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MODIFIED RULES FOR MODIFIED BUGS: Balancing Safety and Efficiency in the Regulation of Deliberate Release of Genetically Engineered Microorganisms

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I. INTRODUCTION

In June 1986, the federal government, through the Office of Science and Technology Policy, published its *Coordinated Framework for Regulation of Biotechnology* ("*Coordinated Framework*").[1] Although the new regulations address almost all areas of federal oversight of biotechnology,[2] the primary focus is on the role of federal agencies in regulating the deliberate release of genetically engineered organisms into the environment.[3] The goal of the *Coordinated Framework* was to remove much of the existing confusion about the federal role in regulating biotechnology and to set out a coherent, comprehensive and stable regulatory policy that would allow the biotechnology industry to develop efficiently and safely.[4]

Unfortunately, the *Coordinated Framework* failed to forge a lasting and broad consensus among industry, scientists, government officials and public interest groups about the extent of regulation that was desirable and necessary. In the two years since implementation of the *Coordinated Framework*, there has

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1. OFFICE OF SCIENCE AND TECHNOLOGY POLICY, COORDINATED FRAMEWORK FOR REGULATION OF BIOTECHNOLOGY, 51 Fed. Reg. 23,302 (1986) [hereinafter COORDINATED FRAMEWORK].

2. Biotechnology can be defined generally as the use of living organisms for applied or commercial purposes. As such, biotechnology has been used in a rudimentary form for centuries. However, the development of new techniques in the last 20 years, such as recombinant DNA technology, has resulted in major, qualitative improvements in scientists' ability to manipulate living organisms for useful purposes. *See generally* OFFICE OF TECHNOLOGY ASSESSMENT, IMPACTS OF APPLIED GENETICS (1981).

3. Most of the public and regulatory attention and concern about deliberate release has focused on the introduction into the environment of genetically altered strains of microorganisms as opposed to plants and animals. This paper also will concentrate on this subject. Some environmental uses for which genetically engineered microbes are being developed include protecting plants against frost, improving nitrogen fixation, substituting microbial agents for chemical pesticides, degrading hazardous wastes, and extracting and recovering minerals and oil. *See* Milewski, *Field Testing of Microorganisms Modified by Recombinant DNA Techniques: Applications, Issues, and Development of 'Points to Consider' Document*, 8 RECOMB. DNA TECH. BULL. 102, 103-04 (1985).

4. *See, e.g.*, Sun, *Biotechnology's Regulatory Tangle*, 225 SCI. 697 (1984).

been growing dissatisfaction on all sides of the issue.[5] Many industry representatives have criticized the regulations as too stringent and as an unnecessary impediment to the development of biotechnology products.[6] On the other hand, the proponents of stronger regulations criticize the *Coordinated Framework* as too weak and warn that without adequate safeguards the deliberate release of genetically altered microbes might pose unacceptable risks to the environment and public health.[7] In the words of one observer, "[t]here's no question but the federal regulations as they stand are inadequate from everybody's point of view."[8]

Dissatisfaction with the current regulations crystallized in 1987 as a result of three key "focusing events."[9] The initial noteworthy event was the first authorized field test of microbes produced by recombinant DNA technology,[10] in late April of 1987. Approximately 2,500 strawberry plants on a test plot in northern California were sprayed with a genetically altered microbial strain known as "ice-minus" or "Frostban," which is designed to inhibit frost formation on plants.[11] The first field test took place after several legal challenges[12] and after strong opposition by some local citizens and officials[13] had resulted in many delays. A further delay resulted from revelations that the company developing Frostban, Advanced Genetics Sciences Inc., had illegally tested the microbe on the roof of its corporate headquarters.[14]

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5. *See, e.g.*, Schneider, *Morass of Gene Regulations Leads to Dismay on All Sides*, N.Y. Times, Sept. 29, 1987, at C1, col. 1.

6. *E.g.*, Withers & Kenworthy, *Biotechnology: Can a New Technology Survive*, 31 ST. LOUIS U.L.J. 673, 677 (1987).

7. *E.g.*, Harlow, *The EPA and Biotechnology Regulation: Coping with Scientific Uncertainty*, 95 YALE L.J. 553, 564 (1986); Florio, *Regulation in Biotechnology*, in BIOTECHNOLOGY: IMPLICATIONS FOR PUBLIC POLICY 41, 43 (1985).

8. *See* Stanfield, *Screened Genes*, NAT'L J., Sept. 26, 1987, at 2420, 2421 (quoting Rebecca J. Goldburg, staff scientist, Environmental Defense Fund).

9. The concept of a "focusing event" was described in KINGDON, AGENDAS, ALTERNATIVES AND PUBLIC POLICIES 99-100 (1984) ("a crisis or disaster that comes along to call attention to the problem, a powerful symbol that catches on, or the personal experience of a policy maker").

10. For a summary of genetically engineered microbes in or near the field testing stage, *see* Marx, *Microbes in or Near Field-Testing*, 237 SCI. 1415 (1987). Although initial field tests are commonly referred to as "small" and are confined to a few acres or less, they still involve release of many billions or trillions of altered microbes. *See* Strauss, *How Many Microbes Really Constitute Environmental Release?*, 5 BIO/TECH. 232, 236 (1987).

11. *First Approved Field Test Begins with Genetically Altered Bacteria*, 11 Chem. Reg. Rep. (BNA) 147 (1987).

12. *E.g.*, Foundation on Economic Trends v. Heckler, 587 F. Supp. 753 (D.D.C. 1984), *aff'd in part and vacated in part*, 756 F.2d 143 (D.C. Cir. 1985); Foundation on Economic Trends v. Thomas, 637 F. Supp. 25 (D.D.C. 1986).

13. *See* Sun, *Local Opposition Halts Biotechnology Test*, 231 SCI. 667 (1986) (Monterey county board of supervisors placed a moratorium on the "ice-minus" field test and forced it to be relocated elsewhere.). *See also* Van Brunt, *Environmental Release: A Portrait of Opinion and Opposition*, 5 BIO/TECH. 558 (1987).

14. Hilts, *Test of Altered Microbe Was Illegal, EPA Says*, The Washington Post, Feb. 27, 1986, at A3, col. 3.

Although the first authorized field test of "ice-minus" was apparently a success in terms of the scientific results, the delays and opposition, combined with recent economic trends, have put the whole project in danger.[15] The "ice-minus" experience provided ammunition to both sides in the biotechnology regulation controversy. For public interest groups, the events demonstrated that the industry cannot be trusted to follow regulations and that the federal agencies lack the ability to adequately supervise industry's compliance.[16] From the industry perspective, the public uproar about, and over-regulation of, a product that carried minimal if any risk rendered an otherwise technically feasible product economically unfeasible.[17]

The second major focusing event of 1987 was a short position paper issued by the National Academy of Sciences (NAS) in August which concluded that much of the concern about the risks from the deliberate release of genetically engineered organisms was overstated.[18] The report, written by a panel of five scientists, concluded that there are no "unique hazards" from the use of recombinant DNA techniques, and that the risks associated with the introduction of genetically engineered organisms into the environment are no greater than those associated with unaltered organisms.[19] The report went on to say that many of the planned introductions of genetically engineered organisms "are either virtually risk-free or have risk-to-benefit ratios well within acceptable bounds."[20] Therefore, "strict and rigid controls" for all genetically engineered organisms to be released into the environment "are not justified."[21]

The NAS report, which was widely publicized, appeared to vindicate the view that the risks from deliberate release are overstated, and that the real danger is that excessive regulation could stifle the young biotechnology industry.[22] The report also trig-

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15. Van Brunt, *Release Data Start to Roll In*, 5 BIO/TECH. 1261 (1987); Schneider, *Biotechnology Lags Despite Success*, N.Y. Times, Jan. 18, 1987, at A10, col. 1.

16. *See* Hilts, *supra* note 14.

17. John Bedbrook, vice president for research at Advanced Genetic Sciences, was quoted to say: "If we have to go through a huge amount of effort to educate every community, the cost is going to be beyond us." *See* Schneider, *supra* note 15.

18. NATIONAL ACADEMY OF SCIENCES, INTRODUCTION OF RECOMBINANT DNA-ENGINEERED ORGANISMS INTO THE ENVIRONMENT: KEY ISSUES (1987).

19. *Id.* at 6.

20. *Id.* at 22.

21. *Id.* at 20.

22. *See NAS Warns Against Rigid Biotechnology Controls*, CHEM & ENG. NEWS, Aug. 24, 1987, at 7, 8; Young & Miller, *The NAS Report on 'Deliberate Release': Toppling the Tower of Bio-Babble*, 5 BIO/TECH. 1010 (1987) (Two senior officials of the Food and Drug Administration comment that the "NAS report provides a logical and appropriate path away from irrational overregulation" of biotechnology.).

gered a backlash from public interest groups and some ecologists who attacked both the substance of the report,[23] and the process by which it was written.[24] While intended as an attempt "to assess in a rational manner" the concerns about deliberate release and to present "a balanced review of the issues" for the general public,[25] the NAS study seems only to have inflamed the controversy.

The third major focusing event of 1987 was the unauthorized injection of genetically engineered bacteria into elm trees by a Montana State University plant pathologist.[26] The researcher, Gary Strobel, admitted that he deliberately ignored federal regulations as an act of "civil disobedience" to protest regulations he called "almost ludicrous."[27] Strobel was sanctioned by the Environmental Protection Agency,[28] and his decision to deliberately flout regulations received almost unanimous condemnation.[29] Nevertheless, Strobel's frustration with the complexity and bur-

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23. For example, Florida State ecologist Daniel Simberloff said the report's focus on the similarities between genetically engineered organisms and those altered by traditional methods was "disingenuous" because: "Techniques involving recombinant DNA are capable of doing things that one could never in a million years have entertained doing by traditional techniques. It's so silly to act like nothing new is going on." *See* Dumanoski, *Academy Report Challenged*, Boston Globe, August 24, 1987, at 41, col. 4. Also, three environmental and citizens groups concerned about environmental risks from biotechnology wrote NAS President Frank Press a letter criticizing the report for focusing on "unique" hazards. The letter says this was misleading for two reasons. First, the report did not define what unique hazards are, and therefore it is not clear what kinds of risks have been ruled out. Second, many conventional risks associated with the introduction of exotic organisms may be magnified by biotechnology, and thus present a danger of significant ecological disruption. *See* letter from National Wildlife Federation, Environmental Policy Institute, and Comm. for Responsible Genetics, to Dr. Frank Press, President, National Academy of Sciences (December 3, 1987) [hereinafter National Wildlife Federation] (Copy on file with author).

24. Ecologist David Pimental of Cornell charged that the membership of the five-member panel "was heavily weighted toward genetic engineering," with only one ecologist represented. Dumanoski, *supra* note 23, at 44. Public interest organizations emphasized that a "24 page pamphlet with only ten references does not provide the needed comprehensive analysis," *See* National Wildlife Federation, *supra* note 23.

25. Frank Press, President of the National Academy of Sciences, in Preface to NAS report, *supra* note 18, at 5.

26. *See* Boffey, *Tree Scientist Tests Bacteria, Disobeying U.S. Regulations*, N.Y. Times, Aug. 14, 1987, at A1, col. 1.

27. *Id.*

28. *See EPA Limits Montana Researcher's Work For Unauthorized Release of Bacteria*, 11 Chem. Reg. Rep. (BNA) 917 (1987). The EPA imposed the strongest sanction possible, but this consisted only of prohibiting Strobel from submitting a testing application or notification to the agency for one year, unless co-sponsored by the university, a colleague, or other "responsible" party. One critic warned that the lack of harsh penalties might tempt other scientists to disregard EPA regulations. *Id.*

29. *See, e.g., Researcher Injects Trees Without Obtaining Federal Regulatory Permit*, 6 BIOTECH. L. REP. 379, 383 (1987) (For example, the President of the Industrial Biotechnology Association said his organization was "appalled at the blatant arrogance" of Strobel and that it could "in no way condone this type of law breaking.").

den of the current regulations[30] struck a sympathetic chord with some and led to renewed calls to relax and simplify the federal regulations.[31] At the same time, a coalition of public interest groups warned that Strobel's action brought into question the adequacy of the federal regulations. These groups urged Congress to take "emergency oversight action" to protect public health and the environment.[32]

The events of 1987 have given a strong impetus to the constituencies on both sides of the issue.[33] Substantial disagreement about the appropriate governmental oversight of deliberate release is inevitable given the unique[34] nature of the regulatory approach needed for this technology. For perhaps the first time, a technology is being regulated before any harm has resulted or any risks have become manifest.[35] While sound policy reasons may underlie this "prospective" regulatory approach, the conse-

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30. *See Federal Rules Should Be Uniform, Simple, Montana Researcher Tells Senate Hearing*, 11 Chem. Reg. Rep. (BNA) 1250 (1987) [hereinafter *Federal Rules*]. Strobel wrote: "I am a scientist, not a lawyer. . . . It seems that the biotechnology guidelines, revised guidelines, regulations and laws of various federal agencies are too numerous, and too difficult for the common practicing scientist to effectively understand and follow." Strobel, *Strobel: 'I Have Acted in Good Faith'*, THE SCIENTIST, Oct. 19, 1987, at 11, 12.

31. *See Senate To Hold Hearings on Regulation; Groups Petition Congress for Oversight*, 11 Chem. Reg. Rep. (BNA) 994 (1987); Schneider, *U.S. Imposes Some Curbs on Gene Expert Who Defied Rules*, N.Y.Times, Aug. 28, 1987, at A10, col. 1; *EPA Deciding What Penalty To Seek Against Researcher Who Released Engineered Bacteria*, 11 Chem. Reg. Rep. (BNA) 885 (1987) ("Strobel's actions have given impetus to a growing faction who think that genetically engineered organisms pose little, if any, risk, and that federal biotechnology regulations are too cumbersome. . . .").

32. *See* Letter from the Center for Rural Affairs, Comm. for Responsible Genetics, Conservation Law Foundation of New England, Environmental Policy Institute, Friends of the Earth, The Labor Institute, Montana Environmental Information Center, National Center for Policy Alternatives, Natural Resources Defense Council, Rural Advancement Fund, South Dakota Resources Coalition, and the Texas Center for Policy Alternatives, to James Wright, Speaker, U.S. House of Representatives (Sept. 9, 1987) [hereinafter Center for Rural Affairs] (Copy on file with author).

33. Not everyone is of the opinion that the current regulatory framework needs major revisions. For example, David Glass of BioTechnica International, one of the first biotechnology companies to have a deliberate release proposal go through a full regulatory review by the federal government, thinks the regulations are working as they should. *See* Schneider, *supra* note 5, at C5. Glass has also stated, with respect to the *Coordinated Framework*, that "with a little bit of tinkering, it serves its purposes, and it is a good and useful framework." Interview with David Glass, Director of Patents and Regulatory Affairs, BioTechnica International, Inc. (Dec. 9, 1987) [hereinafter Glass].

34. *See infra* notes 101-25 and accompanying text.

35. *See, e.g.*, statement of Elizabeth A. Milewski, an EPA specialist on biotechnology, in Stanfield, *supra* note 8, at 2421; Hardy & Glass, *Our Investment: What is at Stake?*, ISSUES IN SCIENCE & TECH., Spring 1985, at 69, 80 ("It is worth noting that the proposed regulation of the biotechnology industry is unique. If regulations are imposed, this would be one of the few cases in which an industry has been subject to significant health and safety controls before any hazards have been proved or any industrial accidents have occurred.").

quences of such a strategy are regulatory problems of enormous difficulty and complexity.

After summarizing the current regulations and the major areas of disagreement that have emerged, this Note discusses possible changes both within and outside the current regulatory framework that may help to reduce the current discord. Many of these changes incorporate ideas and initiatives that have recently been proposed and considered by policy-makers and government officials in response to the problems encountered in the first two years of experience with the *Coordinated Framework*. These proposals will likely result in a new round of administrative activity to modify the current regulatory regime.

II. CURRENT REGULATIONS

A. Background

Federal oversight of biotechnology began with the publication of the National Institutes of Health (NIH) Recombinant DNA Guidelines in 1976.[36] The Recombinant DNA Advisory Committee (RAC), composed of experts from a variety of fields and disciplines, was established in 1974 to develop and supervise the NIH Guidelines, and continues to perform this function today.[37] The NIH Guidelines are primarily directed at the contained uses of recombinant DNA organisms. The Guidelines contain three problems which limit their applicability to the regulation of deliberate release.[38] First, the NIH Guidelines are only mandatory for institutions receiving NIH research grants; compliance by industry is voluntary. Second, the Guidelines do not apply to genetically engineered organisms created by traditional methods. Third, the characteristics and risks of deliberate release experiments are significantly different from those conducted in enclosed vessels.[39] As the inadequacy of the NIH Guidelines for overseeing

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36. The original guidelines were published at 41 Fed. Reg. 27,902 (1976). Since then, the guidelines have been repeatedly amended and relaxed, with the most recent version published at 51 Fed. Reg. 16,958 (1986). *See* KRIMSKY, GENETIC ALCHEMY (1982) for a comprehensive review of the events and developments leading up to the issuance of the NIH Guidelines. For a recent discussion of the NIH Guidelines and their application, see Naumann, *Federal Regulation of Recombinant DNA Technology: Time for Change*, 1 HIGH TECH. L.J. 61, 65-70 (1986); Fogleman, *Regulating Science: An Evaluation of the Regulation of Biotechnology Research*, 17 ENVTL. L. 183, 205 (1987); Note, *Inadequacies in the Federal Regulation of Biotechnology*, 11 HARV. ENVTL. L. REV. 491, 496-500 (1987).

37. *Id.*

38. *See* GENERAL ACCOUNTING OFFICE, BIOTECHNOLOGY: AGRICULTURE'S REGULATORY SYSTEM NEEDS CLARIFICATION (GAO/RCED-86-59), March 1986, at 20.

39. *See, e.g.*, McGarity & Bayer, *Federal Regulation of Emerging Genetic Technologies*, 36 VAND. L. REV. 461, 467-72 (1983) (since genetically engineered organisms can be controlled and monitored much more easily with contained uses than deliberate release, the risks involved in the former are much more manageable than those with the latter).

deliberate release became apparent and as preparations for the first field tests began, several federal agencies engaged in a "turf battle" to gain jurisdiction over deliberate release.[40] The result was increased confusion and uncertainty which created strong pressure for a more coordinated regulatory initiative by the federal government.

B. The Coordinated Framework

In an effort to remove the regulatory uncertainty and confusion, the Reagan Administration in April 1984 formed an interagency working group under the White House Cabinet Council on Natural Resources.[41] The group was charged with reviewing current regulations and laws and recommending administrative or legislative actions to clarify and improve the government's regulatory policy.[42] Seventeen federal agencies and executive offices were represented in the working group. The working group published a proposed *Coordinated Framework for the Regulation of Biotechnology* in December 1984[43] followed by a revised final version in June 1986.[44]

The framework consists of a matrix of ten existing statutes administered by five different agencies.[45] Although within the framework each agency will be responsible for developing and administering its own regulations, an attempt will be made to adopt consistent definitions and approaches wherever possible. The jurisdiction to regulate the manufacture or release of a particular biotechnology product is to be determined by a product's use.[46] To

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40. *See* Kriz, *Growing Biotechnology Industry Sparks Governmental Turf Battle Over Federal Regulation of Potential Health and Environmental Risks*, 8 Chem. Reg. Rep. (BNA) 393 (1984).

41. The working group later became the Domestic Policy Council Working Group on Biotechnology through the Office of Science and Technology Policy. *See* COORDINATED FRAMEWORK, *supra* note 1, at 23,302.

42. *See* 49 Fed. Reg. 50,857 (1984).

43. OFFICE OF SCIENCE AND TECHNOLOGY POLICY, PROPOSAL FOR A COORDINATED FRAMEWORK FOR REGULATION OF BIOTECHNOLOGY, 49 Fed. Reg. 50,856 (1984) [hereinafter DRAFT COORDINATED FRAMEWORK].

44. *See* COORDINATED FRAMEWORK, *supra* note 1. For an analysis of the *Coordinated Framework* and the agencies and statutes included in its regulatory matrix, *see generally* Withers, *Biotechnology: An Industry Perspective*, 34 KANSAS L. REV. 665, 668-72 (1986); Fogleman, *supra* note 36, at 229-64; and Note, *supra* note 36, at 495-501, 522-27.

45. The five agencies are the Environmental Protection Agency (EPA), the Department of Agriculture (USDA), the Food and Drug Administration (FDA), the National Institutes of Health (NIH) and the Occupational Safety and Health Administration (OSHA). COORDINATED FRAMEWORK, *supra* note 1, at 23,303.

46. *See* ISSUES IN THE FEDERAL REGULATION OF BIOTECHNOLOGY: FROM RESEARCH TO RELEASE: REPORT PREPARED BY THE SUBCOMM. ON INVESTIGATIONS AND OVERSIGHT OF THE HOUSE COMMITTEE ON SCIENCE AND TECHNOLOGY, 99th Cong., 2nd Sess. 79 (1986) ("FDA reviews foods, food additives, human drugs, medical devices & biologics and animal

the extent possible, responsibility for regulating a specific product will be assigned to a single agency, but when jurisdiction overlaps one agency will be designated the lead agency.[47] An inter-agency Biotechnology Science Coordinating Committee (BSCC) will be responsible for ensuring the coordination and consistency of scientific policy and scientific reviews.[48]

Instead of proposing new statutes carefully drafted to address the specific regulatory challenges of biotechnology, the framework relies on existing laws whose enactment predated the development of the new biotechnologies. This decision was based on convenience and on the difficulty in drafting a single law to encompass the diversity of biotechnology products.[49] Although the published framework addresses the regulation of all biotechnology products, the major focus is on the oversight of deliberate release. The Department of Agriculture (USDA) will be responsible for regulating the deliberate release of plants and animals and some microbes used in agriculture. However, the Environmental Protection Agency (EPA) will be the lead agency for regulating most releases of genetically engineered microbes.[50] Because of its central role, this Note will focus on the EPA's regulation of biotechnology, particularly under the authority of the Toxic Substances Control Act (TSCA).

C. The Toxic Substances Control Act

The EPA announced in the *Coordinated Framework*[51] that it intends to regulate microbial pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA);[52] all other genetically engineered microbes will fall within the EPA's jurisdiction under the TSCA.[53] TSCA provides a "catch-all" authority for regulating deliberate releases not covered by narrower statutes

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drugs. USDA reviews animal biologics, plants, animals, microorganisms with agricultural uses, and potential plant pests. EPA reviews pesticides, microorganisms in contained uses, and microorganisms used for non-agricultural purposes.") [hereinafter ISSUES].

47. *See* COORDINATED FRAMEWORK, *supra* note 1, at 23,303.

48. *See* 50 Fed. Reg. 47,175 (1985).

49. *See* COORDINATED FRAMEWORK, *supra* note 1, at 23,303 ("The existing health and safety laws had the advantage that they could provide more immediate regulatory protection and certainty for the industry than possible with the implementation of new legislation. Moreover, there did not appear to be an alternative, unitary, statutory approach since the very broad spectrum of products obtained with genetic engineering cut across many product uses regulated by different agencies.").

50. For example, according to David Glass of BioTechnica International, the USDA defers to the EPA to take the lead in reviewing most release proposals of genetically engineered microorganisms. Glass, *supra* note 33.

51. COORDINATED FRAMEWORK, *supra* note 1, at 23,314.

52. 7 U.S.C. §§ 136-136(y) (1982).

53. 15 U.S.C. §§ 2601-2629 (1982).

or guidelines and is likely to be the mainstay of the government's regulatory framework.[54] Most microorganisms produced for deliberate release will be regulated under TSCA, including those for "pollutant degradation, enhanced oil recovery, metal extraction and concentration, and certain non-food agricultural applications, such as nitrogen fixation."[55]

The TSCA was passed in 1976 [illegible] perceived gaps in the federal government's authority to control chemical hazards.[56] Existing environmental laws at that time were limited to regulating particular uses or sources of exposure, and the EPA did not have authority to act until after exposure to a toxic substance had occurred.[57] In contrast, the TSCA was drafted to give the EPA broad regulatory power to regulate chemicals from all sources and at all stages of use, including prior to manufacture. This comprehensive regulatory authority made the TSCA the instrument of choice for regulation of biotechnology.[58]

The heart of the TSCA regulatory regime is the requirement that manufacturers submit a "pre-manufacturing notice" (PMN) to the EPA prior to the production or testing of a new chemical substance.[59] The statute specifies that a PMN must include information on the identity, nature, and proposed use of the new substance, as well as any health or safety data "in the possession or control of the person giving such notice."[60] Upon receipt of a PMN, the EPA has ninety days[61] to act in one of three ways. The EPA can do nothing, in which case the substance is placed on the inventory list of existing substances and can be produced and used in any amount, for any purpose, by any manufacturer.[62] Alterna-

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54. *See* Note, *Designer Genes That Don't Fit: A Tort Regime For Commercial Releases of Genetic Engineering Products*, 100 HARV. L. REV. 1086, 1090 (1987) ("[T]he TSCA constitutes the principal federal biotechnology regulatory regime.").

55. DRAFT COORDINATED FRAMEWORK, *supra* note 43, at 50,887.

56. For a review of the history of TSCA and its application to chemicals, *see* THE TOXIC SUBSTANCES CONTROL ACT POLICY RESEARCH PROJECT, LYNDON B. JOHNSON SCHOOL OF PUBLIC AFFAIRS, THE UNIVERSITY OF TEXAS AT AUSTIN, THE TOXIC SUBSTANCES CONTROL ACT: OVERVIEW AND EVALUATION (1982) [hereinafter TSCA PROJECT]. Also, *see generally* Gaynor, *The Toxic Substances Control Act: A Regulatory Morass*, 30 VAND. L. REV. 1149 (1977).

57. *See* TSCA PROJECT, *supra* note 56, at 10.

58. *See, e.g.*, McGarity & Bayer, *supra* note 39, at 537 ("Only the TSCA provides a comprehensive weapon that can target all risks and all stages of production.").

59. 15 U.S.C. § 2604(a) (1982).

60. 15 U.S.C. § 2604(d)(1) (1982). The submitter of the PMN must also include a description of any other data concerning the environmental or health effects of the substance that are "known" or "reasonably ascertainable" to the person making notice. 15 U.S.C. § 2604(d)(1)(C) (1982).

61. 15 U.S.C. § 2604(b)(1)(B) (1982). The review period can be extended by the EPA upon showing of "good cause" for up to an additional 90 days. 15 U.S.C. § 2604(c) (1982).

62. The unrestricted use of chemicals on the inventory list can, however, be limited in two ways. First, other statutes may regulate the production or use of the substance. Second, the EPA can promulgate a Significant New Use Rule under TSCA to require a new PMN for each new use of the substance. 15 U.S.C. § 2604(a)(2) (1982).

tively, the agency may determine that it does not have enough information to make a proper evaluation of the substance's safety, and that the new substance will likely result in significant exposure or *may* represent an "unreasonable risk" to public health or the environment. After making this determination, the EPA can either issue a unilateral order or negotiate a consent order with the manufacturer permitting restricted use of the substance until further data are available to evaluate risks.[63] Finally, the EPA can determine that the substance *will* present an "unreasonable risk," in which case it can restrict or prohibit the production or use of the substance.[64]

The EPA faced several immediate problems in applying the TSCA to the regulation of biotechnology products.[65] The first difficulty is that the TSCA gives the EPA authority to regulate "chemical substances,"[66] and there is some question as to whether living microorganisms developed for deliberate release fall within this definition. Although there are arguments both supporting and refuting the EPA's assertion[67] that genetically engineered microbes are "chemical substances," the balance of evidence seems to support the agency's conclusion.[68] Nevertheless, "this question is ripe for litigation,"[69] especially by a party otherwise dissatisfied with EPA regulatory decisions.[70]

The EPA also faced a problem in defining which altered microorganisms were "new" and therefore thus subject to PMN review. In the draft proposal of the *Coordinated Framework* published in 1984, the EPA proposed to classify all microor-

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63. 15 U.S.C. § 2604(e) (1982).

64. 15 U.S.C. § 2604(f) (1982).

65. For a more thorough discussion of the application of TSCA to biotechnology, *see generally* Schiffbauer, *Regulating Genetically Engineered Microbial Products Under the Toxic Substances Control Act*, 15 ENVTL. L. REP. 10279 (1985); Harlow, *supra* note 7, at 563-69; Vandenbergh, *The Rutabaga That Ate Pittsburgh: Federal Regulation of Free Release Biotechnology*, 72 VA. L. REV. 1529, 1546-49, 1553-58 (1986); and Fogleman, *supra* note 36, at 254-63.

66. TSCA defines "chemical substance" 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 or occurring in nature." 15 U.S.C. § 2602 (2)(B) (1982).

67. *See* DRAFT COORDINATED FRAMEWORK, *supra* note 43, at 50,886-87 for EPA's explanation of why living organisms meet the definition of "chemical substance" as defined in TSCA.

68. *See* Kriz, *supra* note 40, at 396; Schiffbauer, *supra* note 65, at 10,281-82; and Vandenbergh, *supra* note 65, at 1553-55.

69. McGarity & Bayer, *supra* note 39, at 506.

70. For example, in 1983, then-acting Assistant Administrator of the EPA, Donald R. Clay, stated that "[c]ompanies have already promised that they'll sue me if I regulate biotechnology] under TSCA." *Quoted in* Sun, *EPA Revs Up to Regulate Biotechnology*, 222 SCI. 823 (1983). On the other side of the spectrum, biotechnology critic Jeremy Rifkin is considering court challenges to the "statutory underpinnings of EPA's review process" in order to block approved deliberate release experiments. *See* Fox, *The U.S. Regulatory Patchwork*, 5 BIOTECH. 1273, 1274 (1987).

ganisms produced by recombinant DNA and other biotechnologies as "new".[71] This policy was criticized as establishing a double standard whereby a genetically altered organism produced through traditional methods (e.g., treatment with mutation-inducing chemicals) would receive little or no review, while the same modified organism produced by recombinant DNA technology would be subject to regulation under the TSCA.[72] Thus, the proposed approach inappropriately focused on the process used to make the product, rather than the product itself. In response to this criticism, the EPA revised its policy in the final draft of the *Coordinated Framework*. The new policy statement by EPA considered only microorganisms containing genetic material from more than one genus[73] (*i.e.*, "inter-generic") as "new" and therefore subject to PMN notification.[74] The EPA also announced that it would issue a Significant New Use Rule (SNUR)[75] to require a PMN for all "intra-generic" microorganisms that are pathogenic or that contain genetic material from pathogens.[76] Manufacturers of genetically engineered microorganisms containing only non-pathogen genetic material from a single genus will not be required to notify the agency prior to environmental release, but will be subject to the general reporting provisions of the TSCA.[77]

A third problem that EPA faced in "fitting" the TSCA to deliberate release was the provision in the statute that exempted from PMN and SNUR notification requirements those substances produced in small quantities solely for experimentation or research.[78] The EPA determined that this research and development (R&D) exemption was not appropriate for deliberate release of genetically engineered microbes because of the potential for even a "small quantity" of such organisms to reproduce and spread.[79] To implement this change, the EPA announced its

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71. DRAFT COORDINATED FRAMEWORK, *supra* note 43, at 50,887.

72. *See* Sun, *Biotech Policy Draws Flood of Comments*, 228 SCI. 1296 (1985).

73. Living organisms are classified into a hierarchy of categories based on their "relatedness." Organisms are first divided into species, which are reproductively separated from each other. The next level of organization is the genus, which consists of a group of closely related species.

74. COORDINATED FRAMEWORK, *supra* note 1, at 23,325. Inter-generic microorganisms containing only certain well-characterized DNA sequences from a different genus will be exempted from PMN notification.

75. 15 U.S.C. § 2604 (a)(2) (1982).

76. COORDINATED FRAMEWORK, *supra* note 1, at 23,328-29.

77. *Id.* at 23,331. The general reporting requirement will be created through a rule to be issued under TSCA section 8(a). 15 U.S.C. § 2607(a) (1982).

78. 15 U.S.C. § 2604(h)(3) (1982).

79. *See* COORDINATED FRAMEWORK, *supra* note 1, at 23,330 for EPA's rationale for this decision. ("Because of their ability to reproduce and therefore increase beyond the amount originally released, living microorganisms used in the environment cannot be considered to meet the commonly understood meaning of 'small quantities' for research and development, and thus do not qualify for the exemption."). *See also infra* note 117 and accompanying text.

intention to issue a rule specifying that microorganisms will not qualify for the R&D exemption.[80] Until the EPA issues rules regarding an R&D exemption, general reporting requirements for intra-generic microorganisms, and a SNUR requirement for pathogens, the agency is relying on voluntary compliance with these provisions by researchers and companies.[81]

III. PROBLEMS WITH CURRENT FEDERAL REGULATIONS

A. Confusing and Overlapping Jurisdiction

A major criticism of the current *Coordinated Framework* is that its matrix of statutes and agencies results in confusing and overlapping jurisdiction.[82] This can have several undesirable consequences.

1. Uncertainty

A complex regulatory matrix may cause uncertainty among researchers and companies in discerning both the appropriate agency or agencies to apply to and the appropriate regulatory requirements of the individual agencies. Indeed, the unauthorized deliberate release by Gary Strobel has been cited as an example of non-compliance resulting from frustration and confusion with "a sea of regulatory actions by a myriad of federal agencies with conflicting definitions."[83]

The problem is less severe with larger biotechnology companies that have experience in dealing with government regulations and that can hire experts to guide projects through the regulatory maze.[84] University researchers and some small com-

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80. COORDINATED FRAMEWORK, *supra* note 1, at 23,331.

81. The issuing of the new rules has been delayed several times. For example, it was reported in June 1987 that the rules would be issued in November of that year. *EPA To Take Action on Chlorinated Solvents, Formaldehyde, Biotechnology, OMB Report Says*, 11 Chem. Reg. Rep. (BNA) 562 (1987). In October 1987, it was announced that the rules had been delayed again until March 1988. *TSCA Rules Delayed Until March 1988; SNUR, R&D Exemption Proposals Expected*, 11 Chem. Reg. Rep. (BNA) 1159 (1987) [hereinafter *TSCA Rules delayed*]. The most recent estimate of when the rules will be issued is July 1988. Personal communication from Jane Rissler, Biotechnology Project Manager, EPA Office of Toxic Substances.

82. *See, e.g.*, Fox, *Senator Vows New Law*, 5 BIO/TECH. 1264 (1987) (quoting Rebecca Goldburg, Environmental Defense Fund, who described the federal regulatory matrix as a "crazy quilt"); Huber, *Biotechnology and the Regulation Hydra*, TECH. REV., Nov./Dec. 1987, at 57 (the "regulation hydra"); Fox, *supra* note 70 at 1273 (a "patchwork"); and Stanfield, *supra* note 8, at 2420 (a "confusing regulatory tangle").

83. Statement by Gary Strobel, *quoted in Federal Rules*, *supra* note 30. For discussion of the Strobel incident generally, *see supra* notes 26-32 and accompanying text.

84. *See, e.g.*, Schneider, *supra* note 5, at C5 ("Executives of biotechnology companies say they expect to be regulated, and they have hired specialists . . . to keep them abreast of changes in Federal rules and to guide projects through the Government.").

panies are less familiar with government regulation and may have proportionally greater problems in compliance. In fairness, however, the complexity of jurisdiction may not be as great as it appears on first examination, and most biotechnology products do fall into a clearly defined "regulatory slot."[85] Nevertheless, a likely, undesirable consequence of uncertainty over jurisdiction is that some scientists may be deterred from conducting any deliberate release experiments, while others may have experiments delayed as a result of failing to foresee the steps needed to satisfy the regulations.[86]

2. Overlap

A network of overlapping statutes, agencies, and jurisdictions will likely result in unnecessary duplication of efforts. Redundant regulation is especially likely if agencies continue to get into "turf battles" such as those that have unnecessarily delayed some biotechnology products in the past.[87] Such delays could be very expensive for companies and could seriously impede the development of new biotechnology products. The *Coordinated Framework* requires the establishment of a lead agency and consolidated or coordinated reviews in cases of overlapping jurisdiction.[88] Recent experience suggests that, as the agencies have gained experience in working with each other and have developed the necessary procedures for effective coordination, this inter-agency coordination is now working much more smoothly.[89]

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85. *E.g.*, David Glass of BioTechnica has commented: "A lot of people say the Framework is confusing because they don't know which agency to go to. With all due respect, the people who say that are usually in academia or whatever and simply aren't used to dealing with the regulatory system. It really is quite clear that if you have a microorganism with pesticidal properties you go to the EPA.... If you have a drug, you go to FDA. There are some grey areas between them, but it's not that difficult to figure out how to navigate between those." Glass, *supra* note 33.

86. The Strobel case seems to be a situation where the researcher did know of the appropriate regulations at the time of the release, but was not aware of EPA's jurisdiction far enough in advance to allow him to obtain permission before undertaking the scheduled experiment. *See* Boffey, *supra* note 26, at A12.

87. *See, e.g.*, Huber, *supra* note 82, at 58 ("Genentech reportedly encountered needless delays and expenses while USDA and FDA argued for more than a year over which agency should regulate the company's new bovine interferon. The agencies were unable to decide whether the product was a 'veterinary biologic' under USDA's jurisdiction or a 'new animal drug' under FDA's control.").

88. COORDINATED FRAMEWORK, *supra* note 1, at 23,303.

89. *See, e.g.*, Fox, *supra* note 70, at 1277 ("Both EPA and USDA officials say that cooperation between the two agencies has improved recently, so there is a reduced likelihood that deliberate release proposals will provoke interagency turf battles.").

3. Inconsistency

Different agencies may adopt different standards of regulatory review, leading to inconsistent and contradictory decisions. Differences in regulatory approaches between agencies are likely given the different missions and goals of the agencies involved.[90] For example, the approach of the USDA, which has a mandate to promote agriculture in the United States, is likely to be quite different from that of the EPA, a regulatory agency charged with protecting the environment.[91] The BSCC was established as an inter-agency coordination mechanism[92] to encourage individual agencies "to adopt consistent definitions of those genetically engineered organisms subject to review" and to "utilize scientific reviews of comparable rigor."[93] Unfortunately, the failure to agree on clear, common definitions of fundamental terms such as "release into the environment"[94] and "genetically engineered" microorganism has led to confusion and violations of the regulations.[95] The coordinating function of the BSCC was put into a state of uncertainty in late 1987 when political infighting and other events led to unconfirmed reports that the Office of Science and Technology Policy was planning to disband or significantly alter the BSCC in the near future.[96]

The confusion, uncertainty and delays that have resulted from the jurisdictional complexity of the *Coordinated Framework* have been criticized by academics,[97] industry representatives[98] and public interest organizations.[99] However, given the variety of products under development by the growing biotechnology industry, a substantial degree of complexity and variation is inevitable for any comprehensive regulatory regime. In the word of one industry official, "we have a patchwork regulatory structure because the products are a patchwork."[100]

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90. *See, e.g.*, Naumann, *supra* note 36, at 81.

91. For a discussion of the "Regulator/Promotor Dilemma", *see* Note, *supra* note 36, at 529.

92. *See supra* note 48 and accompanying text.

93. COORDINATED FRAMEWORK, *supra* note 1, at 23,303.

94. *See* COORDINATED FRAMEWORK, *supra* note 1, at 23,307.

95. *See generally* ISSUES, *supra* note 46 at 76. For example, the lack of a clear and consistent definition of "release into the environment" created confusion about whether injecting microorganisms into trees and inoculating swine with a genetically engineered live virus constituted "deliberate release."

96. *See* Fox, *supra* note 70, at 1274.

97. *See, e.g.*, Schneider, *supra* note 5, at C5 ("But university researchers, unaccustomed to regulation, are balking at the rules. . . .").

98. *See, e.g.*, Withers & Kenworthy, *supra* note 6, at 692 (Two Monsanto Agricultural Company attorneys urge that "more clarification is needed to avoid unnecessary delay, duplicate reviews, and conflicting regulatory decisions.").

99. *See, e.g.*, Center for Rural Affairs, *supra* note 32, at 1. Twelve public-interest groups claim the current regulations are "confusing, duplicative, and operating without clear Congressional sanction."

100. *See* Glass, *supra* note 33.

B. Disagreement About Risks From Deliberate Release

Views on appropriate levels of regulation are largely determined by assumptions about the risks that need to be addressed. Uncertainty and disagreement about the risks posed by the deliberate release into the environment of genetically engineered microorganisms underlie disputes on all other regulatory issues. Since the number of known introductions of genetically engineered microorganisms into the environment is very limited, there are no significant empirical data for directly estimating the risks presented by this technology.

Much of the current thinking on the risks of deliberate release is based on conceptual "models"[101] and comparisons to existing phenomena. One model frequently used to gauge the risks from deliberate release is based on introductions of foreign species into new environments.[102] While most such introductions do not result in any detectable harm, experience with chestnut blight, dutch elm disease, kudzu vines, and gypsy moths demonstrates that newly introduced species spread and can cause significant ecological disruption and substantial economic damage.[103] A novel organism with new traits created in a laboratory might present a risk similar to that presented by an existing species imported from a different continent.[104] However, the relevance of the introduced species analogy is not universally accepted. Critics of this model argue that genetically engineered microorganisms, unlike foreign species introduced into new environments, will be reintroduced into their native environments and thus will be subject to the same environmental checks and controls as the parental organisms from which they were derived.[105] This argument is in turn weakened by evidence demonstrating that a "small" genetic change can release an organism from its normal constraints, sometimes resulting in a major ecological impact.[106]

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101. *See* Regal, *Models of Genetically Engineered Organisms and Their Ecological Impact*, 10 RECOMB. DNA TECH. BULL. 67 (1987). Ecologist P.J. Regal describes and critiques some ten different conceptual models that have been advanced to predict the risks associated with deliberate release of genetically engineered organisms.

102. Sharples, *Spread of Organisms with Novel Genotypes: Thoughts from an Ecological Perspective*, 6 RECOMB. DNA TECH. BULL. 43 (1982).

103. *Id.* at 50.

104. Regal, *supra* note 101, at 77("An organism with new biological properties will be an exotic element in nature whether its origins are the laboratory or a distant continent.").

105. *E.g.*, NATIONAL ACADEMY OF SCIENCES, *supra* note 18, at 14; *see also* Davis, *Domesticated Bacteria or Andromeda Strains?*, 7 BIOESSAYS 87 (1987).

106. *E.g.*, Sharples, *supra* note 102, at 54. *See also The Potential Environmental Consequences of Genetic Engineering: Hearings Before the Subcomm. on Toxic Substances and Environmental Oversight of the Sen. Comm. on the Environment and Public Works*, 98th Cong., 2d Sess. 138 (1984) (prepared testimony of Daniel Simberloff, Department of Biological Science, Florida State University) (Simberloff reviews several examples of a small, naturally

Another consideration for risk assessment is represented by the numerous past examples of "deliberate release" of bacteria altered by traditional genetic methods such as mutation and selection. For example, large quantities of improved nitrogen-fixing strains of *Rhizobia* have been added to agricultural soils to increase productivity,[107] and some genetically manipulated species of *Thiobacillus* have been used in mining to extract metals from ores[108]–all without any significant negative health or environmental impact. Although new genetic technologies permit major manipulations not possible with the traditional techniques,[109] advocates of deliberate release maintain that many of the genetically engineered microorganisms being developed for deliberate release also can be, or have been, created by the traditional methods.[110] Microorganisms created by the new techniques are altered in a much more direct and precise manner and thus are less likely to exhibit unexpected side effects.[111]

No significant risk has been objectively demonstrated for any planned deliberate release.[112] On the other hand, no planned ex-

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arising genetic mutation resulting in major ecological changes and concludes, "I contend that release of genetically engineered organisms into the environment is clearly part of this continuum. In fact, it is from an ecological standpoint exactly the same as when a new mutant occurs naturally to a native species.").

107. Hardy & Glass, *supra* note 35, at 71.

108. Young & Miller, *Hazards of Genetic Engineering*, 326 NATURE 326 (1987) (letter to editor).

109. *See* Regal, *supra* note 101, at 71 ("Traditional breeding does nothing as ambitious as taking the genes for human interferon and placing them in corn. We also read of attempts to place cattle genes in tomatoes, and other laboratory wonders.").

110. *See* Marx, *Assessing the Risks of Microbial Release*, 237 SCI. 1413, 1413-14 (1987). For example, strains of the "ice-minus" bacteria have been produced by both recombinant DNA technology and conventional mutagenesis and selection. *See supra* notes 11-17 and accompanying text.

111. *Id.* at 1414; Hardy & Glass, *supra* note 35, at 80.

112. Other than general concerns that genetically engineered microorganisms in the environment might spread and transfer their genetic information and possibly cause some dislocation of other species, few realistic scenarios for specific hazards have been postulated. Some specific risks have been speculated upon, with varying degrees of plausibility, but with little supporting data. For example, it has been suggested that the "ice-minus" bacteria might adversely affect the susceptibility to freezing of beneficial insects and native plants. Pimental, *Genetic Engineering for Biological Control: Environmental Risks*, Genewatch (Comm. for Responsible Genetics), Nov-Dec. 1985, at 5, 6 ("What if the new [strain] adversely affects the honeybee, which is the major crop pollinator, responsible for $20 billion worth of crops, as well as diverse native plants?"). Another possible risk is that a genetically engineered *Pseudomonas* strain, being developed for insect control in soil by inserting the toxic element from another bacterial species, may also be pathogenic to various beneficial insects and earthworms. *Id.* at 6. Other concerns include the possibility that bacteria modified to digest oil spills might persist and threaten naturally occurring oil reserves, or that organisms with improved nitrogen-fixation capabilities may inadvertently alter the earth's nitrogen cycle. *See* Deatherage, *Scientific Uncertainty in Regulating Deliberate Release of Genetically Engineered Organisms: Substantive Judicial Reviews and Institutional Alternatives*, 11 HARV. ENVTL. L. REV. 203, 207 (1987). Finally, social and economic harm might result if a biotechnology product that substantially increases agricultural productivity results in a glut of farm products, causing crop

periment has been proven safe. General perceptions of the risks from deliberate release of genetically engineered microorganisms are based almost entirely on conceptual models, hypothetical reasoning, and analogies of questionable validity. It is therefore not surprising that there is so much uncertainty and disagreement about the risks posed by deliberate release.[113]

Given the absence of any useful and proven generalizations about the risks from deliberate release, regulators must rely on case-by-case evaluations in attempting to predict possible hazards. There is no standard battery of tests or risk assessment methodologies for genetically engineered microorganisms, such as there is for toxic chemicals.[114] Regulators try to assess the characteristics and behavior of the microbe with whatever data

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prices to drop and many small farmers to go out of business. McGarity, *Regulating Biotechnology*, ISSUES IN SCIENCE & TECH., Spring 1985, at 40, 43. While these possible risks are very hypothetical, it may be that actual risks from deliberate release are intrinsically unpredictable. *See* THE ENVIRONMENTAL IMPLICATIONS OF GENETIC ENGINEERING: STAFF REPORT PREPARED BY SUBCOMM. ON INVESTIGATIONS AND OVERSIGHT OF HOUSE COMM. ON SCIENCE AND TECHNOLOGY, 98th Cong., 2d Sess. V, at 10 (Feb. 1984) [hereinafter ENVIRONMENTAL IMPLICATIONS]. Industry advocates respond that the specific risks put forward by critics are "highly improbable" and "apocalyptic," and should be used neither to determine a sound regulatory policy nor be allowed to impede the attainment of the potential benefits from uses of modified microorganisms in the environment. Withers & Kenworthy, *supra* note 6, at 677. For example, the "ice-minus" bacteria may significantly reduce the $1.5 billion lost by U.S. farmers each year due to frost damage to crops. Elmer-DeWitt, *Tubers, Berries and Bugs*, TIME, May 11, 1987, at 63. Other engineered microbes, such as those being developed to degrade toxic wastes, may result in a substantial net decrease in risks to health and the environment. *See* Roberts, *Discovering Microbes with a Taste for PCBs*, 237 SCI. 975, 977 (1987). *See also infra* note 124.

113. *See* Alexander, *Ecological Consequences: Reducing the Uncertainties*, ISSUES IN SCI. & TECH., Spring 1985, at 57, 61. At one extreme is the view that there is a substantial certainty of serious harm resulting from modified microorganisms in the environment. *See The Biotechnology Science Coordination Act of 1986: Hearings Before the Subcomm. on Natural Resources, Agricultural Research and Environment and Subcomm. on Science, Research and Technology of the House Comm. on Science and Technology*, 99th Cong., 2d Sess. 96 (1986) [hereinafter *B.S.C. Act*] (Statement of Jeremy Rifkin, President, Foundation on Economic Trends). At the other extreme is the view that genetically engineered microorganisms, with a few exceptions, pose no greater risk than bacterial strains that have been field tested in the past. *See, e.g.*, Davis, *Bacterial Domestication: Underlying Assumptions*, 235 SCI. 1329, 1335 (1987). Perhaps the most accepted position is that the "potential environmental risks associated with the deliberate release of genetically engineered organisms or the translocating of any new organism into an ecosystem are best described as 'low probability, high consequence risk;' that is, while there is only a small possibility that damage could occur, the damage that could occur is great." Environmental Implications, *supra* note 112, at 9.

114. Issues, *supra* note 46, at 88. However, the EPA has significantly increased funding in recent years for a research program to develop a risk assessment methodology for genetically engineered microorganisms in the environment. Marx, *supra* note 110, at 1413. *See also* Levin, Seidler, Borquin, Fowle & Barkay, *EPA Developing Methods to Assess Environmental Release*, 5 BIO/TECH. 38 (1987) [hereinafter Levin].

and information they have available.[115] However, this undertaking is limited by the regulator's inability to predict with certainty how altered genes will interact with the environment. While some risks may become apparent during the risk assessment process, in the end the safety concerns can be resolved only by field testing the altered microorganism. Thus, regulators face a "Catch-22" dilemma. They want to approve only those deliberate release field tests that are safe, but in many cases they will need the results of field tests to determine that a particular microorganism is in fact safe.[116]

This regulatory dilemma has high stakes because, unlike the risk involved with a field test of chemicals, that associated with the field test of a potentially hazardous microorganism might be much greater than the contamination of the few acres of land on which the test is conducted. Genetically engineered microbes are living organisms that may reproduce and spread, so that potential harm might not be limited to the test site.[117] Some industry representatives have disputed the likelihood of this possibility.[118] Experimental evidence indicates that bacterial populations introduced into the environment almost always undergo precipitous decline.[119] Nevertheless, past experience with some introduced foreign species shows that such organisms can reproduce and spread in some circumstances.[120]

Finally, even if a field test is approved and found to be safe, the question remains whether larger-scale commercial applications will also be safe. There is some evidence of a "threshold effect," where populations of organisms of sufficient numbers

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115. The risk presented by a particular genetically engineered microorganism is usually considered to be the product of the probabilities of the following five factors: 1. Will the microorganism survive in the natural environment? 2. Will it proliferate? 3. Will it be dispersed to distant sites? 4. Will its genetic information be transferred to other species? 5. Will the engineered microorganism be harmful? *See* Alexander, *supra* note 113, at 63. Regulators attempt to answer these five questions using data from laboratory and greenhouse tests of the engineered microorganism, the specifics about the new genetic traits and changes that are available, and known facts about the release environment and the behavior of the parental microorganism.

116. *See, e.g.*, Brill, *Safety Concerns and Genetic Engineering in Agriculture*, 227 SCI. 381, 383 (1985).

117. *See, e.g.*, Alexander, *supra* note 113, at 66. *See also supra* note 79.

118. David Glass of BioTechnica stated: "There are chemical and biological limits on how rapidly an organism can grow. . . . You're just not going to see a one acre test plot growing up to eat Cleveland." Glass, *supra* note 33.

119. ALEXANDER, *Spread of Organisms with Novel Genotypes*, in BIOTECHNOLOGY AND THE ENVIRONMENT: RISK & REGULATION 115, 120 (1985). However, in some cases a microorganism artificially introduced into a natural environment can replicate and grow. *Id.* at 120-21.

120. Sharples, *supra* note 102, at 45. The fungus responsible for chestnut blight was brought to the U.S. from Asia in the early 20th century on nursery plants. The fungus has since spread, probably to a large extent through human activities and commerce, and has now almost completely eliminated the American chestnut.

survive while smaller populations do not.[121] In addition to the probability of survival, the scale of usage might also influence the nature of detrimental effects. For example, while systemic hazards, such as alterations in weather patterns and general disruptions of ecological processes, may be insignificant with small-scale field tests, these hazards may become a serious problem when the cumulative effects of many large-scale applications are realized.[122] Another possibility is that undesirable events may have a very low but real probability of occurring in any single release of a particular engineered microorganism, but if the microorganism is tested and used many times the probability of an undesirable event becomes unacceptably high.[123]

The undetermined nature of risks presented by deliberate release, and uncertainty about the scale of usage at which such risks will be manifested, make risk assessment very difficult and controversial. After considering what is known or can be reasonably ascertained about the risks and benefits[124] of a particular release, regulatory agencies are forced to make difficult decisions based on both scientific and value judgments.[125] Such judgments are inevitably subjective, imperfect and vulnerable to criticism. Dissatisfaction, from many points of view, about the procedures, scope, rigor and outcomes of the risk assessment for deliberate release explains much of the current discontent with federal regulatory policy.

C. Regulatory Burden and Adequacy

A growing number of critics believe the federal government's current regulations of deliberate release are either too stringent, representing unnecessary impediments to the biotechnology industry,[126] or too lax, providing inadequate protection for public

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121. Sharples, *Regulation of Products from Biotechnology*, 235 SCI. 1329, 1331 (1987) ("Ecologists have repeatedly observed threshold effects in the abilities of populations to survive. Large and concentrated numbers of organisms above critical population sizes may gain footholds where small populations cannot.").

122. *See* Marx, *supra* note 110, at 1417.

123. *See* Alexander, *supra* note 113, at 64.

124. The benefits of environmental uses of genetically engineered microorganisms are also uncertain; as with risks, they may become clear only with the results of field testing. This creates a serious problem for biotechnology companies, because they must decide to take their deliberate release product through the regulatory matrix *before* they know how well the product's performance in the field meets expectations.

125. For a discussion of the issues raised when regulatory agencies make decisions based in part on uncertainty and values, *see* Harlow, *supra* note 7, at 560; Deatherage, *supra* note 112, at 214-17.

126. *See, e.g.*, Withers & Kenworthy, *supra* note 6, at 677; Federoff, *Impeding Genetic Engineering*, N.Y. Times, Sept. 2, 1987, at A27, col. 1.

health and the environment.[127] While much of the disagreement is based on general perceptions about the risks of deliberate release, there are some specific aspects of regulatory review that have been singled out for criticism.

1. Lack of Permit Requirement

An issue of concern to those who believe the current regulatory regime is too lax is that the TSCA, under which many deliberate release proposals will be reviewed, does not require a permit for approval. Rather, a researcher or company need only notify the EPA of its intentions by submitting a PMN;[128] it is then up to the agency to take some action if it needs more information or has concerns about the proposed release. The burden of proof is on the agency to establish reasons for delaying or prohibiting the planned release[129] and the agency has only 90 days to make the required finding.[130] Therefore, unlike other statutes that require an applicant to demonstrate the product's safety before a permit is granted, the TSCA carries a presumption that the product is safe unless the agency can show otherwise.[131]

Furthermore, the TSCA requires only that applicants submit relevant information in their possession or reasonably ascertainable;[132] the Act does not establish standardized data requirements. Under TSCA, the EPA must make a formal finding that the proposed release may present an "unreasonable risk" or will result in substantial human exposure before the EPA can require additional information.[133] This time-consuming promulgation of rules on a case-by-case basis is likely to be very burdensome, consuming scarce regulatory resources. The process also gives the EPA considerable discretion. There is concern that as the number of submitted proposals grows, as the agency's work load increases, and perhaps as some complacency develops after the first

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127. *See, e.g.*, Wilker & Shulman, *Who Is Protecting the Public's Health?*, 4 BIO/TECH. 824 (1986); Harlow, *supra* note 7, at 563.

128. *See supra* note 59 and accompanying text.

129. *See* McGarity, *Legal and Regulatory Considerations in Environmental Biotechnology Applications*, 8 RECOMB. DNA TECH. BULL. 1, 5 (1985). The EPA generally cannot act under TSCA until the Administrator makes a finding that the product represents an "unreasonable risk." *See, e.g.*, 15 U.S.C. § 2604 (f)(1) (1982). Although the "unreasonable risk" standard is used approximately 30 times in the TSCA, the term is not defined anywhere in the statute. 15 U.S.C. § 2602 (1982).

130. *See supra* note 61.

131. Issues, *supra* note 46, at 84 ("There is a presumption under TSCA that a product is safe unless EPA can show otherwise.").

132. 15 U.S.C. § 2604 (d)(1) (1982).

133. 15 U.S.C. § 2604 (e)(1)(A) (1982). The EPA also has the option of negotiating a consent order with the applicant that limits testing until further information is developed. *See supra* note 60 and accompanying text.

few successful field tests, the EPA will not exercise its discretionary power for selective interdiction as often as it should.[134] This concern has led to suggestions that the TSCA be changed into a statute requiring permits for biotechnology products.[135]

The biotechnology industry appears opposed to alteration of the TSCA into a permitting statute on several grounds.[136] First, the basis for transforming the TSCA into a permitting statute for biotechnology products rests on an *a priori* assumption that there are some special, unique risks associated with such products.[137] Second, changing the regulatory approach would require new forms, rules and standards, thus creating more delays and regulatory uncertainty. Industry representatives question the need for a new approach when there is no evidence that the present PMN system is ineffective.[138] Finally, a permitting approach with standardized requirements might be too rigid with respect to the variety of products submitted for review and with regard to new information obtained over time.

2. *Early Regulatory Intervention*

Industry is concerned that the regulation of biotechnology products will begin at a very early stage in a product's development. The small-scale field testing of genetically engineered microorganisms begins early in the research stages of a potential new product, since such tests are necessary for the company to determine the product's performance.[139] Because it is uncertain at this early stage whether the microorganism will develop into a marketable product, biotechnology companies risk investing substantial time and money meeting regulatory requirements for

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134. *B.S.C. Act*, *supra* note 113, at 261 (statement of Margaret Mellon, then of the Environmental Law Institute) ("Unlike FIFRA, under TSCA EPA can legally simply fail to review organisms. The success of the TSCA program is therefore going to depend on EPA's vigor in exercising its authority in the case of each organism it reviews.").

135. *See, e.g.*, Issues, *supra* note 46, at 92 ("The Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology recommends that "the head of each agency regulating [release of intergeneric organisms and pathogens] should require permits for their release, using existing statutory authority where available, and should seek additional permitting authority from the Congress where necessary."). *See also B.S.C. Act*, *supra* note 113, at 269 (American Chemical Society "supports the concept of a permitting process for those genetically engineered organisms to be released intentionally into the environment.").

136. *E.g.*, *B.S.C. Act*, *supra* note 113, at 70 (statement of Industrial Biotechnology Association); *id.* at 199 (statement of David Glass, BioTechnica Int'l).

137. *Id.* at 69 (statement of Industrial Biotechnology Association).

138. *Id.* at 70.

139. *Id.* at 197 (statement of David Glass, BioTechnica Int'l) ("[G]reenhouse experiments cannot adequately predict a product's performance under the more demanding conditions of the open field. Therefore, companies must generally conduct field tests at a very early stage of product development, and these initial field tests will involve highly preliminary product candidates."). *See also supra* note 124.

a product that may turn out to be unsuccessful. Therefore, government regulation at such an early stage in product development "taxes" research and may stifle innovation.[140] The regulation of small-scale field testing of biotechnology products also places them at a competitive disadvantage relative to chemicals or microbial products produced by conventional genetic techniques.[141] The biotechnology industry is concerned that early regulation will discourage the commercialization of otherwise beneficial and profitable products. Yet, the uncertainty about the risks of genetically engineered microorganisms, even from small-scale field tests, supports the need for early regulation.[142] There is no consensus on how to balance these conflicting economic and safety concerns, and opinions vary depending on the weight and plausibility assigned to each concern.

3. *Burden on Academics*

Academics are those most seriously affected by cumbersome regulatory burdens. University researchers usually do not have the time or expertise to prepare complex application materials for each field test they might wish to conduct.[143] On the other hand, there is concern that the field tests of some academics may not be subject to any governmental oversight at all. University researchers whose investigations are funded by the federal government are regulated by the federal funding agency.[144] However, non-federally funded university research projects involving deliberate release are regulated according to product classifica-

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140. *Id.* ("Placing a large regulatory burden on these limited-acreage preliminary tests would lead to excessive time and cost requirements for safety testing at a very early stage of product development. If this occurs, companies, particularly small ones, must seriously consider whether to continue development of agricultural biotechnology products.").

141. TSCA exempts from PMN review the manufacture and use of "small quantities" of chemical substances for research and development purposes. 15 U.S.C. § 2604 (h)(3) (1982). However, this exemption will be foreclosed for genetically engineered microorganisms intended for use in the environment. *See supra* note 80 and accompanying text. According to one industry official, this decision moves regulation "two to four years back into the research process as to where they were regulating before. This creates a substantial number of risks." Stanfield, *supra* note 8, at 2422 (quoting Will D. Carpenter, Vice President of Technology at Monsanto Agricultural Co.). *See also* Huber, *supra* note 82, at 64 ("A company seeking to develop a genetically altered pesticide, for example, must invest large sums at the very beginning to satisfy agency requirements. But the same manufacturer can test hundreds of conventional chemical alternatives and select only the most promising before having to do battle with local and Washington officials.").

142. *See supra* note 117 and accompanying text.

143. *See* Schneider, *supra* note 5, at C5.

144. For research funded by the USDA, *see* Guidelines published at 51 Fed. Reg. 23,369 (1986). NIH-funded projects involving environmental release will be reviewed by the RAC unless approved by some other federal agency. *See* COORDINATED FRAMEWORK, *supra* note 1, at 23,350.

tion. The EPA would normally regulate many of these release experiments under TSCA. However, the TSCA specifically exempts non-commercial research from PMN review.[145] Therefore, environmental releases of microorganisms under TSCA, conducted by university professors who are supported by non-commercial contracts from private sources, may be completely free of any regulation or notification requirements. Since the risks presented by a particular microorganism are independent of the source of the release, this gap in the regulations may represent a serious loophole if a significant number of privately funded releases meet the criteria for "non-commercial."

D. What to Regulate?

The EPA's policy statement on deliberate release in the federal government's *Coordinated Framework* indicated that the agency would require only inter-generic microorganisms to be reviewed under TSCA's PMN requirements.[146] In addition, the agency intends to issue a SNUR to require review of microorganisms containing genetic material from pathogenic sources.[147]

This scheme of tiered regulation was based on at least two important policy grounds. First, limiting regulation primarily to inter-generic microorganisms avoids double standards that unfairly burden biotechnology products. Genetic alterations within a single species or genetic exchanges between closely related species of the same genus are relatively common in nature, or readily accomplished with traditional genetic techniques.[148] To single out for regulation only those intra-generic microorganisms created by biotechnology would be discriminatory and counter to the *Coordinated Framework*'s philosophy of regulating the product rather than the process.[149] A second reason for the tiered regulatory approach is that, in principle, scarce regulatory resources may be concentrated on those products that present the greatest risks. The EPA asserts that inter-generic combinations of genetic material are more likely to result in new traits and therefore require closer scrutiny because of the potential for un-

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145. *See* 15 U.S.C. § 2604(i)(1982). The EPA is considering the possibility of applying regulatory requirements for "commercial" research to any biotechnology proposal "seeking protection for confidential business information." *See Planned EPA Proposal Would Require TSCA Reporting For All Company Research*, 10 Chem. Reg. Rep. (BNA) 746, 747 (1986).

146. *See supra* note 74 and accompanying text.

147. *See supra* note 75 and accompanying text.

148. COORDINATED FRAMEWORK, *supra* note 1, at 23,317 ("[W]hile genetic exchange occurs naturally and somewhat commonly among many microorganisms, it is more likely to occur in nature within a single genus than across many different genera.").

149. *See id.* at 23,302-03.

expected consequences.[150] The use of genus designations to define which microorganisms will be subject to PMN review has the apparent advantage of providing a clear and convenient dividing line.[151] However, this "bright line" rule may be excluding from review some releases that can cause problems, while subjecting to full regulation many other releases that are very unlikely to have significant risks.[152]

A problem with the current scheme is that taxonomic classification of microbes is inexact and controversial. The concept of "genus" has only a tenuous connection to the natural world. While in many cases higher organisms can be relatively easily assigned to the same genus on the basis of obvious similarities, the grouping of bacterial species into genera is somewhat arbitrary. The assigned boundaries between genera often appear capricious and are subject to change over time. Thus, demarcation lines between genera will often have little relevance for risk assessment.[153]

Even if microbial taxonomy were not so arbitrary, experts who sharply disagree on the risks from deliberate release and the need for regulation do agree on the invalidity of the government's assumption that combinations of distantly related organisms are more dangerous than closely related combinations.[154] Thus, the EPA's reliance on the distinctions between inter-generic and intra-generic combinations is unsound.

E. Insufficient Regulatory Resources

Efficient and effective government oversight of biotechnology, with minimum regulatory burden on industry and maximum protection from potential hazards to the public and the environment, requires availability of adequate regulatory resources. Two of the most important regulatory resources are adequate time and

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150. *Id.* at 23,317 ("EPA's policies will give particular regulatory attention to organisms that have a significant probability of exhibiting a new trait or combination of traits. . . . [C]ombinations of genetic material from microorganisms from different genera are more likely to result in new traits than combinations of genes from microorganisms within the same genus.").

151. *Id.* ("[G]enus designations provide a practical criterion for administrative and regulatory purposes.").

152. *See* Schneider, *supra* note 5, at C5.

153. *See, e.g.*, Davis, *supra* note 113, at 1333.

154. *E.g.*, Bernard Davis, a Harvard bacterial physiologist, and a strong critic of overregulation of biotechnology, concludes that "distant organisms are less (rather than more) likely to yield dangerous hybrids than more closely related ones. . . ." *Id.* at 1335. In an accompanying article, Oak Ridge National Laboratory ecologist Frances Sharples, who is concerned about the possible risks from deliberate release experiments, concurs that "the assertion that gene transfers between species in the same genus will always represent less risk than gene transfers between organisms in two different genera is highly suspect." Sharples, *supra* note 121, at 1331.

adequate staff; the EPA may not have enough of either to properly regulate biotechnology under TSCA.

The TSCA provides for a 90-day review period for PMN submissions. The EPA is able to evaluate chemicals in this short period by comparisons with the known effects of structurally similar chemicals.[155] Similar "quick and dirty" risk assessment techniques are not available for genetically engineered microorganisms, yet the risks involved are much more uncertain and difficult to determine. The EPA currently spends approximately ten times as much staff effort evaluating a biotechnology PMN as it does a chemical PMN.[156] In fact, the first PMN review of a deliberate release proposal under TSCA took approximately seven months, more than twice the usual time allotted by the statute.[157] Even after the EPA staff gains experience and accumulates data, it is questionable whether three months will be adequate for a comprehensive review.[158]

Proposals to increase the review period for biotechnology products to six months or longer,[159] however, would be extremely onerous for the biotechnology industry, especially considering the seasonal nature of many field tests. A genetically engineered microorganism under development for use in the environment must be field tested many times before it will be ready for the market. Many products, especially those intended for use in agriculture, can be tested only at particular times of the year, and test results may not be available for several months. To avoid wasting an entire year, a company or researcher must have time to evaluate the results of a field test conducted in the summer of year one, to incorporate these into a plan and application for a test in the next year, and to have this application reviewed and approved before spring planting in year two.[160] The maximum time allowable for regulatory review in this tight schedule is only about four months.[161] Alternatively, companies would have to wait two years between tests, a potentially prohibitive delay given the number of tests required and the financial pressures on private companies to get products to market.

It would be possible to shorten review periods and avoid backlogs by hiring additional EPA staff. However, the EPA's Office of

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155. *See* Schiffbauer, *supra* note 65, at 10,284.

156. *EPA Struggling With User Fees Rule, OTS Head Says; Consent Orders, PMNs Discussed*, 11 Chem. Reg. Rep. (BNA) 1326 (1987) [hereinafter *EPA*].

157. *See* Schneider, *supra* note 5, at C5.

158. Harlow, *supra* note 7, at 565.

159. *See, e.g.*, NATURAL RESOURCES DEFENSE COUNCIL, COMMENTS ON PROPOSAL FOR A COORDINATED FRAMEWORK FOR REGULATION OF BIOTECHNOLOGY, SUBMITTED TO OFFICE OF SCIENCE AND TECHNOLOGY POLICY, April 15, 1985, at 34; Harlow, *supra* note 7, at 570.

160. *See B.S.C. Act*, *supra* note 113, at 201 (statement of David Glass, BioTechnica Int'l).

161. Glass, *supra* note 33.

Toxic Substances, which administers the TSCA, has traditionally been understaffed,[162] and there are indications that this trend is continuing for biotechnology regulation.[163] Moreover, the situation can only worsen as the number of biotechnology PMN applications increases dramatically over the next few years.[164] An EPA official has already acknowledged that no increases in staff are expected given the problem of the federal budget deficit.[165] There are predictions that "under these circumstances the EPA will either accumulate a backlog of applications, or–more likely–fail to review them adequately."[166] The federal government has attached great importance to the role of biotechnology in contributing to the nation's economy and improving the competitiveness of the United States.[167] If such beliefs are genuine, the federal government should invest the relatively small amount of money needed to ensure an effective regulatory system that will minimize inconvenience and delays to the industry while protecting public health and the environment. In the words of one industry official, "if the government is going to regulate this industry, it should spend the money and do it right."[168]

F. Confidential Business Information

Confidential business information (CBI) is an issue that has not yet emerged as a major area of controversy, but is likely to become increasingly important in the near future. Section 14 of the TSCA provides that PMN submitters can protect trade secrets in their application by employing the CBI designation.[169] With the exception of most health and safety data, CBI cannot be publicly disclosed by the EPA. The agency's administration of the TSCA's

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162. *See Debating EPA's New Chemicals Program: A Forum*, EPA J., June 1985, at 12 (statement of Senator Dave Durenberger).

163. *See Excerpt From OMB Annual Regulatory Program Covering EPA Pesticides, Toxic Substances Programs*, 11 Chem. Reg. Rep. (BNA) 574, 588 (1987).

164. The number of biotechnology PMNs submitted to TSCA is expected to increase from 7 in fiscal 1987, to 15 to 20 in fiscal 1988, and 45 to 50 in fiscal 1989. *See EPA*, *supra* note 156.

165. *Id.*

166. Fogleman, *supra* note 36, at 262 (summarizing statement of Representative James Florio before the Biotechnology Conference of the Brookings Institute, Feb. 18, 1986).

167. *E.g.*, DRAFT COORDINATED FRAMEWORK, *supra* note 43, at 50,856 ("The United States is now the world leader in biotechnology. This leadership is derived from a strong science base, a vigorous entrepreneurial spirit and availability of venture capital. New uses of biotechnology have created intense domestic and international competition. Several other nations have elevated the development of biotechnology to a national priority. The tremendous potential of biotechnology to contribute in the near term, and to fill society's needs and alleviate its problems in the longer term makes it imperative that progress in biotechnology be encouraged.").

168. Glass, *supra* note 33.

169. 15 U.S.C. § 2613 (1982).

CBI provisions requires a delicate balancing between the public's right to know and the protection of genuine trade secrets.[170]

Public disclosure of information contained in PMNs allows independent scientists and public interest groups to monitor the standards and performance of the regulatory agency. This independent oversight can bring attention to flaws or omissions in regulatory decisions and can help build public confidence in both the regulated technology and the regulatory process. Moreover, the oversight function is particularly important for deliberate release proposals because of the substantial uncertainty and subjectivity involved in regulatory decision-making. In theory, the TSCA's requirement for disclosure of health and safety data should provide the information necessary for independent evaluation of proposals. However, in actual practice with chemical PMNs, important information relevant for determining potential hazards is frequently protected from public disclosure.[171] In fact, 1984 statistics indicate that the identification of the chemical was kept confidential in 87% of chemical PMNs, while other information often designated as CBI included company name (70%), plant site (60%), intended use (62%), exposure (42%) and environmental release (33%).[172] Similarly broad claims of CBI in biotechnology PMNs are likely to create increased distrust and opposition to environmental uses of biotechnology products.

Biotechnology companies have legitimate concerns that too much disclosure will allow competitors access to trade secrets, thereby threatening the competitive position of the firm that has developed the product at great expense. Such disclosures will remove the incentive for investment in research and development and diminish the industry's attractiveness to venture capital.[173] Grounds for this fear are provided by statistics indicating that 90% of Freedom of Information Act requests for chemical CBI protected under TSCA were filed by business competitors.[174] The biotechnology industry in particular is vulnerable to economic harm from public disclosure because regulation occurs at such an early stage of product development. Companies will often have to provide information to a federal agency before patent protection is available.[175]

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170. *See generally* Abramson, *Confidential Business Information Versus the Public's Right to Disclosure–Biotechnology Renews the Challenge*, 34 KANSAS L. REV. 681 (1986).

171. According to Senator Dave Durenberger, "Virtually all risk-relevant data that are included in premanufacture notices are screened from public view by the industry's blanket claims of confidentiality." *See supra* note 162, at 12.

172. EPA statistics, *reproduced in* Durenberger, *No 'Bright Line' Possible by Law; But Too Much CBI Designated Too Casually*, ENVTL. FORUM, July 1984, at 18, 20.

173. Withers & Kenworthy, *supra* note 6, at 696.

174. *See* Hussey, *Confidentiality Under TSCA: Industry's Perspective*, ENVTL. FORUM, July 1984, at 19, 22.

175. *See* Withers & Kenworthy, *supra* note 6, at 694-95.

As of the date of this writing, the CBI issue has not emerged as a major controversy because the first few biotechnology PMNs contained very little or no CBI.[176] However, this situation will probably change within several years as more products approach the field testing stage.[177] The EPA has announced that it intends to be much stricter in accepting CBI claims with biotechnology PMNs than it has been with chemicals. Furthermore, agency officials will ask firms to substantiate confidentiality claims much earlier in the review process.[178] However, it is uncertain whether the EPA's new policy will, or can, satisfy the purposes and interests of both the industry and public interest organizations.

IV. ALTERNATIVES OUTSIDE THE CURRENT REGULATORY REGIME

A. Tort System

One possibility for avoiding many of the problems with current federal regulations is to replace the regulatory schemes with greater reliance on the tort system to control deliberate release.[179] Although courts have not yet had to deal with any accidents or harm from environmental uses of genetically engineered microorganisms, they likely would, and probably should, impose a strict liability standard on such damages.[180]

The tort system has several advantages as compared to the federal regulatory system.[181] Instead of relying on uncertain and disputed predictions of risks, the tort system would address actual harms. Companies would be allowed to proceed with releases they considered to be safe, but would be required to compensate victims for any damages that result. Tort liability would provide an incentive for companies to do background safety research on

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176. *EPA Wants Few Confidentiality Claims for PMN Submissions, Agency Official Says*, 11 Chem. Reg. Rep. (BNA) 941 (1987).

177. David Glass of BioTechnica predicts: "In the first few years of biotechnology you will probably see companies being fairly open . . . but it will reach a point where, for example, if we're going to go to the field with twelve different (genetic) constructs, we might want to tell the world what we're working on but we're certainly not going to tell the world anything about why those constructs are different from each other. Whether you need to know that to do a good health and safety assessment I don't know." Glass, *supra* note 33.

178. *EPA Wants Few Confidentiality Claims for PMN Submissions, Agency Official Says*, *supra* note 176.

179. *See* Note, *supra* note 54, at 1096 (A modified tort system for regulating environmental releases of genetically engineered products is proposed.).

180. *See* Gilmore, *Creation of Life: A New Frontier for Liability?*, 13 PAC. L.J. 99, 102-13 (1981); Dahl, *Strict Product Liability For Injuries Caused by Recombinant DNA Bacteria*, 22 SANTA CLARA L. REV. 117, 127-34 (1982); Huber, *supra* note 82, at 63; Note, *supra* note 54, at 1094-96.

181. *See generally* Note, *supra* note 54, at 1093.

potential hazards and to develop safeguards to control and minimize risks. Since manufacturers have the experts and information to evaluate products and risks, they are in the best position to determine the optimal level of precautions.[182] It is both inefficient and costly for government agencies to duplicate this information and expertise in order to make regulatory decisions. Since the tort system would apply to any genetically engineered microorganism that causes harm, there would be no need to go through the difficult and controversial process of developing risk categories (for example, by making questionable distinctions between inter-generic and intra-generic organisms). Furthermore, with a tort system, biotechnology companies would not have to risk trade secrets by submitting confidential information to reviewing agencies. Finally, the burden of regulating products at a very early stage in development would be removed.

Despite these apparent advantages, the use of the tort system to regulate deliberate release would likely create more problems than it would solve. First, it may be nearly impossible to identify victims and to prove causation of harm from genetically engineered microorganisms released into the environment.[183] For example, an environmental release might cause some indigenous species to be displaced or destroyed.[184] Such ecological disruptions might not result in any direct or immediate harm to humans, and yet it is probably widely believed that such changes are undesirable, either on a *per se* basis or because of the possibility of unforeseeable, long-term and detrimental consequences to humans. In the absence of immediate and direct victims, there is little likelihood that individuals would initiate tort suits, although public interest organizations may at least have standing to do so.[185]

Someone who is harmed faces several obstacles in establishing the liability of the company that released the hazardous microorganism. Consider a hypothetical case of an individual farmer whose crop yields are reduced one year as a result of below average rainfall. Assume, as has been speculated, that widescale use of the "ice-minus" bacteria may alter rainfall patterns,[186] and

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182. Of course decisions made by experts in the best position to determine the optimal level of safety are not always found to be socially or legally acceptable. *See, e.g.*, Grimshaw v. Ford Motor Co., 119 Cal.App.3d 757, 174 Cal. Rptr. 348 (1981) (Ford Motor Company's cost-benefit analysis of the Pinto's fuel tank design represented "callous indifference to public safety.").

183. *See generally* Gilmore, *supra* note 180, at 113-20; Dahl, *supra* note 180, at 135-37; Note, *supra* note 54, at 1094.

184. *See* Sharples, *supra* note 121, at 1329.

185. *See generally* Sierra Club v. Morton, 405 U.S. 727 (1972); United States v. Students Challenging Regulatory Agency Procedures, 412 U.S. 699 (1973).

186. *See* Marx, *supra* note 110, at 1417.

that repeated uses of an "ice-minus" strain by a company in the neighboring state were responsible for the reduced rainfall on the farmer's land. Unless informed otherwise, the farmer will probably blame the reduced rainfall on seasonal variation and will not even consider the possibility that a genetically engineered microbe was responsible. Even if the farmer does suspect the true cause, he is still faced with the difficult problem of proving causation.[187] He must also prove that a particular company was responsible for his harm, even though several different companies may be using similar products in his part of the country.[188] In addition to all these problems, the transaction costs of initiating a suit for tort damages may be prohibitive.

If the farmer somehow manages to establish liability on the part of the responsible company, he may still have a problem recovering damages. Many biotechnology companies are new, and relatively small, and may not have sufficient assets to withstand a large damage claim.[189] The problem of judgment-proof firms is exacerbated by the unavailability of liability insurance for companies undertaking releases of genetically engineered microorganisms into the environment.[190] It may be even harder for a victim to recover damages if the liable party should happen to be a university professor rather than a private company.

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187. It has been proposed that the burden on the plaintiff to prove causation be reduced by setting up a system of presumptions. Note, *supra* note 54, at 1098. According to this proposal, a "government regulatory agency should be charged with drawing up a list of types of illnesses and other phenomena that are known to be associated, with specific probability, with the results of genetic engineering experiments. . . . A schedule of probabilities could be constructed for each type of release." If a harm included in the schedule occurs, a plaintiff would be entitled to recover from the biotechnology manufacturer the percentage of his damages that corresponds to the probability of causation according to the appropriate schedule. This proposal seems unworkable, at least at this time. No specific hazard has been demonstrated for any genetically engineered microorganism being developed for environmental release, and a scientific basis for quantifying such risks is completely lacking.

188. The problem of identifying the proper defendant may be solved if the court adopts the approach of Sindell v. Abbott Laboratories, 26 Cal.3d 588, 607 P.2d 924 (1980), allocating liability in proportion to market share.

189. *See* OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONG., COMMERCIAL BIOTECHNOLOGY: AN INTERNATIONAL ANALYSIS 97 (1984); Harlow, *supra* note 7, at 556.

190. It has been almost impossible for biotechnology companies to obtain liability insurance for environmental uses of genetically engineered products. *See Releasing Genetically Engineered Organisms Into the Environment: Hearings Before the Subcomm. on Toxic Substances and Environmental Oversight of the Senate Comm. on Environment and Public Works*, 99th Cong., 2d Sess. 19 (1986) (One company was offered a $1 million policy for a $400,000 annual premium.). *But see Product & Professional Liability Insurance for Biotechnology Products Now Available*, 6 BIOTECH. L. REP. 404 (1987) (The Association of Biotechnology Companies has announced that it has secured, after lengthy negotiations, product and professional liability insurance for biotechnology products, including those released into the environment.).

There are other problems with reliance on the tort system to regulate deliberate release. Since the risks from deliberate release are so uncertain, it is very important that initial field tests are closely monitored for evidence of possible hazards. While a government regulatory program can require such monitoring in all cases, reliance on common law remedies would leave decisions about monitoring to companies. If some companies chose neither to monitor nor to conduct adequate risk assessments, some otherwise discoverable hazards will not become apparent until long after the product has been put into wide use and great harm has resulted.[191] Finally, since living microorganisms have the potential to survive, reproduce and spread, hazardous releases may result in irreparable changes to the ecosystem.[192] For these reasons, use of prospective review to discover and eliminate risks in advance will be more effective than retrospective attempts to remedy harm after it has occurred.

Not only would the tort system fail to achieve optimum risk levels, but it would have other failings in comparison to government regulation. An important secondary function of government regulation of biotechnology is to build public confidence in the safety of the new industry,[193] a function tort liability is less likely to achieve. In fact, waiting for an accident to occur before intervening could be disastrous. Any serious harm would undermine public and investor confidence and would set the industry back many years.[194] A final concern is that reliance on the courts to regulate biotechnology may invite a flood of spurious claims which, even if unsuccessful, would impose a debilitating burden on the industry.[195] In summary, while tort remedies may be avail-

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191. *See* McGarity & Bayer, *supra* note 39, at 478.

192. *See* Robbins, *Release of Genetically Engineered Organisms*, Genewatch (Comm. for Responsible Genetics), May-August 1984, at 1, 14 ("The cost of being wrong about a chemical could be calculated. One could estimate how many people would be exposed and understand the consequences of a false negative test, where we treated a truly hazardous chemical as if it were safe. The dangers associated with false negatives in predictive ecology testing might be far more severe, because the ultimate damage might be irreversible. With chemicals the epidemiology eventually becomes evident and in time to limit the damage. No such action may be possible when an organism has become a permanent part of the world ecosystem.").

193. *See* Stanfield, *supra* note 8, at 2420 (quoting Peter Carlson of Crop Genetics International Inc.) ("Regulations are an independent demonstration that what we're doing is safe and [will] put to bed a lot of public trust issues that we have to deal with."). *See also* Tangley, *New Biology Enters a New Era*, 35 BIOSCI. 270, 274 (1985). The public does seem concerned about potential risks from environmental uses of genetically engineered microorganisms. According to one survey, nearly 70% of the public thinks it is very or somewhat likely that genetically manipulated bacteria capable of reproducing will pose a danger to the environment. *See* OFFICE OF TECHNOLOGY ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY: PUBLIC PERCEPTIONS OF BIOTECHNOLOGY 63 (1987).

194. *See* Stanfield, *supra* note 8, at 2422.

195. *See* Huber, *supra* note 82, at 64.

able if any harm should result from environmental uses of genetically engineered microorganisms, the tort system is not a suitable alternative to pre-release administrative review by federal agencies.

B. Congressional Legislation

The United States has yet to enact any national legislation specifically drafted for the oversight of biotechnology. Instead, the government has relied solely on administrative rule-making and on re-interpretation of existing statutes. Over a dozen bills to regulate recombinant DNA laboratory experiments were introduced in Congress during the 1970's.[196] However, none were passed, in large part due to lobbying efforts by scientists concerned about regulation of basic scientific research.[197] With the advent and rapid growth of the biotechnology industry, Congressional concern shifted from basic research in the laboratory to deliberate release of genetically engineered organisms into the environment. Again, several bills were introduced,[198] but none reached even the subcommittee mark-up stage of legislation.[199] Rather than enacting new legislation, Congress has deferred to the *Coordinated Framework* developed by the executive branch of the federal government.

Despite the failure of past Congressional initiatives, many feel that only new legislation can overcome perceived inadequacies in the current federal regulatory regime.[200] The support for new legislation appeared to increase following the Gary Strobel incident.[201] There have been proposals for Congress to enact a com-

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196. ISSUES, *supra* note 46, at 2. *See generally* KRIMSKY, *supra* note 36, at 312-37; Naumann, *supra* note 36, at 88-90.

197. *See* KRIMSKY, *supra* note 36, at 327 ("The passage of some form of legislation, considered a near certainty in the spring [of 1977], had turned into a very dim prospect by the late fall. The scientific lobby was the major reason for the change in congressional mood behind strong legislation.").

198. *E.g.*, S. 1967, 99th Cong., 1st Sess. (1985) (Amends TSCA to include genetically engineered microorganisms, and requires permit and minimum data standard for any deliberate release into the environment.); H.R. 4452, 99th Cong., 2d Sess. (1986) (Requires permit under TSCA for environmental release, establishes by statute a Biotechnology Science Coordinating Comm. for inter-agency coordination and a Biotechnology Science Research Program.). *See generally* Note, *supra* note 36, at 543-47; ISSUES, *supra* note 46, at 16-17.

199. *See, e.g.*, Center for Rural Affairs, *supra* note 32, at 4.

200. *See* Fogleman, *supra* note 36, at 264-265 ("The *Coordinated Framework*'s attempt to fit regulation of biotechnology research under existing laws is ill-advised. The attempt invites judicial challenges, intra- and inter-agency jurisdictional disputes, potentially inflexible regulations, public distrust and the forced uniform application of different statutory mandates." (footnotes omitted)). *See also* Vandenbergh, *supra* note 65, at 1563; Naumann, *supra* note 36, at 90.

201. *See, e.g.*, *Federal Rules*, *supra* note 30; *Senator Vows New Law*, *supra* note 82; Center for Rural Affairs, *supra* note 32, at 5.

prehensive new statute that would cover all regulated biotechnology products and perhaps create a new "super agency" to administer the statute.[202] Other proposals have been more modest, such as amendment of existing statutes to make them more appropriate for biotechnology regulation. For example, the TSCA could be amended to require a permit for biotechnology products, and the jurisdiction of the statute could be explicitly extended to include genetically engineered microbes.[203]

Creation of new biotechnology regulatory legislation has been strongly resisted by many industry and government officials on several grounds.[204] First, the broad spectrum of biotechnology products makes regulation by a single agency or statute impractical.[205] Second, codifying biotechnology regulations will reduce administrative ability to modify the regulations as data and experience accumulate. For example, the NIH Recombinant DNA Guidelines have been progressively relaxed as gradual accumulation of data and experience has demonstrated the relative safety of most recombinant DNA experiments.[206] The very fact that many changes to the *Coordinated Framework* are being considered or proposed within less than two years of its publication attests to the need for flexibility. A third reason for the opposition is that new legislation would lead to further regulatory delays while the statute is drafted, enacted and implemented. Some four years after the drafting of the *Coordinated Framework* began, in the spring of 1984,[207] many of the key rules for application of existing statutes to biotechnology have not been issued.[208] To begin this long process again may be disastrous for the biotechnology industry, which requires a predictable and stable regulatory environment for its longterm planning.[209] Finally, a newly implemented and comprehensive statute may contain its own inadequacies and weaknesses, and thus risk "the vagaries of untried approaches."[210]

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202. *Id.* ("We also strongly urge that Congress consider a 'new-law/one-agency' option for biotechnology regulation."); Naumann, *supra* note 36, at 90; Fogleman, *supra* note 36, at 265, 267.

203. *E.g.*, McGarity, *supra* note 112, at 54, 55; Vandenbergh, *supra* note 65, at 1563-65.

204. *See, e.g.*, *B.S.C. Act*, *supra* note 113, at 61 (The Industrial Biotechnology Association, an industry trade group, believes no new legislation is needed.); *Federal Rules*, *supra* note 30; *Senator Vows New Law*, *supra* note 82.

205. *See supra* note 49; *see also Senator Vows New Law*, *supra* note 82 (EPA Assistant Administrator John Moore opposes new legislation. "The diversity of products makes it inappropriate. If regulation were unified, it might prove more stifling.").

206. *See* OFFICE OF TECHNOLOGY ASSESSMENT, *supra* note 2, at 216.

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

208. *See supra* note 81.

209. *See, e.g.*, Hardy & Glass, *supra* note 35, at 81.

210. Korwek & De La Cruz, *Federal Regulation of Environmental Releases of Genetically Manipulated Microorganisms*, 11 RUTGERS COMPUTER & TECH. L. J. 301, 382 (1985).

While there are some Congressional proponents of new biotechnology legislation, there is insufficient support for any major revisions of the present federal regulatory regime.[211] Such changes at this time could be disruptive and could lead to further costly delays and confusion. However, amended legislation that clarifies the applicability of existing laws to biotechnology could strengthen the *Coordinated Framework* without impeding its implementation. Most importantly, Congress can authorize increased funding so that the involved agencies have adequate resources to ensure prompt and safe regulation of biotechnology products.

C. State Regulations

In the late 1970s and early 1980s, concern about inadequacies in federal regulation of recombinant DNA research led the states of New York and Maryland, along with several cities and towns, to enact their own regulations or ordinances to oversee such research.[212] A new wave of state and local regulations may result if states lose confidence in the current federal regulatory framework.[213] Already, the Monterey County Board of Supervisors in California has adopted an ordinance banning deliberate release experiments, following the controversy over planned "ice-minus" field tests in that county.[214]

More recently, bills to regulate deliberate release have been introduced in two state legislatures, although neither is likely to be adopted into law at this time. The first proposed state law was introduced into the New Jersey State Senate in 1986, and would have required a state commission to approve all environmental releases of genetically engineered microorganisms in the state.[215] Although the bill was passed in the State Senate unanimously, it was defeated in the State Assembly in January 1988 after heavy lobbying by some industry groups.[216] The second state bill was introduced into the California State Senate in March 1987 and would have required environmental impact reports and state-is-

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211. *See* Fox, *supra* note 70, at 1276 (Representative George Brown is quoted as saying "In my opinion, the regulatory system is not working well. But Congress is not yet prepared to move on it.").

212. KRIMSKY, *Regulation of Biotechnologies: State and Local Roles and Initiative*, BIOTECH. AND THE ENVIRONMENT: RISK AND REGULATION 159, 160 (1985).

213. *See* Fox, *supra* note 70, at 1276 ("[T]here is renewed concern that, if state regulators lose confidence in federal regulators, they may develop a patchwork of regulations instead of abiding by a single national standard.").

214. *See supra* note 13.

215. S. 1123, New Jersey (1986) (copy on file with author).

216. *New Jersey Rejects Limits on Genetic Testing*, N.Y. Times, Jan. 12, 1988, at A18, col. 3.

sued permits for all releases of novel organisms into the open environment.[217] Although California has not enacted this bill, it has established its own coordinated regulatory framework for biotechnology using existing state statutes and eleven state regulatory agencies.[218]

There are several major problems with reliance on state legislation and regulation to ensure the safety of environmental uses of genetically engineered organisms. First, state regulations may impose excessive and redundant requirements on firms already subject to federal regulations. Second, many if not most state governments will lack the resources and expertise necessary to conduct complete and careful regulatory reviews, bringing into question the quality of regulatory decisions. Third, and perhaps most important, different states will have different standards and requirements. Biotechnology companies might be induced or forced to move to states with few or no regulations, causing economic dislocation in states with tougher standards and increased risks in states with lower standards.

While recognizing the disadvantages of using state laws to regulate biotechnology, some critics of the federal regulatory framework see state regulations as necessary if federal loopholes cannot be closed.[219] According to this view, states will have no choice but to act if they are to fulfill their obligations to protect citizens' health, safety and welfare. A secondary advantage of state legislation is that it may foreclose the need for municipal ordinances, which would create an even more patchwork regulatory system.[220] As might be expected, industry does not favor new state legislation to regulate biotechnology, especially if such legislation will result in redundant regulations and an extra layer of bureaucracy.[221] However, some industry officials believe that

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217. S. 844, California (1987) (copy on file with author). *See also Effective Communications Can Pre-Empt 'Overzealous' Regulation, IBA Meeting Told*, 11 Chem. Reg. Rep. (BNA) 436, 437 (1987).

218. Fox, *California First To Frame Biotech Statutes*, 5 BIO/TECH. 316, 317 (1987).

219. *See* KRIMSKY, *supra* note 212 at 177. According to a representative of one public interest group, "I think state governments have a duty to protect public health and safety, and so if the federal government's regulations are inadequate, the states have a responsibility to step in." Interview with Nachama Wilker, Executive Director of the Comm. for Responsible Genetics, in Boston, (January 29, 1988) [hereinafter Wilker].

220. *See* Dorsey, *Genetic Engineering Must be Regulated*, N.Y. Times, Aug. 24, 1986, at 26 (New Jersey State Senator John Dorsey, sponsor of the defeated New Jersey bill to regulate biotechnology, argues that "Control at the state level would prevent a hodgepodge of local ordinances regulating the release of biotechnically engineered material."). Less than a month after the legislative defeat of the New Jersey state bill to regulate biotechnology, the Township of Shamong became the first New Jersey local government to adopt an ordinance regulating deliberate release of genetically engineered microorganisms (copy of ordinance on file with author).

221. *See, e.g., New Jersey Rejects limits on Genetic Testing, supra* note 216; *Effective Communications Can Pre-Empt 'Overzealous' Regulation, IBA Meeting Told, supra* note 217, at 437.

state agencies can play a useful role in working with federal agencies to review the safety of deliberate release proposals.[222] In summary, state regulations may not be a feasible alternative to adequate federal regulations at this time, but action by state agencies may be a useful supplement to federal oversight.

V. CHANGES WITHIN THE CURRENT FEDERAL REGULATORY REGIME

A. New Risk Assessment Categories

An efficient method for allocating scarce governmental resources available for biotechnology regulation would be to create risk categories subject to different levels of regulatory scrutiny, depending on the magnitude of the hazards involved.[223] The problem lies in creating and defining different risk categories. The current federal approach is to use the clearly delineated, but scientifically vague, line between inter-generic and intra-generic organisms to distinguish those releases that will require prior review from those that will not.[224] Unfortunately, the government's approach is much too blunt, subjecting many releases that may present no significant risks to full reviews while allowing other releases that may present hazards to escape any advance regulation.[225] It now appears that the federal government is reconsidering its current approach and will at least make some modifications in the near future.[226]

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222. For example, David Glass of BioTechnica, whose company recently had a field testing proposal approved by the Wisconsin state government, has a view of the role of state regulation that "maybe isn't shared by everyone in the industry. We actually found some value in the state's participation in Wisconsin for a number of reasons. The public wanted it, the agencies of course wanted to be involved in some way, and more importantly they brought a perspective on certain issues that the agencies in Washington would just not be sensitive to. So, there definitely is a role for state agencies in any type of review like this. Having them involved really gave us some added public credibility .... [The public] just trusts their own state agencies more than they trust Washington. There's no reason for any state government to set up its own BSCC, its own EPA, its own crazy review procedures. But, there's every reason for state agencies to be notified, for state agencies to have a role in the federal process, and for there to be this type of interaction." *See* Glass, *supra* note 33.

223. *See, e.g.*, NATIONAL ACADEMY OF SCIENCES, *supra* note 18, at 19 ("If we are to proceed prudently with the use of R-DNA-engineered organisms, we must create categories that permit us to classify relative risks associated with environmental introductions, so that levels of containment and environmental assessment will be appropriate to the intended use.").

224. *See supra* note 74 and accompanying text.

225. *See supra* note 152 and accompanying text.

226. *See* Schneider, *supra* note 5, at C5. *See also TSCA Rules Delayed*, *supra* note 81 (The EPA is considering a SNUR rule that would require review of organisms that "would have the ability to displace other organisms in the environment, transfer genes to other microbes, affect human health or the environment, or cause ecological destruction.").

An alternative regulatory approach would involve risk categories based on known characteristics and properties of the microorganism rather than on somewhat meaningless taxonomic classifications.[227] The advantage of such an approach is that the risk categories will be based on sounder biological principles. The disadvantage is that this type of regulation will be much harder to administer. With the current system, federal agencies can determine whether a microorganism is inter-generic and therefore subject to regulation simply by comparing the scientific names of the species from which genetic material was derived. With the proposed system, there is no *a priori* way to classify microorganisms into risk categories without first knowing something about their biological attributes.

A regulatory system using risk categories based on biological properties would probably have to encompass a two-step process. All companies or researchers planning environmental releases of genetically engineered microorganisms would be required to submit a brief summary of the microorganisms' characteristics and the test site parameters. The regulatory agency would then evaluate the proposal using a standardized checklist or dichotomous decision tree that would allow each proposal to be quickly rated with respect to key risk variables.[228] From the results of this preliminary evaluation, each proposal would be placed into a risk category that would lead to a full review, an abbreviated review, or no further review.

Recently, a similar system has been implemented for reviewing new chemicals under TSCA. Here, all new chemicals undergo an initial 14-day review and those found to be in low-risk categories are exempted from full PMN review.[229] While risk assessments of biotechnology products are neither as rapid nor as well developed as those for chemicals, there are criteria by which the relative safety of different types of genetically engineered microorganisms can be judged.[230] The problem will be in clearly specifying what information companies will be required to sub-

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227. *See Panel to Consider Ranking Microbes by Effects Rather Than Pathogenicity*, 11 Chem. Reg. Rep. (BNA) 767 (1987) (proposal of Robert Colwell, a member of EPA's Biotechnology Science Advisory Comm.). A similar concept has been supported by the National Academy of Sciences, *see supra* note 18, at 20, and by some industry representatives. *See* Withers & Kenworthy, *supra* note 6, at 690.

228. Risk variables that might be included in preliminary evaluation include the size of the planned release, the location and conditions of the test site, the availability and effectiveness of monitoring and control techniques, and "ecologically important characteristics of an organism" such as "survival, reproductive potential, dispersal characteristics, pathogenicity, competitiveness, and the manner in which it is involved in essential processes in the ecosystem." *See* NATIONAL ACADEMY OF SCIENCES, *supra* note 18, at 20.

229. *See* Todhunter, *PMN Exemptions: A Defense*, ENVTL. FORUM, Feb. 1983, at 34, 36.

230. *See supra* note 115.

mit for use in the preliminary evaluation. Asking too much will be an onerous burden on companies; not asking enough will lead to ineffective risk evaluations. Agencies will have to prepare standardized checklists or decision trees that list the exact questions or factors that will be analyzed in the initial review. Companies will then have the burden of producing experimental data or well-supported arguments to answer these questions if they want their proposals exempted from further review.

A two-stage review system using risk categories based on important biological properties will correct the two major weaknesses of the current approach. First, no genetically engineered microorganism will be released into the environment without at least an abbreviated review by a federal agency. Second, those microorganisms that are very unlikely to involve significant risks, as determined by the preliminary evaluation, will no longer be required to undergo a full regulatory review. A new two-stage review process can be incorporated into the current framework. This process will be a significant improvement over the current system both in protecting public safety and reducing wasteful over-regulation. Although initially the preliminary evaluation will be somewhat inexact, it will become progressively more refined as agencies gain experience and knowledge.

B. Developing New Monitoring and Control Traits

Much of the political controversy and regulatory complexity associated with the environmental release of genetically engineered microorganisms is caused by the uncertainty about the risks involved. Therefore, any measure that reduces this uncertainty makes the regulatory task more straightforward and acceptable. One important approach for increasing predictability and safety would be the development of methods to monitor and control genetically engineered microorganisms after they are released.

Effective methods for tracking and identifying genetically engineered microorganisms released into the environment are essential for understanding and minimizing the risks from such releases. Without such techniques, "all debates over releasing recombinant organisms boil down to belief and educated guesswork."[231] Most of the worst-case scenarios for deliberate release experiments involve the proliferation and widespread dispersal of the genetically engineered microorganism. Monitoring techniques that make possible accurate tests for the presence of the altered bacteria at various distances from the test site will

231. McCormick, *Detection Technology: The Key to Environmental Biotechnology*, 4 BIO/TECH. 419 (1986).

help to alleviate much of the uncertainty. Also, reliable methods for identifying released microorganisms can be used to determine if there is any association between the microbe and unexplained environmental or public health disturbances that occur in surrounding regions. By providing early warning of possible risks or hazards, or by demonstrating the absence of such problems, monitoring and tracking techniques can create confidence and reduce uncertainty.

An operable tracking methodology has several important requirements. It must be sufficiently sensitive to detect very low levels of the genetically engineered bacteria in the environment. It must also be highly specific in order to distinguish the released microbe from similar indigenous strains. Finally, a tracking technique must be practical, fast and inexpensive. Current methods of detecting and identifying microorganisms in environmental samples suffer from deficiencies of one or more of these criteria.[232]

The same technology that is used to create genetically engineered microorganisms with beneficial new traits can also be used to introduce marker genes into microbes to make the latter easier to detect and identify in the environment. For example, the Monsanto Company has developed a marker system that will cause genetically engineered bacteria to turn blue when grown on an appropriate medium.[233] Microorganisms that have been engineered to contain the marker genes can be easily detected with a sensitivity several orders of magnitude greater than that possible with previous techniques.[234] Monsanto has recently received approval under TSCA to test the marker system in the environment.[235] If the markers work as designed, the company will be able to introduce beneficial traits into the marked microorganisms and to undertake field tests with much greater certainty about the fate of the released microorganisms.

Another way of reducing uncertainty about the fate of released microorganisms is to employ biological control mechanisms that restrict the proliferation of released microorganisms over time or in space. For example, scientists have recently developed a "suicide gene" for controlling genetically engineered microorganisms released into the environment.[236] The suicide gene will randomly self-activate and kill a given fraction of released

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232. *See* Levin, *supra* note 114, at 43. Current detection techniques include selective media, fluorescent antibodies and hybridization with DNA gene probes.

233. *See* Marx, *supra* note 110, at 1414-15.

234. Peter Drahos, a Monsanto scientist who helped develop the marker system, claims that the system is so efficient "that you can find one in a gram of soil, which is several hundred times better than any other technique we tried." *Id.* at 1415.

235. *EPA Approves South Carolina Field Test of Engineered Bacteria by Monsanto, Clemson*, 11 Chem. Reg. Rep. (BNA) 1157 (1987).

236. *See* Molin, Klemm, Poulsen, Biehl, Gerdes & Andersson, *Conditional Suicide System for Containment of Bacteria and Plasmids*, 5 BIO/TECH. 1315, 1316 (1987).

microbes per unit time, but will neither debilitate surviving cells nor interfere with their intended function. Such a system will effectively limit the potential of released microorganisms to spread to other locations or to survive after a given length of time. Alternative systems for containing released microorganisms have also been proposed. For example, the new traits in genetically engineered microorganisms could be introduced on genetic elements incapable of being transmitted to other species.[237] Released microorganisms could also be genetically "crippled" such that survival in the environment is possible only as long as the researcher provides a required nutrient not sufficiently available in nature.[238] Finally, genetically engineered microorganisms could be derived from tropical species unable to survive exposure to cold winter temperatures.[239]

By substantially reducing the uncertainty and risks of environmental uses of genetically engineered microorganisms, new monitoring and control technologies may help resolve many of the currently intractable regulatory and political problems involved with deliberate release experiments. The federal government should encourage the development of improved tracking and control mechanisms by increasing R&D funding in this area and by giving regulatory priority to field test proposals that include such safeguards. Once proven in the field, effective tracking and control systems could be made mandatory for any environmental release that is potentially hazardous.

C. Local Review Committees

Federal agencies regulating biotechnology are expected to become overwhelmed and ineffective as the number of release proposals increases.[240] One approach for preventing this regulatory break-down would be to decentralize regulatory reviews. The EPA has recently proposed the establishment of local environmental bio-safety committees (EBCs) to oversee planned environmental releases by nearby research institutions.[241] Local EBCs would be responsible for initial reviews of proposed releases, although the EPA would retain the right to re-

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237. *See* Withers & Kenworthy, *supra* note 6, at 690.

238. *See* Vandenbergh, *supra* note 65, at 1565, note 236.

239. *See* Pimental, *Down on the Farm: Genetic Engineering Meets Ecology*, TECH. REV., Jan. 1987, at 24, 29.

240. *See, e.g., EPA Advisory Board Supports Concept of Environmental Biosafety Comms.*, 11 Chem. Reg. Rep. (BNA) 1619, 1620 (1988) [hereinafter *EPA Advisory Board*]. *See also supra* notes 164-66 and accompanying text.

241. *See Environmental Safety Comms. Could Review Small Releases, Moore Says*, 11 Chem. Reg. Rep. (BNA) 1158 (1987) [hereinafter *Environmental Safety Comms.*]; *EPA Advisory Board*, *supra* note 240 at 1619.

examine any decision by a local committee. According to one EPA official, the EBCs would serve as a "surrogate agency presence."[242] Each environmental bio-safety committee would include scientists and other specialists from different fields of expertise as well as community representatives.[243] At least initially, only small-scale field tests would be approved by EBCs, with reviews of large-scale field tests and commercial applications remaining with the EPA's central office.[244] The EBCs would be similar in function and structure to existing institutional bio-safety committees (IBCs), which oversee compliance with the NIH Recombinant DNA Guidelines.[245] However, unlike the current IBCs, EBCs would have statutory authority to enforce their decisions.[246]

The primary purpose of the EBC proposal is to reduce substantially the workload and backlog of the central EPA office. Qualified scientists on EBCs will ensure that each small-scale release proposal is given a thorough local review. Meanwhile, the EPA will be able to redirect and concentrate its resources on careful scrutiny of riskier large-scale releases as well as on broader policy problems. Moreover, local reviews may have several secondary advantages. For example, since the EPA's Washington office, with its potential backlog of proposals will be bypassed, researchers should be able to get release proposals approved more quickly. Academic researchers in particular will benefit from the presence of local committee members, who are familiar with the regulations and can be consulted about regulatory requirements, deadlines and exemptions. Assuming that each EBC will include representatives of the community, the establishment of many local EBCs will open opportunities for public participation in the regulatory process.[247] Finally, the participation of greater numbers of scientists and citizens in the review process will enhance the over-all interest in and knowledge of the issues involved, and

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242. *Environmental Safety Comms.*, *supra* note 241.

243. *See EPA Advisory Board*, *supra* note 240, at 1620.

244. *Environmental Safety Comms.*, *supra* note 241.

245. Most laboratory experiments involving recombinant DNA are now reviewed solely at the local level by IBCs, if at all. An IBC is defined in the NIH Guidelines for Research Involving Recombinant DNA Molecules, 51 Fed. Reg. 16,959 (1986). Every institution conducting or sponsoring recombinant DNA research covered by the Guidelines is required to establish an IBC, consisting of not less than five persons with appropriate expertise, to review certain categories of recombinant DNA experiments.

246. *See EPA Advisory Board*, *supra* note 240, at 1620.

247. IBCs are required to include at least two members unaffiliated with the research institution who "shall represent the interest of the surrounding community with respect to health and the protection of the environment. Members meet this requirement if, for example, they are officials of State or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns in the community." 51 Fed. Reg. 16,962 (1986).

will contribute beneficially to societal decisions about regulation of new technologies such as deliberate release.

The EBC proposal has not been formally adopted by the EPA, and there are several important questions remaining to be answered.[248] Will the EBCs require funding, and if so, where will it come from? First, since the number of release proposals from any one institution or region is likely to be small, the time commitments of committee members should not require financial compensation. However, if EBCs require significant overhead expenses or paid staff, the costs of the EBC system could become large and counterproductive. Other questions relate to the quality of regulatory reviews by local committees. Will all EBCs have access to specialists with the appropriate expertise who are willing to serve? Who will choose the members of the EBC? Will it be possible for an institution or a private company to "stack" an EBC with members who are not committed to reviewing proposals with appropriate rigor? Will the quality and standards of review differ significantly between EBCs, leading to inconsistencies and "forum shopping?" According to one official, the EPA would probably establish a certification and auditing procedure for EBCs.[249] However, if the EBCs cannot be relied upon to operate properly independent of close supervision, they may create more problems than they solve. Another issue is whether the views of the community representatives would be given proper consideration by the other members of the EBC. Finally, will there be a procedure for researchers or concerned citizens to appeal EBC decisions to the EPA? Assuming such questions can be adequately resolved, the EBC concept will be very useful, and probably necessary, given the increasing number of release proposals.

D. Government-Operated Test Plots

One possibility for enhancing public and environmental safety, while simultaneously reducing the regulatory burden on companies, is to conduct small-scale field tests of genetically engineered microorganisms at government-operated test plots. Such an idea has been considered for some time by federal agencies,[250] and has received the support of some industry representatives.[251] Recently, a major report by the National Research

248. Many of these questions were raised at a Biotechnology Science Advisory Board meeting at which the concept of EBCs was approved. *See EPA Advisory Board*, *supra* note 240, at 1620. *See generally* Bereano, *Institutional Biosafety Comms. and the Inadequacies of Risk Regulation*, SCI., TECH. & HUMAN VALUES, Fall 1984, at 16 (The author considers many similar questions in his analysis and criticisms of the functioning of IBCs.).

249. *See Environmental Safety Comms.*, *supra* note 241.

250. *See* Crawford, *Larger Public Sector Role Sought on Biotech*, 232 SCI. 15 (1986).

251. *See, e.g.*, *B.S.C Act*, *supra* note 113, at 198.

Council recommended the establishment of "publicly owned, geographically isolated, and professionally managed test sites."[252] The report suggested that between five and ten existing government-owned field stations be selected as test plots for genetically engineered organisms.[253]

Federally funded and operated test sites would have many advantages. It is expensive and inefficient for each company to select, prepare and study its own test site. The alternative to using a large number of hastily chosen and temporary test sites is to maintain a small number of permanent, first-class facilities. Since only a few sites are needed, much more care can be taken to select prime locations. With a limited number of facilities, comprehensive assessments of indigenous organisms and other relevant ecological characteristics may be more feasible. Sophisticated monitoring equipment and laboratories could be established on-site. Government officials and other experts could be present to carefully supervise each release experiment. Even with all of these improved safety precautions, the overall cost of each test could be reduced through cost sharing and economies of scale. The government's costs could be minimized by charging companies for all on-site expenses, but it would still be cheaper and quicker for companies to use the government's ready-made facilities than to establish new sites. One disadvantage in the use of limited numbers of government-operated testing facilities is that the ecological community and species surrounding a particular facility may not be representative of the actual locations in which the genetically engineered microorganism will be used on a commercial basis. Nevertheless, the federal test site proposal is one that could simultaneously benefit biotechnology companies, federal regulatory agencies and public safety. The federal government should move quickly to establish such facilities.

E. Confidentiality Agreements

Public interest organizations and biotechnology companies have conflicting positions regarding disclosure of confidential business information contained in deliberate release proposals. Fortunately, the interests behind these opposing positions may not be completely incompatible. Companies are concerned with protecting trade secrets from business competitors, while public interest groups are worried that critical information about potential risks will be hidden from the public. The interests of both

252. COMMITTEE ON A NATIONAL STRATEGY FOR BIOTECHNOLOGY IN AGRICULTURE, NATIONAL RESEARCH COUNCIL, AGRICULTURAL BIOTECHNOLOGY: STRATEGIES FOR NATIONAL COMPETITIVENESS 128 (1987).

253. *Id.* at 129.

groups may be satisfied by agreements that give public interest organizations full access to all information in submitted proposals in return for pledges not to disclose confidential business information. Similar arrangements for the regulation of other technologies have been supported in the past by both industry and environmental groups.[254]

The biotechnology industry and public interest groups are likely to have reservations about such confidentiality agreements. Companies may have doubts about the intentions of a public interest group that suddenly appears very interested in gaining access to confidential information contained in biotechnology proposals. Such suspicions could be eased by requiring all representatives of public interest groups given access to confidential information to demonstrate that they have no financial or other relationship with any competing company or its agents. Criminal sanctions could also be included in the relevant statutes.[255] On the other hand, some public interest organizations feel that signing a confidentiality agreement abrogates a duty to inform the public of risks.[256] Arguably, public interest organizations have nothing to lose with such confidentiality agreements. If they do not sign the agreement, they will not have access to the information and the public will not be warned if some important data about potential risks is not disclosed. If they do sign the agreement and discover the undisclosed risk, they may not be able to do anything about that specific problem but may be able to warn the public that the disclosure system is not working as it should. For example, if information is being improperly withheld, a public interest group could, without disclosing the specific information it had sworn to keep confidential, denounce the agency and industry for abusing the confidentiality provisions. Such an action is likely to receive considerable attention given the media inter-

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254. *See, e.g.*, Abramson, *supra* note 170, at 699-700. A legislative proposal was developed by a coalition of industry and environmental groups in 1986 to permit limited public access to CBI included in applications for pesticide permits. The proposal would also apply to microbial pesticides produced by biotechnology. Members of the public would be able to inspect the documents at the EPA office providing they could demonstrate that they were not acting on behalf of any industrial competitor.

255. TSCA currently provides for a $5,000 fine or one-year jail sentence or both for any government employer or contractor who wrongfully discloses CBI. 15 U.S.C § 2613(d) (1982). Such a provision could be extended to include public interest group representatives given access to confidential information. Confidentiality agreements would need to address problems such as allocating the burden of proof when confidential information improperly ends up in the hands of competitors.

256. For example, Nachama Wilker, Executive Director of the Comm. for Responsible Genetics, has expressed such concerns. "It puts a member of a public interest organization in an untenable position, because we have a responsibility to notify the public when we see practices or experiments that are of questionable safety. So, when we sign a confidentiality agreement, we put ourselves in a fundamental conflict of interest." Wilker, *supra* note 219.

est in genetic engineering controversies, and would pressure the agency to reform its procedures. On the other hand, if only legitimate trade secrets are being kept confidential, the public interest groups will be able to assure themselves and the public that the disclosure system is functioning well. Thus, such agreements can serve as important confidence-building measures.

VI. CONCLUSION

The stakes involved in the deliberate release of genetically engineered microorganisms into the environment are very high. On one hand, the technology promises enormous benefits for undertakings such as agriculture, mining and pollution control. On the other hand, some environmental releases may cause irreversible disruptions of the ecosystem, resulting in substantial hazards to public health or the environment. The high stakes involved are accompanied by great uncertainty regarding the risks and benefits of deliberate release. With such a high-stakes, high-uncertainty venture, serious tensions between the promoters of the technology and the protectors of public health and the environment are inevitable.

The federal government, in drafting its *Coordinated Framework for Regulation of Biotechnology*, attempted to balance the interests of those seeking protection of the public health and the environment with the interests of the industry in avoiding a stifling regulatory burden. In 1987, it became increasingly obvious that few, if any, of these conflicting interests had been adequately addressed by the new federal regulatory framework. There is growing frustration and impatience within the biotechnology industry and among many academics regarding the burdens and delays from a perceived over-regulation of many biotechnology products. On the other side of the issue, public interest organizations and some scientists believe that the current regulations are inadequate and superficial, and have little or no chance of leading to discovery and prevention of real hazards that may exist. Regulators thus face growing pressure from one group of interests to relax the regulations and from another group to strengthen them. These tensions can be expected to escalate dramatically as the effectiveness and efficiency of the regulatory process break down under the strain created by the growing number of release proposals. Clearly, some changes are needed.

The current federal regulations are unlikely to be replaced *in toto* by the tort system, Congressional legislation or state regulation, although these mechanisms may take on a supplementary role. The most promising approach for improving the regulation of deliberate release is represented by a series of more modest

changes within the current federal regulatory framework. While the goals of minimizing risks and minimizing regulatory burdens are usually in opposition, there are several changes that further both goals. These initiatives either are being considered by federal agencies or have been proposed. Risk categories that are more scientifically sound will reduce the over-regulation of the release of relatively safe microorganisms while preventing regulatory exemptions for the release of microorganisms that may present significant risks. Improved detection and control systems will facilitate the safe testing of genetically engineered microorganisms in the environment. The establishment of local environmental bio-safety committees will increase total regulatory resources and help ensure that each release proposal is thoroughly and promptly reviewed. The use of government-operated testing facilities will reduce the costs and delays of field test preparations for companies, while providing the best available safeguards and government supervision. Finally, confidentiality agreements between biotechnology companies and public interest groups will ensure that all information is available for risk assessments by non-governmental experts, without jeopardizing trade secrets. Taken together, these changes should reduce both the risks and the regulatory burden of deliberate release experiments and should appeal to everyone desiring efficient *and* safe technology.