beneficial genetically engineered products, and promoting meaningful public participation in the regulatory decision-making process. Part III recommends changes to the current regulatory schemes to further the goals of environmental regulation.

I. GENETIC ENGINEERING: TECHNOLOGY AND REGULATION

Assessing and incorporating new technologies, such as genetic engineering, into the fabric of community life involves a complex appraisal of scientific ability with respect to societal values. This section discusses various aspects of the technological assessment of the deliberate environmental release of genetically engineered organisms. First, the science of genetic engineering and some current commercial applications are discussed. Then ecological and economic issues associated with the development of genetic engineering techniques are explored. This section concludes with a discussion of the current legislative schemes guiding the development of genetic engineering techniques.

A. Genetic Engineering: The Technology

1. The Science of Genetic Engineering

The term "genetic engineering" describes techniques used to alter the genetic material of a living cell.[3] In genetic engineering, the gene or genes encoded for a desired characteristic are extracted from one organism's genome[4] and integrated into the genome of another organ-

3. *Glossary of Biotechnology Terms,* 1 HIGH TECH. L.J. 253, 255 (1986) [hereinafter *Glossary*]. Physical characteristics are passed from one generation to the next through discrete segments of deoxyribonucleic acid (DNA) called genes. S. WOLFE, BIOLOGY: THE FOUNDATIONS 188 (1977). Genes provide directions for all cellular activity and physical characteristics. Each inherited characteristic is determined by the information in the DNA code. *Id.*

4. The genome is "[t]he basic chromosome set of an organism—the sum total of its genes." *Glossary, supra* note 3, at 255.

ism.[5] This enables the receiving organism to produce a specific product or provides it with a new characteristic.[6]

2. *Commercial Applications: Environmental Release*

Genetic engineering technology is applied, both experimentally and commercially, to most life forms, including humans.[7] Contemplated releases of genetically engineered organisms cover an enormous range of species, environments and intended applications.[8] Applications involving microorganisms are the most diverse of all.[9] Microorganisms are the best—and the most troubling—candidates for application of genetic engineering technology. Because of their size, mobility, and the limited understanding of microscopic ecosystems, there is a very real danger that the release of genetically engineered microorganisms will unintentionally wreak environmental havoc.

3. *Ecological Assessment: Complexity and Risk*

The major environmental concern over the deliberate release of genetically engineered organisms is the potential for unforeseen and

5. For a more detailed discussion of the science of genetic engineering and its applications, see 1 U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY: OWNERSHIP OF HUMAN TISSUES AND CELLS 41–45 (1987) [hereinafter OWNERSHIP].

6. Consider the corn borer, an insect that causes $400 million in damage each year to corn crops, although farmers spend $50 million per year on insecticides to combat it. A toxin produced by the bacteria *Bacillus thuringiensis,* the *B.t.* toxin, is fatal to corn borers. Genetic engineering technicians can remove the *B.t.* toxin gene from *Bacillus thuringiensis* and insert it into a plant-dwelling bacteria. Corn seed is then infused with the genetically engineered bacteria. The toxin-producing bacteria multiplies and carries the toxin throughout the mature corn plant, providing resistance to corn borer damage. Sterling, *Agbio Products Edge Closer to Marketplace,* GENETIC ENGINEERING NEWS, May 1988, at 15. This illustration is a relatively simple application. Most authorities agree that the Pandora's box of genetic engineering is only open a crack. *See* 3 RODGERS, ENVIRONMENTAL LAW: PESTICIDES AND TOXIC SUBSTANCES 500–01 (1988).

7. *See* OWNERSHIP, *supra* note 5, at 31–45. For a more detailed discussion of current commercial applications of genetically engineered organisms, see 3 U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY: FIELD-TESTING ENGINEERED ORGANISMS: GENETIC AND ECOLOGICAL ISSUES 125–33 (1988) [hereinafter ECOLOGICAL ISSUES].

8. For example, researchers are attempting to manipulate plants to increase resistance or tolerance to disease and herbicides, increase nutritional quality, and possibly produce crops capable of growing in extreme drought or saline conditions. ECOLOGICAL ISSUES, *supra* note 7, at 5. Genetic engineering of animals focuses on altering livestock, poultry, and fish to enhance weight gain, growth, reproductive performance, and disease resistance. *Id.* at 6.

9. *See id.* at 7–8. Commercial applications of microorganisms include increasing the nitrogen fixation efficiency of certain bacteria to increase crop yields, enhancing bacterial ability to consume petroleum and hazardous wastes, and conferring insecticidal properties to root-dwelling bacteria to reduce crop losses from insect larvae. *Id.*

long-term detrimental ecological effects.[10] This results from a limited understanding of the enormously complex ecosystems that make up the natural environment.[11] A significant ecological disaster from existing applications is unlikely.[12] Nevertheless, one small, unintentional ecological disruption could be devastating.[13] In the face of technological complexity and uncertainty, agency decisionmakers must assess the risks of environmental release of genetically engineered organisms.[14]

4. Economic Assessment: The Cost of Commercialization

The expected commercial value of genetic engineering techniques and applications is immense.[15] Presently, however, regulations are ambiguous and compliance is both expensive and time-consuming for the biotechnology industry.[16] The complex regulatory structure and lengthy approval processes impede commercialization of genetic engineering technologies without producing corresponding benefits for the environment and public safety.[17]

B. Current Regulatory Structure

1. Federal Regulation: The Coordinated Framework

Currently, six federal agencies regulate biotechnology under the authority of a mosaic of federal statutes, commonly know as the

10. *Id.* at 15.

11. *Id.* at 20. Numerous species of plants, animals and microorganisms form natural communities, interacting in a complex "living dance" which cycles vital nutrients and energy to all living organisms. *Id.*

12. *Id.* According to the Office of Technology Assessment (OTA), significant ecological disruption is unlikely because of "[t]he high degree of functional redundancy among species (particularly microbes) involved with such processes (e.g., nutrient cycles or energy flow) and the resilience and buffering in natural ecosystems." *Id.* at 16.

13. *Id.* at 20.

14. Risk assessment is not new to the scientific or legal community. *See generally* Rodgers, *Benefits, Costs, and Risks: Oversight of Health and Environmental Decisionmaking,* 4 HARV. ENVTL. L. REV. 191 (1980). Although numerous risk assessment protocols have been developed for the release of genetically engineered organisms, none has received wide acceptance. ECOLOGICAL ISSUES, *supra* note 7, at 120.

15. *See Industry and Government Experts Project Bright Future for Biotech at IBA Annual Meeting,* IBA REPORTS, Nov. 1989, at 1.

16. The OTA considers regulatory uncertainty a major factor hampering commercialization of biotechnology. 4 U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY: U.S. INVESTMENT IN BIOTECHNOLOGY 11 (1988) [hereinafter INVESTMENT].

17. Ambiguous regulations influence cost, marketing time, and research and development requirements. *Id.*

"Coordinated Framework."[18] The Environmental Protection Agency's statutory authority is typical of the agencies involved in regulating deliberate release experiments.[19] The EPA uses its existing statutory authority under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)[20] and the Toxic Substances Control Act (TSCA)[21] to regulate deliberate release experiments.[22] The EPA is also constrained by the National Environmental Policy Act (NEPA),[23] which requires federal agencies to consider the potential environmental impact of their actions.

a. Federal Insecticide, Fungicide and Rodenticide Act

FIFRA requires pesticides to be registered with the EPA as a precondition of their distribution or sale.[24] Under FIFRA, the EPA registers the pesticide if it will not cause "unreasonable adverse effects on the environment."[25] Manufacturers must obtain an experimental use permit (EUP) to conduct the small-scale field testing necessary to develop sufficient data for a registration application.[26] Most initial deliberate release experiments involving genetically engineered organ-

18. The Office of Science and Technology Policy's Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (1986) [hereinafter Coordinated Framework]. The six agencies are the: United States Department of Agriculture, Environmental Protection Agency (EPA), Food and Drug Administration, National Institutes of Health (NIH), National Science Foundation, and Occupational Safety and Health Administration. *Id.* at 23,303. The Coordinated Framework is an interagency cooperative agreement designed to integrate the operations of the federal agencies regulating biotechnology. *Id.* at 23,302–03. The Coordinated Framework provides that "agencies will seek to operate their programs in an integrated and coordinated fashion and together should cover the full range of plants, animals and microorganisms derived by the new genetic engineering techniques." *Id.* at 23,303. Under the Coordinated Framework, agency jurisdiction is based primarily on the type and function of the manipulated organism and the intended product use. *Id.* at 23,304.

19. This Comment focuses primarily on the EPA's role. The regulatory policy developed by the EPA is typical of the federal agencies participating in the Coordinated Framework. *Id.* at 23,303.

20. 7 U.S.C.A. §§ 136–136y (West 1980 & Supp. 1990).

21. 15 U.S.C.A. §§ 2601–2671 (West 1982 & Supp. 1990).

22. Coordinated Framework, *supra* note 18, at 23,302, 23,314–15.

23. 42 U.S.C.A. §§ 4321–4370b (West 1977 & Supp. 1990).

24. 7 U.S.C.A. § 136a(a). The FIFRA application is limited to those genetically engineered organisms (or their products) which are intended for use as a "pesticide," as defined by 7 U.S.C.A. § 136(u). *See also,* Coordinated Framework, *supra* note 18, at 23,315.

25. 7 U.S.C.A. § 136a(c)(5)(C)–(D). Under FIFRA, a product causes "unreasonable adverse effects" if it poses an "unreasonable risk" when balanced against "the economic, social, and environmental costs and benefits of the use of [the] pesticide." *Id.* § 136(bb). The specific registration requirements are detailed in 40 C.F.R. § 158 (1989).

26. 7 U.S.C.A. § 136c(a). Traditionally, the EPA exempted EUP requirements for small-scale field tests (those less than ten acres). But the EPA has eliminated this exemption for deliberate release experiments of genetically engineered organisms. Coordinated Framework, *supra* note 18, at 23,320–21.

isms fall within the EUP requirements.[27] Once the applicant complies with EPA reporting requirements for an EUP, the experiment may proceed unless the EPA determines that it will pose an "unreasonable risk."[28] The EPA then reviews the data generated during small-scale field testing. The EPA must register the product unless it can prove that the product poses an "unreasonable risk."[29]

The FIFRA permitting process offers a very limited opportunity for public participation. The EPA publishes applications for EUPs "of regional or national significance"[30] in the Federal Register. A public hearing is possible if there is "sufficient interest."[31]

b. Toxic Substances Control Act

TSCA is the regulatory catch-all statute. TSCA gives the EPA authority to regulate all chemical substances[32] which present an "unreasonable risk of injury to health or the environment."[33] Under the Coordinated Framework, TSCA covers genetically engineered organisms not designed for use as pesticides, and therefore not regulated under FIFRA. With TSCA, the EPA regulates the environmental release of genetically engineered organisms through premanufacturing notification[34] (PMN) and significant new use rule[35] (SNUR) requirements. These require the manufacturer to provide a wide variety of information regarding product efficacy and monitoring.[36] This information enables the EPA to assess the risks associated with the new chemical substance. Simultaneously, the manufacturer must establish a prima facie case for chemical substance safety by submitting any test data regarding the substance's health and environ-

27. Reporting requirements for EUP applications vary depending upon the source of the introduced genetic material relative to the host organism. Coordinated Framework, *supra* note 18, at 23,321–22. The EPA must review EUP applications within ninety days. *Id.* at 23,321.

28. *Id.* at 23,323–24.

29. *See id.* at 23,323–24.

30. 40 C.F.R. § 172.11(a) (1989).

31. *Id.* at § 172.11(b).

32. A chemical substance is defined by statute as "any organic or inorganic substance of a particular molecular identity, including . . . any *combination* of such substances occurring in whole or in part as a result of a chemical reaction." 15 U.S.C.A. § 2602(2)(A) (emphasis added). The EPA claims authority to regulate genetically engineered organisms because "[m]icroorganisms and their DNA molecules are *'chemical substances'*." Coordinated Framework, *supra* note 18, at 23,324 (emphasis added).

33. 15 U.S.C.A. §§ 2603–05.

34. *Id.* at § 2604.

35. *Id.* at § 2604(a)(1)(B).

36. *See* Coordinated Framework, *supra* note 18, at 23,326–27, 23,330. *See also,* 15 U.S.C.A. §§ 2604(a), (b), (d), 2607(b); 40 C.F.R. §§ 720–721 (1989).

mental effects which are in the manufacturer's possession or control.[37] Once the PMN or the SNUR is submitted, the EPA may require the manufacturer to develop further information to aid in predicting health and environmental effects of product use.[38] PMN and SNUR review must be completed by the EPA within 90 days of submission.[39] Once the manufacturer establishes prima facie proof of product efficacy, the EPA has the burden of determining whether manufacturing and releasing the chemical substance presents an unreasonable risk to the environment.[40] The EPA maintains copies of submitted PMNs, with confidential business information deleted, for public review.[41] The public is afforded a 30-day period after the PMN is made available to provide comments to the EPA.[42]

c. *National Environmental Policy Act*

NEPA requires federal agencies to document and consider the potential environmental effects of their actions.[43] NEPA imposes no substantive environmental protection standards. Agency decisionmakers need not give any particular weight to environmental concerns; environmental protection is only one of many factors considered.[44] NEPA's EIS requirements apply to deliberate release experiments where a federal agency has oversight responsibility.[45]

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37. Coordinated Framework, *supra* note 18, at 23,326. *See* 40 C.F.R. § 720.50 (1989); 3 RODGERS, ENVIRONMENTAL LAW: PESTICIDES AND TOXIC SUBSTANCES 375 (1988). PMN requirements for small-scale field testing have been outlined by the EPA. *See* Coordinated Framework, *supra* note 18, at 23,327–28.

38. *See* 15 U.S.C.A. § 2603(a).

39. *Id.* § 2604(c); Coordinated Framework, *supra* note 18, at 23,330 (an additional 90-day extension is available).

40. RODGERS, *supra* note 6, at 375. "[T]he realities of commercial momentum, time lags in the acquisition of studies, the necessities of administrative justification, and difficulties of interpretation may conspire to fix on the agency the lion's share of legal responsibility customarily associated with burden of proof." *Id.* at 376.

41. Coordinated Framework, *supra* note 18, at 23,328.

42. *Id.*

43. The heart of NEPA is section 102(2)(C), codified at 42 U.S.C.A. § 4332(2)(C) (1982). This section directs federal agencies to compile an environmental impact statement (EIS) on every "recommendation or report on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment." *Id.*

44. *See* Kleppe v. Sierra Club, 427 U.S. 390, 410 n.21 (1979).

45. For example, in Foundation on Economic Trends v. Heckler, 756 F.2d 143 (D.C. Cir. 1985), the court enjoined a deliberate release experiment until the National Institutes of Health (NIH) properly complied with EIS requirements. The court required NIH approval because the experiments were conducted at an institution receiving NIH funds for genetic engineering research. 756 F.2d 143, 150 n.3 (D.C. Cir. 1985). Note however, that under the functional equivalency doctrine the EPA is not always required to prepare a formal NEPA EIS. If the EPA action occurs within a regulatory framework that emphasizes consideration of environmental

2. *State Regulatory Schemes: The North Carolina Genetically Engineered Organisms Act*

A few states have supplemented the Coordinated Framework regulatory scheme with additional legislation.[46] North Carolina passed the most comprehensive statute to date.[47] The North Carolina Genetically Engineered Organisms Act (North Carolina Act) is designed "to regulate the release and commercial use of genetically engineered organisms in order to protect agriculture, public health, and the environment."[48] The purpose of the North Carolina Act is to provide a means of assessing "the potential risks and effects of releases of genetically engineered organisms without undue governmental interference with the progress and commercial development of biotechnology."[49] The North Carolina Act prohibits the deliberate release of a genetically engineered organism without prior authorization.[50] Under the North Carolina Act, the permitting process parallels any corresponding federal permit requirements. If necessary, however, the state authority may impose more stringent limitations on the methods and extent of release or even deny, suspend or revoke any permit.[51]

The Genetic Engineering Review Board[52] (the Review Board) is authorized to carry out the provisions of the North Carolina Act.[53] The Review Board consists of ten members: three political appointees from the state Departments of Natural Resources and Community Development, Human Resources, and Agriculture; four representatives from local universities; and one representative each from a public

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issues in a manner similar to that required under NEPA, a formal EIS is not required. *See* RODGERS, *supra* note 6, at 68–70.

46. State legislation addressing the deliberate release of genetically engineered organisms ranges from directing an environmental quality board to study the question, *see, e.g.*, MINN. STAT. §§ 1161C.91–.95 (1988), to requiring concurrent state agency notification when federal pre-release approval is required, *see, e.g.*, ILL. REV. STAT. ch. 111.5, paras. 7601–11 (1988), WIS. STAT. § 146.60 (1988).

47. N.C. GEN. STAT. §§ 106-765 to -777 (1989). The North Carolina Act has been touted as "a watershed in the previous polarization between the biotech industry, academic groups, public interests advocates and government officials regarding environmental biotech issues." Mackler, *ABC Dialog*, GENETIC ENGINEERING NEWS, Nov./Dec. 1989, at 63.

48. N.C. GEN. STAT. § 106-767.

49. *Id.* § 106-765.

50. The North Carolina Act sets forth the requirement for authorization as follows: "[a] genetically engineered organism may not be released into the environment, or sold, offered for sale, or distributed for release into the environment unless a permit for its release has been issued pursuant to this Article." *Id.* § 106-772.

51. *Id.* Violators of the North Carolina Act are subject to a civil penalty of not more than $10,000. *Id.* § 106-776.

52. *Id.* § 106-769.

53. *Id.* § 106-770.

interest organization, a farm organization, and the biotechnology industry.[54]

The North Carolina Act requires public notice of all proposed releases.[55] Any person may request a public hearing, but the Review Board has ultimate control over such requests.[56] In all cases, the Review Board must rule on a permit request within 150 days of application.[57] The North Carolina Act provides for limited public access to confidential business information if required for effective review.[58]

II. THE CURRENT APPROACH TO REGULATING THE ENVIRONMENTAL RELEASE OF GENETICALLY ENGINEERED ORGANISMS: INEFFECTIVE REGULATION

The primary purpose of environmental legislation, in the face of uncertainties like those posed by genetic engineering, should be the preservation of environmental integrity. "Environmental integrity" is the health of the diverse biological and chemical interrelationships which are the fabric of ecological systems. Legislation designed to preserve environmental integrity should have three goals. First, to ensure that agencies properly weigh environmental values, environmental legislation should establish strong substantive standards for environmental protection. Second, because protecting environmental integrity is a community concern, environmental legislation should promote meaningful public participation in regulatory decisionmaking. Finally, environmental legislation should provide a stable, predictable regulatory structure for the commercial development of beneficial technologies.

A. Substantive Environmental Protection and the Current Regulatory Schemes

The current regulatory structure fails to provide substantive environmental protection. At best, the Coordinated Framework adopts a weak "unreasonable risk" standard that strongly favors industry.[59] At

54. *Id.* § 106-769.

55. *Id.* § 106-773. At a minimum, public notice is given through publication in general circulation newspapers in counties where the release is to take place. *Id.*

56. *Id.* If the Review Board determines that there is sufficient public interest to justify a hearing, the hearing is held in the county where the proposed release will occur. *Id.* § 106-773(b).

57. *Id.* § 106-773. This period may be extended with the applicant's consent. *Id.*

58. *Id.* § 106-774.

59. *See supra* notes 25, 33 and accompanying text.

worst, it merely imposes ineffective procedural hurdles to commercial development.[60] Although the North Carolina Act is an earnest step forward, it fails to include adequate substantive criteria in its regulatory structure.

1. Federal Regulation Provides Little Substantive Environmental Protection

The Coordinated Framework does not sufficiently protect the environment. The first problem is that no federal law imposes strong substantive standards. For example, NEPA guidelines are purely procedural. NEPA delineates the steps to an "environmentally informed" agency decision but requires nothing in terms of substantive results. NEPA is indifferent to outcomes provided the agency follows the appropriate procedures.[61] Requiring an EIS merely ensures that an agency considers potential environmental consequences.

The substantive standards in TSCA and FIFRA are weak as well. Manufacturers are not required to prove that a deliberate release of a genetically engineered product will meet an environmental safety standard. Instead, the Coordinated Framework statutes place the burden on the agency to protect environmental integrity using meager substantive standards. For example, TSCA's standard of unreasonable risk, because it is structured to avoid impeding technological innovation, is biased in favor of product approval.[62] The EPA must determine on the basis of the PMN that the substance may present an unreasonable risk.[63] But the EPA is under rigid time constraints to determine the existence of unreasonable risk.[64] If it fails to act within 90 days of PMN submission, with a possible 90-day extension, the unevaluated environmental release may proceed.[65] Therefore, manufacturers have little incentive to develop sufficient data on the environmental risks associated with deliberate release experiments.

60. *See supra* notes 43–45 and accompanying text.

61. Baltimore Gas & Elec. Co. v. NRDC, 462 U.S. 87, 92 (1983). Courts are not free to impose rigorous procedural hurdles as an alternative to substantive review. As the Supreme Court stressed in Vermont Yankee Nuclear Power Corp. v. NRDC, 435 U.S. 519, 523–25 (1978), courts are not free to impose "hybrid" procedures beyond those set out in NEPA and the Administrative Procedures Act. Agency decisionmaking is procedurally confined only by explicit statutory provisions.

62. "TSCA is known as a balancing law, invoking the noncommittal language of 'unreasonable risk' no less than thirty-eight times in a statute of sixty-four pages. . . . TSCA is the only environmental statute to insist that regulation should not impede technological innovation." RODGERS, *supra* note 6, at 372.

63. 15 U.S.C.A. §§ 2603(a), 2605(a).

64. Coordinated Framework, *supra* note 18, at 23,328.

65. *Id.*

Similarly, under FIFRA a manufacturer need not meet a stringent product safety standard, but merely has to show its product has "no unreasonable adverse effects."[66] To deny pesticide registration or an EUP, EPA must evaluate the applicant's data and find that product use would result in "unreasonable adverse effects" on the environment.[67] Under both statutes, environmental protection varies with the quantity and quality of data the agency demands. The utilitarian standards, combined with the limited resources of overtaxed federal agencies, work to the applicant's advantage and against protecting the environment.

Limited judicial oversight further compounds the shortcomings in existing federal law. Courts are reluctant to scrutinize agency decisions involving complex scientific questions beyond the "arbitrary and capricious" standard.[68] In effect, under this standard of review the courts are removed from the decisionmaking process in all but the most extreme cases of abuse of agency discretion. The statute that guides agency decisionmaking must identify explicit substantive environmental protection standards for the courts to reach a substantive environmental safety issue, so that the courts have law to apply. This makes the articulation of environmental safety standards especially important.

2. *The North Carolina Act Fails to Adequately Promote Substantive Environmental Protection*

While the North Carolina Act acknowledges public concern over the unknown risks associated with the environmental release of genetically engineered organisms, it adds little to the substantive environmental protection afforded by the Coordinated Framework. Although the North Carolina Act seems to elevate protection of the environment above the unreasonable risk criteria of TSCA,[69] it timidly places this burden on commercial development. Each mention of environmental protection is offset by language promoting commercial development.[70]

66. *See supra* notes 24–29 and accompanying text.

67. 7 U.S.C.A. § 136a(c)(5).

68. Davis, *The "Shotgun Wedding" of Science and Law: Risk Assessment and Judicial Review*, 10 COLUM. J. ENVTL. L. 67, 97 (1985). *See* Baltimore Gas & Elec. Co. v. NRDC, 462 U.S. 87, 97–98 (1983) (agency "expertise" demands extreme deference by the Court).

69. *See supra* notes 32–40 and accompanying text.

70. The North Carolina Act states, "it is incumbent upon the State . . . to take responsible, timely and minimally burdensome measures to ensure that the public and the environment are protected and that risks from the environmental use of new genetically engineered organisms are promptly addressed, while simultaneously allowing biotechnological research and product development to advance." N.C. GEN. STAT. § 106-765 (1989).

Further, the North Carolina Act fails to specify the duty decisionmakers owe to environmental protection. The North Carolina Act requires that whenever possible the Review Board work "in concert with the federal regulatory authorities," utilizing "forms or formats required by the federal government for actions similar to those regulated under [the Act and] base its decision on the data submitted with the federal application."[71] Thus, the standard of environmental protection under the North Carolina Act depends upon the applicable federal statutory requirements because the evidence a manufacturer must produce to satisfy the regulatory environmental assessment will vary in relation to the federal requirements. Most importantly, the North Carolina Act fails to clarify whether the manufacturer or the agency carries the burden of showing the safety or risk of a proposed release.

B. Public Participation and the Current Regulatory Schemes

Under the Coordinated Framework, communities are powerless in the environmental review and decision-making process. The North Carolina Act provides some improvement over the Coordinated Framework, but meaningful public participation in agency decisionmaking remains limited.

1. Federal Regulation Does Not Promote Meaningful Public Participation in the Environmental Review Process

The existing matrix of federal statutes establishes meaningful participation between manufacturers and the agencies. The process, however, leaves out those most affected by any unforeseen hazards—the local communities. Generally, public comment is invited only through notification of a contemplated release in the Federal Register.[72] Federal statutes do not require agencies to notify local communities of contemplated releases in their area. The Coordinated Framework also includes few mechanisms for direct public intervention and participation in agency review of environmental release permits. The scarcity of mechanisms for participation and the highly technical nature of the issues driving the decisionmaking operate to exclude most community members from meaningful participation in agency decisionmaking.[73]

71. *Id.* § 106-772(b).

72. *See supra* notes 30–31, 41–42 and accompanying text.

73. This has led some environmental groups to reduce grassroots educational efforts and increase internal scientific and legal expertise, further hampering public involvement. *See* Pollack, *Reimagining NEPA: Choices for Environmentalists,* 9 HARV. ENVTL. L. REV. 359, 362–63 (1985).

2. *The North Carolina Act Fails to Adequately Promote Meaningful Public Participation in the Environmental Review Process*

The North Carolina Act improves upon the Coordinated Framework in several ways. First, it provides for community involvement through public notice and comment, and through discretionary public hearings.[74] Second, the North Carolina Act provides a mechanism for access to otherwise confidential business information as long as it is necessary for effective participation in the permit review process.[75] Finally, the North Carolina Act creates a broader decision-making base by mandating a diverse Review Board membership.[76] The broader spectrum of representation on the Review Board may foster more meaningful public participation by expanding the scope of issues considered during rulemaking and permit review.

Although these components improve the Coordinated Framework, the North Carolina Act nullifies one of the few effective tools local communities use to control their immediate environment—the local environmental ordinance.[77] The North Carolina Act requires localities to funnel their concerns into the notice and comment and discretionary hearing procedures rather than allowing more stringent local ordinances. Given the North Carolina Act's weak substantive environmental standards,[78] it is unlikely that the environmental concerns of North Carolina localities will be properly addressed in the permitting process.

C. *The Current Regulatory Effects on Industry*

The balkanized federal jurisdiction and the conglomeration of statutes, regulations, and guidelines under the Coordinated Framework are complex and confusing. Compliance with current regulations unnecessarily wastes industrial resources. The North Carolina Act makes the process more efficient by granting oversight authority to a single agency. The North Carolina Act also provides increased stability by prohibiting regulation below the state level.

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74. *See supra* notes 55–56 and accompanying text.

75. Ultimately, the Review Board determines whether the information should be disclosed. N.C. GEN. STAT. § 106-774 (1989).

76. *See supra* note 54 and accompanying text.

77. *See infra* note 83 and accompanying text.

78. *See supra* text accompanying notes 69–71.

1. *The Coordinated Framework Provides an Unstable Regulatory Environment*

The Coordinated Framework inefficiently regulates technological development. Currently, businesses seeking to move their genetic engineering research and development efforts from the laboratory into the environment must find their way through the Coordinated Framework agency and jurisdictional maze.[79] Unless the various federal agencies coordinate their regulatory efforts and unify their regulatory requirements, variable substantive standards of review will result.[80] This does not promote the predictable, consistent regulatory environment which is essential for industry to develop intelligent testing programs directed toward well-defined standards. An unpredictable regulatory environment wastes resources unnecessarily.[81]

2. *The North Carolina Act Provides a Stable Regulatory Environment*

The North Carolina Act minimizes the regulatory burden on the biotechnology industry by centralizing oversight authority and by prohibiting local regulation of environmental releases. Unlike the balkanized federal scheme, the Review Board under the North Carolina Act is responsible for all proposed environmental releases of genetically engineered organisms. Thus, the Review Board can provide consistent, predictable oversight.

One of the primary deficiencies in risk assessment of environmental releases is the lack of comprehensive field-testing data. As part of the permitting requirements, the Review Board reviews data submitted with corresponding federal permit applications.[82] In effect, the North Carolina Department of Agriculture acts as a clearinghouse for all proposed releases within their jurisdiction. Presumably, the North Carolina Department of Agriculture will develop the expertise to assess proposed releases quickly and competently. As the agency's knowledge grows, its increasing efficiency will benefit industry by making environmental regulations less burdensome and less expensive.

79. Unpredictable regulatory requirements and potential time delays translate into increased costs. *See supra* notes 16–17 and accompanying text.

80. In theory, the Biotechnology Science Coordinating Committee, under the auspices of the Office of Science and Technology Policy, coordinates the agencies associated with the Coordinated Framework. Coordinated Framework, *supra* note 18, at 23,306. The Committee's authority and vitality, however, are questionable. *See* Recommendations of the Administrative Conference of the United States, 1 C.F.R. § 305.89-7 (1990).

81. *See,* INVESTMENT, *supra* note 16, at 11.

82. N.C. GEN. STAT. § 106-772 (1989).

The North Carolina Act also prevents local counties and municipalities from enacting further regulations governing the release of genetically engineered organisms.[83] If local governments in other states feel that federal or state regulators do not provide adequate community protection, they may act to protect themselves. For example, in 1986, despite National Institutes of Health (NIH) and EPA review and a court challenge,[84] the Monterey County, California, Board of Supervisors used a county ordinance to halt a proposed field test.[85] If the federal regulatory structure does not provide adequate environmental protection, local governments may produce even more extensive regulations in the future. Local regulations compound the time and expense required for biotechnology companies to gain approval for deliberate releases. The North Carolina Act prevents local intervention, creating a regulatory climate more conducive to the safe and efficient development of genetic engineering technology.

III. RECOMMENDATIONS FOR COMPREHENSIVE REGULATION

New legislation is needed to correct the shortcomings of the current regulatory framework.[86] The legislation must ensure the protection of environmental integrity through firm substantive standards and review procedures designed to enforce them. New legislation should also include broader mechanisms for community involvement in the agency decision-making process. Finally, review of proposed deliber-

83. Section 106-775 states that "[n]o county or municipality shall enact any regulation or ordinance regulating the release of genetically engineered organisms." N.C. GEN. STAT. § 106-775 (1989).

84. *See* Foundation on Economic Trends v. Thomas, 637 F. Supp. 25, 29 (D.D.C. 1986); Howard, *Halting Designer Bacteria,* NEWSWEEK, Feb. 10, 1986, at 8.

85. The Monterey County ordinance required a local land use permit because of the danger to public health posed by the use of "animals" (bacteria) in the experiment. *See* Sun, *Local Opposition Halts Biotechnology Test,* 231 SCIENCE 667 (1986); A Novel Strain of Recklessness, N.Y. Times, Apr. 6, 1986, at E22, col. 1. The EPA subsequently suspended its approval of the field test and fined the company $13,000 when it discovered that environmental release experiments had been conducted without approval. *See* Sun, *EPA Reduces Penalty Against Biotech Firm,* 232 SCIENCE 1495 (1986). Clearly the Monterey County Board of Supervisors' concern was appropriate.

86. Numerous corrective alternatives have been suggested by other authors. *See, e.g.,* Deatherage, *Scientific Uncertainty in Regulating Deliberate Release of Genetically Engineered Organisms: Substantive Judicial Review and Institutional Alternatives,* 11 HARV. ENVTL. L. REV. 203 (1987) (less deferential standard of judicial review and unified agency authority); Note, *The Rutabaga That Ate Pittsburgh: Federal Regulation of Free Release Biotechnology,* 72 VA. L. REV. 1529 (1986) (clarify agency jurisdiction, stiffen reporting requirements, and create a centralized data bank).

ate releases should be concentrated under a centralized federal authority.

A. Substantive Environmental Protection

The current federal and state regulatory frameworks offer inadequate standards for review of proposed deliberate releases. New legislation must elevate the importance of protecting natural ecosystems in deliberate release decisionmaking. Protecting environmental integrity in the face of the uncertainties associated with the environmental release of genetically engineered organisms should be paramount. A strong presumption toward preserving environmental integrity should be explicit in the statute.

The burden of proving product safety should fall on those who create the risk to the environment.[87] The law cannot realistically require eliminating all risk, but the standard of certainty must shift toward safety and preventing environmental degradation. A minimal risk standard is acceptable.

New legislation should include product "essentiality" criteria. An agency should consider the following three factors: (1) the degree to which application of the new organism may replace other, more environmentally intrusive, technologies; (2) the degree to which the new use causes environmental degradation through increased chemical or pesticide use and other hazards; and (3) the degree to which other less intrusive or more predictable alternatives are available to accomplish a similar function.[88]

These essentiality criteria should be included in NEPA EIS requirements. Consideration of direct and indirect environmental effects, alternatives to proposed actions, and mitigation plans are all elements of environmental impact assessments.[89] The essentiality criteria should be incorporated in the assessment process. Preserving environmental integrity should be the primary value guiding the decisionmaking process. Including essentiality criteria would add strong envi-

87. For example, in 1986, Congress considered a bill that placed the burden on the party applying for a permit under the Coordinated Framework. The appropriate provision stated, "[t]he applicant or permit holder shall at all times have the burden of demonstrating that the activities in question will not constitute an unreasonable risk to human health, welfare, or the environment." H.R. 4452, 99th Cong., 2d Sess., 132 CONG. REC. H1433 (1986) (the Biotechnology Science Coordination Act of 1986).

88. FIFRA specifically excludes an essentiality test from the pesticide authorization process. 7 U.S.C.A. § 136a(c)(5) (1980).

89. *See* 40 C.F.R. § 1502 (1989).

ronmentally protective standards to the Coordinated Framework's scientific criteria.

B. Promoting Meaningful Community Participation

In a democratic system, communities must be able to actively participate with agencies in decisions shaping their environment.[90] Administrative decisionmaking should not merely operate on the public's behalf, but should also encourage public deliberation of such important decisions.[91] New legislation should foster meaningful public participation in agency review of deliberate release experiments.

Participation in agency decisionmaking requires resources and expertise that are not generally available to the public. New legislation should support public interest representation and advocacy.[92] Two possible alternatives for this support are agency appointed counsel[93] and a separately financed organization to represent public interests.[94] Legislation should provide adequate financing,[95] ensure independence from the regulated industry and the regulating agency,

90. Obviously, community participation occurs through the electoral process but environmental decisions are predominantly made at the federal or state agency level. Although new technologies are embraced with little public scrutiny or debate, their adoption may greatly affect the quality of the community environment. *See* Winner, *Technology as Legislation,* in LIFE AFTER '80: ENVIRONMENTAL CHOICES WE CAN LIVE WITH 152, 157 (K. Courrier ed. 1980). Legislation should encourage community participation in assessing new technologies. *See* Sewell & O'Riordan, *The Culture of Participation in Environmental Decisionmaking,* 16 NAT. RESOURCES J. 1, 16 (1976).

91. *See* Reich, *Public Administration and Public Deliberation: An Interpretive Essay,* 94 YALE L.J. 1617, 1637 (1985). For a discussion of the many reasons justifying maximum citizen participation, see McLachlan, *Democratizing the Administrative Process: Toward Increased Responsiveness,* 13 ARIZ. L. REV. 835, 850–52 (1971).

92. Promoting public involvement does not serve environmental protection alone. The public is increasingly suspicious of scientists, more so of "impartial" government agencies, and even more so of industry, especially where ethical and environmental issues are concerned. Empowering local communities bolsters public confidence in the decision-making process and leads to better understanding of the technology itself. Public trust is also built through educating and involving the public. *See* Carter, *The Bellman, the Snark, and the Biohazard Debate,* 3 YALE L. & POL'Y REV. 358, 392–93 (1985); *see also,* Lazarus & Onek, *The Regulators and The People,* 57 VA. L. REV. 1069, 1092–93 (1971).

93. For example, the Interstate Commerce Act gives the Interstate Commerce Commission power to appoint counsel to represent unrepresented groups in their proceedings. 49 U.S.C.A. § 10301(f)(1) (1982). *See also* 15 U.S.C.A. §§ 42, 57(a)(h) (1988) which give the Federal Trade Commission authority to appoint counsel and to provide attorneys' fees. *See generally* Everett, *Financial Assistance For Public Interest Group Participation in Environmental Decisionmaking,* 10 ENVTL. L. 483 (1980).

94. *See* Osborn, *Federal Funds for Public Interest Law: Plausibility, Politics and Past History,* 13 ARIZ. L. REV. 932 (1971).

95. Financing could be maintained by charging the regulated industry for permits.

ensure accountability to the public, and ensure availability of technical expertise for meaningful participation.[96]

Finally, new legislation should ensure that deliberate release rulemaking and permits are managed by a diverse group of specialists. The North Carolina Act, with a diverse Review Board,[97] provides a starting point for federal legislation. The ideal federal regulatory system should be governed by an independent commission representing a broad spectrum of academic specialties and a full range of community interests.

C. *Providing A Stable Regulatory Environment*

The fifty states, with their imaginary boundaries and parochial interests, should not be left to develop piecemeal legislation to control the wide-ranging environmental impacts of the deliberate release of genetically engineered organisms. If genetic engineering technology is as successful as many believe it will be, the federal government should not avoid taking a more active role in guiding its future. The appropriate legislative response should be carried out at the federal level. Nationwide environmental protection must begin with a uniform, safety-conscious regulatory framework. States should be able to supplement this federal legislation when needed to suit their local environment.[98]

Until the federal government provides a comprehensive and effective statutory framework, however, states must act to protect their environment. States should provide an efficient and predictable framework for industrial growth as they address public concern over safety and protecting the environment. Given the reality of genetic engineering technology, state legislatures must reduce the risks of the deliberate release of genetically engineered organisms.

IV. CONCLUSION

The current regulatory framework guiding the development of genetic engineering technology does not meet the goals of effective environmental regulation. State and federal governments must develop effective regulatory strategies while biotechnology is in its infancy. Economic development of beneficial aspects of genetic engineering technology can occur without undue risk to the environment.

96. Lazarus & Onek, *supra* note 92, at 1105.

97. *See supra* note 54.

98. Assessment of a proposed deliberate release should include consideration of the peculiarities of the local environment.

Regulatory approaches need only include a broader perspective. A uniform statutory authority, which includes substantive environmental standards, procedural safeguards, and broad public participation, will most effectively accomplish the goals of environmental regulation of this industry.

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