THE RUTABAGA THAT ATE PITTSBURGH: FEDERAL REGULATION OF FREE RELEASE BIOTECHNOLOGY*

When the Environmental Protection Agency (EPA) first approved a field test of a bioengineered microbe,[1] one EPA official remarked: "We're not expecting this to be the rutabaga that eats Pittsburgh."[2] But regulators cannot afford to be wrong. Bioengineered microbes may serve many useful purposes, but they may also cause harm to the environment and to human health.[3] Although the risks of an accident stemming from the deliberate release of bioengineered microbes into the enviroument may be low, the resulting damage could be substantial.

This note examines the possible consequences of two recent trends in biotechnology—the development of bioengineered microbes for environmental release and the emergence of a vigorous biotechnology industry—on federal environmental regulation. These two developments have produced regulatory confusion in an area that can ill afford uncertainty. Biotechnology companies eager to recapture their research investments through the commercialization of bioengineered products are pressing understaffed regulatory agencies to permit the release of microorganisms produced by bioengineering techniques into the environment.[4]

This regulatory confusion is well illustrated by the conflicting treatment the courts have given two virtually identical proposals for deliberate release experiments. In 1984, federal district court Judge John Sirica enjoined a university-sponsored field test of a bioengineered microbe that had been approved by the National Institutes of Health (NIH).[5] Within a

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[1] Bioengineering is "the application of biological science towards technological ends such as the production or use of chemicals or life forms for commercial or potentially commercial uses." The Potential Environmental Consequences of Genetic Engineering: Hearings Before the Subcomm. on Toxic Substances and Environmental Oversight of the Senate Comm. on Environment and Public Works, 98th Cong., 2d Sess. 42 (1984) [hereinafter Senate Hearings on Environmental Consequences] (statement of Dr. John A. Moore, Assistant Administrator for Pesticides and Toxic Substances, EPA). The first bioengineered life form to be approved for testing outside the laboratory was the ice-minus bacterium, a genetically engineered microorganism designed to lower the frost temperature of certain plants. See infra note 27.

[2] Henderson, EPA Expected to Approve First Genetic Test, Wash. Post, Oct. 30, 1985, at A1, col. 2, A26, col. 3. (quoting Steven Schatzow, director of pesticide programs, EPA).

[3] See infra text accompanying notes 29-37.

[4] Although bioengineering permits the development of many organisms for many uses, this note only addresses rDNA microorganisms designed for environmental release.

[5] See Foundation on Econ. Trends v. Heckler, 587 F. Supp. 753, 769 (D.D.C. 1984), aff'd

year, the EPA approved essentially the same experiment[6] under the sponsorship of a private biotechnology company.[7] Again the release was challenged in federal district court, but this time Judge T.F. Hogan refused to grant an injunction.[8] These inconsistent outcomes are due in large part to inadequate regulatory guidelines.

In Part I, this note discusses the rapidly evolving science underlying the development of bioengineered microbes and the growing biotechnology industry it has spawned. In Part II, the note reviews the federal government's regulatory response to these developments. The analysis in Part III identifies two crucial flaws in the present system of biotechnology regulation: its uncertainty will stifle commercial development in biotechnology, and it will not produce sufficient data to enable regulators adequately to assess the special risks created by deliberate releases.[9] After examining governmental efforts to assess similar risks in the nuclear power industry, the part argues that regulators of deliberate releases should assemble a central data base of information about each release for use in future risk assessment. In Part IV, the note recommends immediate modification of the regulatory scheme to clarify agency jurisdiction and statutory authority, to stiffen reporting requirements, and to create a centralized data bank. The part also suggests that the EPA adopt a long-term strategy of incorporating research scientists into the regulatory process, in order to keep pace with the rapidly changing science of biotechnology. The note concludes that limited statutory reform and a consistent data base available to expert regulators will improve risk assessment and enable the safe development of a vigorous biotechnology industry.

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in part, vacated in part, 756 F.2d 143 (D.C. Cir. 1985). Judge Sirica also enjoined further NIH approval of any other deliberate release experiments pending preparation of a "programmatic" Environmental Impact Statement (EIS) addressing the broad environmental concerns involved in authorizing deliberate release experiments, as required by § 102(2)(c) of the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. § 4332(2)(C) (1982). See *Foundation on Econ. Trends*, 587 F. Supp. at 769; infra note 56 (discussing NEPA's EIS requirements). This portion of the decision was reversed on appeal. See Foundation on Econ. Trends v. Heckler, 756 F.2d 143, 158-60 (D.C. Cir. 1985). These decisions are discussed in detail at infra notes 51-76 and accompanying text.

[6] The initial experiment involved application of ice-minus bacteria to potato plants. See Norman, Judge Halts Gene-Splicing Experiment, 224 Sci. 962, 962 (1984). The second experiment involved application of the same strain of bacteria to 2,400 strawberry plants. See Hilts & Henderson, EPA Clears Way for Release of New Antifrost Microbe, Wash. Post, Nov. 15, 1985, at A2, col. 5.

[7] The biotechnology company was Advanced Genetic Sciences, Inc. See Hilts & Henderson, supra note 6, at A2, col. 5.

[8] See Foundation on Econ. Trends v. Thomas, 637 F. Supp. 25, 29 (D.D.C. 1986).

[9] This type of risk is described hereinafter as "low probability/high consequence" risk. See infra note 203 and accompanying text.

I. Recombinant DNA Technology and the Emerging Biotechnology Industry

The process that spawned the biotechnology industry, known as "recombinant deoxyribonucleic acid (rDNA) technology,"[10] involves the insertion of one or more small segments of one organism's genetic material, or DNA, into the DNA of another organism. DNA is composed of two strands of nucleotides arranged in a double helix.[11] Each strand is made up of chains of four base nucleotides that appear in varying order;[12] the order of the nucleotides determines the variability of the genetic traits that pass from generation to generation as the organism reproduces.[13] Biotechnology uses several techniques to alter this genetic sequence of nucleotides. The method most frequently employed uses proteins known as "restriction enzymes"[14] to cut the DNA of an organism at specific points, separating certain segments of DNA from the double helix.[15]

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[10] Biotechnology has its origins in the ability of biologists to recombine or splice the genetic sequence of one organism into the sequence of another organism and to have that recombined sequence reproduced in the offspring, thus the term "recombinant DNA." See Grobstein, The Recombinant-DNA Debate, Sci. Am., July 1977, at 24-25. A number of recombinant DNA processes are currently being performed, including many that use varying amounts of human intervention in the exchange of genetic materials. As used in this note, the term "recombinant DNA" refers to all of these processes.

[11] See generally id. at 22-33 (overview of the mechanics of rDNA production).

[12] DNA nucleotides include cytosine, guanine, adenine, and thymine. See id. at 24.

[13] See id. The nucleotides are "read" in sets of three, called "codons," by other molecules in the cell. Each codon determines, through several intermediate steps, the position of a specific amino acid in a protein molecule. The sequence of amino acids in turn establishes the structure and function of the protein molecule, which, with other proteins, determines virtually every property of the organism. The entire set of codons required to produce the amino acid sequence of a particular protein is called a "gene." See id. at 24, 29.

Each double helix of DNA is called a "chromosome." A chromosome contains many genes. Each organism, in turn, contains a specific number of chromosomes; this number varies greatly from one type of organism to another. See H. Curtis, Biology 209 (3d ed. 1979). In addition, some bacteria contain one or more "plasmids," which are circular strands of self-replicating DNA separate from the chromosomes. See id. at 25.

Replication occurs when the twin strands of DNA separate in order to form a second DNA double helix. Absent mutations, the original sequence will be reproduced in exactly the same form in the new strand of DNA. Any mutations or other changes that occur when new nucleotides join the parent DNA, however, will be reproduced in the new strand of DNA. See id. at 24.

[14] See id. Restriction enzymes leave the DNA with "sticky ends"—ends of the DNA strand that will readily attach to complementary segments of DNA. Because the same four nucleotides are found in the DNA of virtually all organisms, complementary sticky ends of the DNA of different types of organisms may join. As a result, scientists can use restriction enzymes to clip a specific gene sequence from the DNA of one organism and insert it into a plasmid of another organism, where the sticky ends will attach to complementary segments of DNA. See id. at 24-25.

[15] See id.

Scientists then insert these DNA segments into another organism's DNA. The DNA inserted in this manner permanently alters the DNA of the second organism and is reproduced in its offspring.[16]

Pittsburgh-eating rutabagas notwithstanding, genetically altered microbes promise efficient solutions to environmental, medical, and agricultural problems that have puzzled scientists for years. Biotechnology's wide range of potential applications has attracted considerable commercial interest. Industry laboratories are already producing and selling artificial human insulin and human growth hormone in substantial quantities,[17] and large-scale commercial production of aspartame using rDNA techniques began in 1983.[18] The Office of Technology Assessment predicts that current biotechnological techniques will soon make possible the production of pharmaceuticals such as antibiotics and vaccines, additives, sweeteners, and other food products, and many types of industrial chemicals.[19] The late 1980's may see sales of biotechnological products for pollution control alone exceed six billion dollars, and annual sales of all biotechnological products may amount to over forty billion dollars by the year 2000.[20] In light of these predictions, it is not surprising that commercial investment in biotechnology has been extensive. DuPont, for example, has invested over 150 million dollars in rDNA research facilities.[21] The industry presently contains over three hundred companies,[22] and to-

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[16] See id.

[17] See Biotechnology Regulation: Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce, 98th Cong., 2d Sess. 32-33 (1984) [hereinafter House Hearing on Biotechnology Regulation] (statement of Dr. Frank E. Young, Commissioner, Food and Drug Administration). Additional products include a prophylactic for bovine scours, porcine diarrhea vaccine, hepatitus B vaccine and diagnostic monoclonal antibodies. See Hardy & Glass, Our Investment: What Is at Stake?, Issues in Sci. & Tech., Spring 1985, at 69, 76.

[18] See Henderson, Aspartame: A Sweet for 2 Biotech Firms, Washington Post, Nov. 5, 1984, § 5 (Washington Business), at 1, col. 4, 31, col. 1. Of course, there have been some striking biotechnology company failures as well. See Armos Corp. Becomes Third Major Biotech Casualty: Files Chapter 11, 1 Biotech. L. Rep. (Liebert) 125, 125 (Aug.-Sept. 1982).

[19] See Office of Technology Assessment, U.S. Congress, Impacts of Applied Genetics: Micro-Organisms, Plants, and Animals 49-132 (1981); McChesney & Adler, Biotechnology Released from the Lab: The Environmental Regulatory Framework, 13 Envtl. L. Rep. (Envtl. L. Inst.) 10,366, 10,366 (1983).

[20] See McChesney & Adler, supra note 19, at 10,366.

[21] Senate Hearings on Environmental Consequences, supra note 1, at 57 (statement of Dr. Alexander MacLachlan, Director, Central Research & Development Dept., E.I. DuPont de Nemours & Co.).

[22] Staff of Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology, 98th Cong., 2d Sess., Report on Environmental Implications of Genetic Engineering 28 (Comm. Print 1984) [hereinafter Staff Report]. The Staff Report concluded that "[b]iotechnology companies are rapidly approaching the point at which they will begin the widespread production of genetically engineered organisms for commercial purposes."

tal investment in these companies exceeds three billion dollars.[23]

Although the first commercial applications of biotechnology occurred in the pharmaceutical industry,[24] many of the most promising products of biotechnology are nonpharmaceutical substances that entail the environmental release of rDNA microbes.[25] Released microbes may enhance the recovery of underground oil and minerals, and may be used as pesticides, as well as for hazardous waste detoxification and other purposes.[26] Perhaps the two best known examples of rDNA microbes designed for environmental release are the ice-minus bacterium that provoked the controversy in *Foundation on Economic Trends v. Heckler*[27] and the oil-eating bacterium that prompted the United States Supreme Court's decision in *Diamond v. Chakrabarty*.[28]

Id. at 1. Since the Staff Report was completed in February 1984, several biotechnological products have been sold commercially. See supra notes 17-18 and accompanying text.

[23] Hardy & Glass, supra note 17, at 74.

[24] See Office of Technology Assessment, U.S. Congress, Biotechnology: An International Analysis 72 (1984). The pharmaceutical industry was able to commercialize biotechnology early because initial federal funds for genetic research targeted biomedical applications, the industry already had experience in converting basic research to commercial levels of production, and profit margins on pharmaceutical products were high enough to enable them to recapture research and development costs. See id.

[25] See id. at 217-25; Staff Report, supra note 22, at 3.

[26] See Office of Technology Assessment, supra note 24, at 217-25; Staff Report, supra note 22, at 3.

[27] 587 F. Supp. 753 (D.D.C. 1984), aff'd in part, vacated in part, 756 F.2d 143 (D.C. Cir. 1985).

The ice-minus bacterium, an rDNA modified version of a bacterium found on many plants, was developed by Dr. Steven Lindow of the University of California at Berkeley. See Hirano, Ecology and Physiology of *Pseudomonas Syringae*, Bio/Technology, Dec. 1985, at 1073. The naturally occurring strain increases plant sensitivity to frost, causing frost to form in plant tissue at relatively mild temperatures. See Environmental Implications of Genetic Engineering: Hearing Before the Subcomm. on Investigations and Oversight and the Subcomm. on Science, Research, and Technology of the House Comm. on Science and Technology, 98th Cong., 1st Sess. 66-67 (1983) [hereinafter House Hearing on Environmental Implications] (statement of Dr. Steven Lindow, Dept. of Plant Pathology, Univ. of Calif. at Berkeley). The ice-minus strain, which is able to colonize on plants formerly inhabited by the naturally occurring strain, causes frost to form on the plants only at lower than normal temperatures. The ice-minus mutant also occurs naturally in small numbers, but can be produced in large quantities using rDNA techniques. See id. at 67. The savings from this lowering of the frost point in citrus fruits and other crops could range from one to three billion dollars per year. Staff Report, supra note 22, at 14. Sales from a commercially viable ice-minus bacterium might reach $100 million per year. Biotechnology: Strawberry Fields Forever, Time, Nov. 11, 1985, at 74.

[28] 447 U.S. 303 (1980) (upholding the patentability of genetically altered life forms).

The petroleum-consuming microbe that was the subject of controversy in *Chakrabarty* has commercial potential because it can degrade the carbon compounds found in petroleum. See id. at 305. The microbe converts petroleum sludge to several more innocuous compounds. See id. Other rDNA microbes also may be able to consume pollutants like the di-

The methods used to produce rDNA microbes designed for deliberate release are the same as those used for other rDNA microbes. Deliberate release microbes, however, differ in one significant way: unlike most other rDNA microbes, which die outside the laboratory,[29] they are designed to survive in the environment long enough to perform a designated task. For this reason, they present significantly greater risks than other rDNA products.[30]

Moreover, microbes designed for environmental release are potentially hazardous, because they may have acquired traits that enable them to outcompete existing organisms in the environment, disturbing the ecological balance of an entire area.[31] Altered microbes released in the environment may also interact with other organisms, exchanging genetic material and creating potentially hazardous new microbes.[32] In addition, deliberately released microbes may cause disease or create toxins hazardous to plants, animals, or humans.[33] Although escaped laboratory-bound microbes present many of the same dangers, the fact that deliberately released microbes are designed to *survive* in the environment exacerbates these problems.[34]

Deliberate release microbes may also pose greater risks than ordinary,

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oxin found at Times Beach, Missouri. See House Hearing on Environmental Implications, supra note 27, at 60 (statement of Dr. Ananda Chakrabarty, Dept. of Microbiology, Univ. of Illinois Medical Center). Similar microbes may be an efficient means of degrading hazardous wastes in landfills and dumpsites. See id. The commercial potential for these waste-consuming microbes will grow as more toxic wastes are produced.

[29] For an explanation of why laboratory organisms die outside the laboratory, see infra text accompanying notes 235-36. There has never been a reported incident endangering humans or the environment with the laboratory-based research. See House Hearing on Environmental Implications, supra note 27, at 38 (statement of Geoffrey M. Karny, Senior Analyst, Biological Applications Program, Office of Technology Assessment). In fact, early guidelines suggested that research be performed on organisms designed to survive only in the laboratory. See Guidelines for Research Involving Recombinant DNA Molecules, 41 Fed. Reg. 27,911, 27,916 (July 7, 1976).

[30] See House Hearing on Environmental Implications, supra note 27, at 38-39 (statement of Geoffrey M. Karny, Senior Analyst, Biological Applications Program, Office of Technology Assessment); Korwek & de la Cruz, Federal Regnlation of Environmental Releases of Genetically Manipulated Microorganisms, 11 Rutgers Computer & Tech. L.J. 301, 308-09 (1985).

[31] See House Hearing on Environmental Implications, supra note 27, at 20-21 (statement of Dr. Frances Sharples, Oak Ridge National Laboratory); McChesney & Adler, supra note 19, at 10,368. This competitive edge may stem from the new microbe's lack of natural enemies, or from a potentially undetectable difference in its ability to survive. See id.

[32] See Staff Report, supra note 22, at 15; infra text accompanying note 217.

[33] See Staff Report, supra note 22, at 16.

[34] See House Hearing on Environmental Implications, supra note 27, at 39 (statement of Geoffrey M. Karny, Senior Analyst, Biological Applications Program, Office of Technology Assessment); Korwek & de la Cruz, supra note 30, at 308.

inert pollutants. Whereas non-biological pollutants do not multiply—and often degrade into harmless substances—microbial pollutants reproduce rapidly.[35] Although both types of pollutants may be dispersed by wind and water, microbes may migrate on their own.[36] Released microbes thus present unique risks to the environment and to human health.[37]

The promise of biotechnological products is matched by the inherent risks involved in an area that scientists are only beginning to understand. These risks are troublesome not because they are highly probable, but because measuring them is tremendously difficult. Establishing the likelihood that an altered microbe will severely disrupt the environment—or worse—is complex and uncertain. The confusion and inadequacy of the federal regulatory system adds to this uncertainty.

II. Federal Regulation of Biotechnology

Scientists first voiced reservations about the potential hazards of rDNA research in 1974.[38] Within two years, the general public became con-

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[35] See McChesney & Adler, supra note 19, at 10,368.

[36] See id.

[37] Interestingly, although rDNA microbes may cause environmental harm, they may also be used to reduce the environmental damage caused by pollutants like oil sludge and toxic wastes. See Powledge, Prospects for Pollution Control with Microbes, Bio/Technology, Nov. 1983, at 743, 743; supra note 28. Thus, concerns about creating new pollution must be balanced against the possibility that overall pollution levels may be reduced.

[38] A committee of scientists chaired by Dr. Paul Berg wrote a letter to the editors of two leading science publications raising the issue of possible hazards from rDNA research and advising scientists to accept a voluntary moratorium on the research until the risks could be investigated. See Letter to the Editor, Potential Biohazards of Recombinant DNA Molecules, 185 Sci. 303 (1974); Letter to the Editor, NAS Ban on Plasmid Engineering, 250 Nature 175 (1974). In addition to Dr. Berg, the letter was signed by Drs. David Baltimore, Herbert W. Boyer, Stanley N. Coben, Ronald W. Davis, David Hogness, Daniel Nathans, Richard Roblin, James Watson, Sherman Weissman, and Norton D. Zinder. The letter called for the NIH to establish a committee of experts to oversee rDNA research and requested the NIH to develop guidelines for investigators working with potentially hazardous recombinant DNA molecules. See Pendorf, Regulating the Environmental Release of Genetically Engineered Organisms: *Foundation on Economic Trends v. Heckler*, 12 Fla. St. U.L. Rev. 891, 897-98 (1985) (explaining the background of the Paul Berg letter).

In February of 1975 the NIH, the National Academy of Sciences (NAS), and the National Science Foundation (NSF) jointly sponsored a conference for scientists involved in rDNA research at the Asilomar Conference Center in Pacific Grove, California. See Dworkin, Science, Society, and the Expert Town Meeting: Some Comments on Asilomar, 51 S. Cal. L. Rev. 1471, 1472 (1978); Pendorf, supra, at 898. The scientists at Asilomar developed and proposed guidelines to ensure the containment of rDNA organisms in the laboratory. Some criticism was leveled at the lack of time the conference devoted to policy discussion and by its exclusion of the press and general public. See Dworkin, supra, at 1472-78. The general public first became concerned about the potential hazards of rDNA research as a result of the publicity surrounding the Asilomar Conference. Scientists were uncertain of the amount

cerned not only about possible leaks of microbes from laboratories, but also about the ethical consequences of modifying the genetic code.[39] Congress responded to these concerns by holding several hearings[40] and introducing at least twelve bills regarding the regulation of rDNA research.[41] Despite the intense congressional interest, however, no legislation emerged.[42]

In response to the growing concern over rDNA research in the scientific community and among the general public, the NIH, which funds most academic rDNA research, directed its Recombinant DNA Advisory Committee (NIHRAC) to develop guidelines for rDNA research.[43] In July 1976, the NIH issued its first Guidelines for Research Involving Recombinant DNA Molecules (the Guidelines).[44] The Guidelines focused on preventing the accidental escape of rDNA products.[45] Five types of research were considered too hazardous to be performed, including the "deliberate release into the environment of any organism containing a recombinant DNA molecule."[46] Under the administration of NIHRAC, the Guidelines have apparently succeeded in their mission—rDNA research has developed rapidly without an accident seriously injuring humans or

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of risk involved in the research, and many feared the worst. See Guthrie, DNA Technology: Are We Ready?, 6 Dalhousie L.J. 659, 664-65 (1981).

[39] See, e.g., Fletcher, Ethics and Recombinant DNA Research, 51 S. Cal. L. Rev. 1131 (1978); Office of Technology Assessment, supra note 19, app. III-A, at 316.

[40] Cf. Staff of the Subcomm. on Science, Technology, and Space of the Senate Comm. on Commerce, Science, and Transportation, 95th Cong., 2d Sess., Recombinant DNA Research and Its Applications: Oversight Report (Comm. Print 1978) [hereinafter Senate Oversight Report] (recommendations based on hearings held in Nov. 1977).

[41] See Wines, Genetic Engineering—Who'll Regulate the Rapidly Growing Private Sector?, 1983 Nat'l J. 2096, 2101.

[42] Congress is now considering two bills on biotechnology regulation. See infra note 142; infra notes 220-34 and accompanying text.

[43] See Senate Hearings on Environmental Consequences, supra note 1, at 34 (statement of Dr. Bernard Talbot, Acting Director, National Institute of Allergy and Infectious Diseases, NIH). The authority to promulgate the Guidelines was derived from the Public Health Service Act, 42 U.S.C. § 241(a)-(b) (1982 & Supp. III 1985). See McChesney & Adler, supra note 19, at 10,370 & n.42.

[44] Guidelines for Research Involving Recombinant DNA Molecules, 41 Fed. Reg. 27,911, 27,912-14 (July 7, 1976) [hereinafter 1976 Guidelines]. The Guidelines classified research on the basis of the perceived hazards of the different types of rDNA research. Each research classification was then assigned to be performed under a corresponding level of containment constraining the research performed under that classification. See id. See generally Senate Hearings on Environmental Consequences, supra note 1, at 33-41 (statement of Dr. Bernard Talbot, Acting Director, National Institute of Allergy and Infectious Diseases, NIH) (discussing the evolution of the Guidelines).

[45] Research was to be performed on organisms desigued to die outside the laboratery. See 1976 Guidelines, supra note 44, at 27,915-17.

[46] See id. at 27,914-15.

the environment.[47]

The NIH has revised and relaxed the Guidelines numerous times since their original promulgation[48] and lifted the general prohibition against the deliberate release of rDNA microbes.[49] The relaxation of the prohibition against deliberate release experiments culminated in the NIH's approval of three such experiments, including the ice-minus release proposed by Dr. Steven Lindow and initially enjoined in *Foundation on Economic Trends v. Heckler*.[50]

A. *Regulation of Deliberate Releases by Federally Funded Institutions*: Foundation on Economic Trends v. Heckler

The NIH approval of the three experiments refueled public debate over rDNA research[51] and provoked the first court challenge to the administration of the NIH Guidelines in the context of deliberate release, *Foundation on Economic Trends v. Heckler*.[52] The plaintiffs in *Founda-*

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[47] See House Hearing on Environmental Implications, supra note 27, at 38 (statement of Geoffrey M. Karny, Senior Analyst, Biological Applications Program, Office of Technology Assessment).

[48] See 43 Fed. Reg. 60,108 (Dec. 22, 1978); 45 Fed. Reg. 77,384 (Nov. 21, 1980); 46 Fed. Reg. 34,462 (July 1, 1981); 47 Fed. Reg. 17,180 (Apr. 21, 1982); 47 Fed. Reg. 38,048 (Aug. 27, 1982); 48 Fed. Reg. 24,556 (June 1, 1983); 49 Fed. Reg. 46,266 (Nov. 23, 1984); 51 Fed. Reg. 16,958 (May 7, 1986).

[49] In 1978 the NIH revised the Guidelines' classifications of experiments and stated that although deliberate release was still prohibited, exceptions could be granted "provided that these experiments are expressly approved by the Director, NIH, with advice of the Recombinant DNA Advisory Committee after appropriate notice and opportunity for public comment." Guidelines for Research Involving Recombinant DNA Molecules, 43 Fed. Reg. 60,108, 60,108 (Dec. 22, 1978) [hereinafter 1978 Guidelines]. Significantly, the NIH did not prepare an Environmental Impact Statement (EIS) for the 1978 revision. See Foundation on Econ. Trends v. Heckler, 756 F.2d 143, 149 (D.C. Cir. 1985); infra note 56 and accompanying text. In 1982 the NIH changed the classification of deliberate release experiments from "Prohibitions" to "Experiments that Require RAC Review and NIH and Institutional Biosafety Committee Approval Before Initiation." See Guidelines for Research Involving Recombinant DNA Molecules, 47 Fed. Reg. 17,180, 17,186-87 (Apr. 21, 1982) [hereinafter 1982 Guidelines]; see also Senate Hearings on Environmental Consequences, supra note 1, at 35 (testimony of Dr. Bernard Talbot, Acting Director, National Institute of Allergy and Infectious Diseases, NIH) (outlining changes made to NIH Guidelines in 1978 and 1982).

[50] See Staff Report, supra note 22, at 17. Because of feasibility problems, the other two experiments—a field test of corn plants and a field test of tobacco and tomato plants—were never performed. See id. at 17 & n.22.

[51] See, e.g., Senate Hearings on Environmental Consequences, supra note 1; House Hearing on Environmental Implications, supra note 27; Staff Report, supra note 22; Begley, Greening the Gene, Newsweek, Nov. 12, 1984, at 103, 103-04.

[52] 587 F. Supp. 753 (D.D.C. 1984), aff'd in part, vacated in part, 756 F.2d 143 (D.C. Cir. 1985). For a description of the case including a listing of sources publishing case documents, see Korwek & de la Cruz, supra note 30, at 311 n.54.

tion on Economic Trends, led by anti-biotechnology activist Jeremy Rifkin,[53] sought an injunction against the approval of Dr. Lindow's ice-minus experiment[54] on two grounds. First, the plaintiffs maintained that in revising the deliberate release portion of the Guidelines in 1978, 1982, and 1983, the NIH had failed to follow the requirements of the National Environmental Policy Act (NEPA).[55] Specifically, the plaintiffs claimed that the NIH should have prepared a programmatic Environmental Impact Statement (EIS) before modifying the Guidelines to permit the deliberate release of any rDNA microbes into the environment.[56]

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[53] For descriptions of Jeremy Rifkin, a leader of the Foundation on Economic Trends, see Marshall, The Prophet Jeremy, New Republic, Dec. 10, 1984, at 20; Cbase, Jeremy Rifkin Usually Infuriates—and Often Bests—Biotech Industry, Wall St. J., May 2, 1986, at 23, col. 4. Other plaintiffs on the first amended complaint were Michael W. Fox, Environmental Action, Inc., and the Environmental Task Force.

[54] The experiment involved spraying a solution containing the ice-minus bacteria on a row of potato plants to determine whether the sprayed plants would be less susceptible to frost damage. See *Foundation on Econ. Trends*, 587 F. Supp. at 755-56; Norman, supra note 6, at 962. For a description of the ice-minus bacterium, see supra note 27.

[55] 42 U.S.C. §§ 4321-4347 (1982).

[56] See *Foundation on Econ. Trends*, 587 F. Supp. at 756-57. Plaintiffs alleged that the NIH's conduct was in violation of § 102(2)(C) of NEPA, which requires a federal agency, before taking major action that may have a significant impact on the environment, to prepare an EIS describing in detail:

> (i) the environmental impact of the proposed action,
>
> (ii) any adverse environmental effects which cannot be avoided should the proposal be implemented,
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> (iii) alternatives to the proposed action,
>
> (iv) the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity, and
>
> (v) any irreversible and irretrievable commitments of resources which would be involved in the proposed action should it be implemented.

42 U.S.C. § 4332(2)(C) (1982).

For a federal agency, the decision whether to prepare an EIS has three steps. First, the agency must determine whether the proposed action is subject to a "categorical exclusion," which means that the agency need not prepare either an EIS or an Environmental Assessment. See 40 C.F.R. § 1501.4(a)(2) (1985). Categorical exclusions are granted to actions that "do not individually or cumulatively have a significant effect on the human environment." Id. § 1508.4. If the agency determines that the activity is not excluded, it must prepare an Environmental Assessment (EA). Id. § 1501.4(b). An EA must "[b]riefly provide sufficient evidence and analysis for determining whether to prepare an environmental impact statement or a finding of no significant impact." Id. § 1508.9(a)(1). Finally, the agency must determine, based on the EA, whether the action will have a significant impact on the environment; if it will, the agency must prepare an EIS. See id. § 1501.4(c). The EIS evaluation process may be required both for a single agency action (such as approval of a specific microbial release) or for an action establishing a broad program or process (such as the NIHRAC procedure for reviewing deliberate release experiments). The latter is known as a "programmatic" EIS. See Foundation on Econ. Trends v. Heckler, 756 F.2d 143, 159 (D.C. Cir. 1985).

Second, the plaintiffs maintained that the procedure used to approve this particular deliberate release—the ice-minus experiment—did not comply with NEPA.[57] Judge John Sirica agreed and granted a preliminary injunction, pending compliance with NEPA, against both the ice-minus experiment and future NIH approval of any other deliberate release experiments.[58] Judge Sirica explicitly exempted NIH approval of *commercial* deliberate release experiments, however, on the ground that NEPA applied only to federally funded institutions.[59]

Scientists immediately criticized the injunction against the ice-minus experiment[60] and predicted that it would have a "tremendous chilling effect" on research.[61] The exemption for commercial research was described as a "gaping loophole"[62] that created a "double standard."[63] One commentator even suggested that the exemption for commercial research would induce a "drain of scientists from the universities into industry or out of the country."[64]

On appeal, the United States Court of Appeals for the District of Columbia Circuit upheld the injunction against the ice-minus experiment but vacated the injunction against future NIH approval of any other deliberate releases as overly broad.[65] In upholding the ice-minus injunction, the District of Columbia Circuit found the NIH's review of the possible environmental consequences of the experiment insufficient to satisfy the requirements of NEPA.[66] Finding, among other problems, that the NIH

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[57] See *Foundation on Econ. Trends*, 587 F. Supp. at 767.

[58] See id. at 769.

[59] See id. at 766-67.

[60] See Norman, supra note 6, at 962.

[61] Id. (quoting Daniel Adams, president of Advanced Genetic Sciences, Inc.).

[62] Id.

[63] Id. at 963.

[64] Id. at 962 (quoting Daniel Adams, president of Advanced Genetic Sciences, Inc.). For a review of the impact of the emerging biotechnology industry on the academic community and the potential "brain drain," see Congressional Research Service, Biotechnology: Commercialization of Academic Research 5 (Issue Brief IB81160) (prepared by J. Johnson) (rev. May 17, 1983).

[65] See Foundation on Econ. Trends v. Heckler, 756 F.2d 143, 160 (D.C. Cir. 1985).

[66] See id. at 154. NEPA requires federal agencies to determine whether an EIS is required by performing a preliminary assessment of possible environmental consequences. See supra note 56. The Court of Appeals noted that the NIH had prepared an EIS shortly after it promulgated the Guidelines, but due to the ban on deliberate releases, the EIS did not contemplate the potential environmental hazards of deliberate release experiments. See Foundation on Econ. Trends v. Heckler, 756 F.2d 143, 148 (D.C.Cir. 1985). The EIS did state that in the event of unintentional environmental release of "organisms containing recombined DNA . . . into the environment, they might, depending on their fitness relative to naturally occuring [sic] organisms, find a suitable ecological niche for their own reproduction. A potentially dangerous organism might then multiply and spread." Id. No EIS measuring the effects of the ice-minus experiment was prepared.

had not considered the environmental effects of the microbe's dispersion,[67] the court stated that "[i]gnoring possible environmental consequences will not suffice. Nor will a mere conclusory statement that the number of recombinant-DNA-containing organisms will be small and subject to processes limiting survival."[68]

In regard to the injunction against future approval of deliberate release experiments, the court noted that development of a new technology with unknown consequences was precisely the type of governmental action that typically required programmatic review.[69] It concluded, however, that NEPA did not require the NIH to prepare a programmatic EIS before beginning to consider applications for approval of deliberate release experiments.[70] Instead, the court found it sufficient that the NIH engage in rigorous case-by-case examination of the environmental consequences of each deliberate release proposal.[71]

In a concurring opinion, Judge MacKinnon asserted that the experiment presented minimal risks, but that the NIH should have performed the proper assessments of environmental consequences to address "lay concerns" with the new technology.[72] He then criticized the Foundation on Economic Trends for failing to object to the approval of deliberate release experiments during the NIH review process.[73] Thus, although the court reaffirmed the NIH's regulatory authority under NEPA, it also recognized that protracted litigation could damage rDNA research.

A significant jurisdictional question remained. The development of the NIH Guidelines had inadvertently created a double standard:[74] whereas scientists conducting rDNA research in facilities receiving federal funds were required to comply with the Guidelines,[75] those in private nonprofit laboratories and commercial enterprises were not.[76] Although *Foundation*

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[67] See Foundation on Econ. Trends v. Heckler, 756 F.2d 143, 153 (D.C. Cir. 1985).

[68] Id. at 154.

[69] See id. at 159 ("[F]ederal development of a new technology with unknown environmental consequences is the type of action in which programmatic considerations are particularly important.").

[70] Id. The court suggested, however, that a programmatic EIS might be required at a later date, when requests for approval of deliberate releases became more frequent. See id. at 159-60.

[71] See id. at 159.

[72] Id. at 161 (MacKinnon, J., concurring).

[73] See id.

[74] See Norman, supra note 6, at 963.

[75] Guidelines for Research Involving Recombinant DNA Molecules, 48 Fed. Reg. 24,556, 24,563 (June 1, 1983) [hereinafter 1983 Guidelines]. The maximum penalty for violating the Guidelines is withdrawal of NIH funds. Senate Hearings on Environmental Consequences, supra note 1, at 37 (statement of Dr. Bernard Talbot, Acting Director, National Institute of Allergy and Infectious Diseases, NIH).

[76] See 1983 Guidelines, supra note 75, at 24,563. These scientists are, however, encouraged

on Economic Trends forced the NIH to assess the environmental hazards of deliberate release experiments by federally funded institutions, the regulation of commercial enterprises was left up to other federal agencies.

B. Regulation of Commercial Deliberate Releases

Soon after the commercialization of biotechnology began, academic scientists and members of the biotechnology industry recognized the need for greater coordination among the federal regulatory agencies sharing responsibility for rDNA.[77] Uncertain of the regulatory picture, biotechnology companies viewed jurisdictional disputes among agencies with suspicion[78] and were less eager to invest in product development.[79]

To address these problems, the Cabinet Council on Natural Resources and the Environment formed the Working Group on Biotechnology "to determine whether the existing regulatory apparatus was adequate to consider the safety and health and environmental effects of modern biotechnology as its products and processes move from contained research laboratories to the marketplace."[80] The Working Group reviewed federal biotechnology regulation and published a proposed regulatory strategy in December 1984[81] and a revised proposal in November 1985.[82] Seven months later, the Working Group published for public comment the final regulatory proposal, entitled "Coordinated Framework for Regulation of

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to comply with the Guidelines voluntarily. See id.

[77] See Sun, Biotechnology's Regulatory Tangle, 225 Sci. 697, 697 (1984); Hilts, Panel Created to Coordinate Biotechnology Policy, Wash. Post, Nov. 12, 1985, at A6, col. 1.

[78] See Rhein & Hall, Splicing Together a Regulatory Body for Biotechnology, Bus. Wk., Jan. 14, 1985, at 69, 69.

[79] See Biotechnology Development: Hearing Before the Subcomm. on Oversight and Investigation of the House Comm. on Energy and Commerce, 99th Cong., 1st Sess. 70 (1985) (testimony of Robert B. Nicholas, Partner, Blum, Nash & Railsback, Wash., D.C.).

[80] House Hearing on Biotechnology Regulation, supra note 17, at 11 (testimony of Dr. Bernadine Bulkley, Deputy Director, Office of Science and Technology Policy, Executive Office of the President). The group was composed of representatives of 15 agencies. See Sun, supra note 77, at 697. Among the agencies were the EPA, the Food and Drug Administration (FDA), the Department of Agriculture (USDA), and the Office of Science and Technology Policy (OSTP), which was formed in April of 1984. See House Hearing on Biotechnology Regulation, supra note 17, at 68 (memorandum of Martin L. Smith, Deputy Assistant Director for Energy and Natural Resources, Office of Policy Development, Executive Office of the President). The name of the Working Group has since been changed to the Domestic Policy Council Working Group, and it is now chaired by the OSTP Director. See Coordinated Framework for Regulation of Biotechnology: Establishment of the Biotechnology Science Coordinating Committee, 50 Fed. Reg. 47,174, 47,175 (proposed Nov. 14, 1985) [hereinafter 1985 Coordinated Framework].

[81] Proposal for a Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. 50,856 (proposed Dec. 31, 1984) [hereinafter 1984 Coordinated Framework].

[82] 1985 Coordinated Framework, supra note 80, at 47,174.

Biotechnology" (the Coordinated Framework).[83]

To enhance agency cooperation, the Coordinated Framework establishes a two-tiered mechanism. As initially proposed, the lower tier consisted of an rDNA science advisory committee in each affected federal agency[84] and the upper tier of a science advisory committee, called the Biotechnology Science Board (BSB), which had substantial power to ensure interagency cooperation and consistency through its review of regulatory procedures in the individual agencies.[85] When the double-review process was attacked as cumbersome and unnecessary,[86] the Working Group responded by stripping the BSB of most of its supervisory powers, remarking somewhat ironically that it believed "interagency information sharing and coordination could be [more] effectively carried out by a structure offering interagency coordination."[87]

In its final form, the Biotechnology Science Coordinating Committee (BSCC), as the Biotechnology Science Board is now called, consists of representatives from NIH, the EPA, the National Science Foundation, the Food and Drug Administration and the Department of Agriculture.[88] The BSCC has four functions: to coordinate scientific information sharing and problem solving; to promote the development of consistent review procedures and assessment techniques by affected agencies; to foster agency cooperation on new scientific issues; and to identify important gaps in scientific understanding of rDNA.[89] In short, the BSCC does not oversee the individual agencies, but operates solely in an advisory capacity.[90] Whether the "watered down" BSCC will have the authority to coor-

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[83] 51 Fed. Reg. 23,302 (June 26, 1986) (as corrected by 51 Fed. Reg. 25,412 (July 14, 1986)) [hereinafter 1986 Coordinated Framework]. The 1986 Coordinated Framework emphasizes the need to minimize regulation to enable the American biotechnology industry to compete successfully with growing international competition. See id. at 23,308.

[84] See 1985 Coordinated Framework, supra note 80, at 47,175.

[85] See id.

[86] See Hilts, supra note 77, at A6, col. 1 (noting that industry representatives feared that a review board would add an additional hurdle to the regulatory process).

[87] 1985 Coordinated Framework, supra note 80, at 47,175.

[88] See id. The final proposal adopts the BSCC structure set forth in the 1985 Coordinated Framework. See 1986 Coordinated Framework, supra note 83, at 23,306.

[89] See 1985 Coordinated Framework, supra note 80, at 47,176. The BSCC has been formed as a committee of the Federal Coordinating Council for Science, Engineering, and Technology, a little known interagency coordinating council of the Office of Science and Technology Policy, Executive Office of the President. The BSCC will be chaired on a rotating basis by the Assistant Director for Biological, Behavioral and Social Sciences of the NSF and the Director of the NIH. See id.

[90] See Hilts, supra note 77, at A6, col. 1 (reporting comment of David T. Kingsbury, Assistant Director for Biological, Behavioral and Social Sciences for the National Science Foundation, that "[w]e are not going to spend our time looking over agency shoulders and saying 'You made a mistake in releasing something, and we'll have to bring it back' ").

dinate federal biotechnology regulation effectively is doubtful.[91]

To accompany the Coordinated Framework, the EPA prepared an agency policy statement (Microbial Product Policy).[92] In the Microbial Product Policy, the EPA has asserted its authority to serve as the principal regulatory agency for the deliberate release of rDNA microbes.[93] At the same time, the EPA has relinquished authority over genetically engineered plants and animals.[94] Under the Microbial Product Policy, the EPA will regulate commercial production of rDNA microbes under two principal statutes: the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)[95] and the Toxic Substances Control Act (TSCA).[96]

1. Statutory Regulation Under FIFRA

FIFRA is the principal statute governing the testing, distribution, and use of pesticides.[97] Because many releases of rDNA microbes will involve pesticides, FIFRA will play a major role in the regulation of the biotechnology industry.[98] Under FIFRA, the EPA cannot authorize the sale or distribution of a pesticide or other regulated substance until it collects sufficient data to ensure that "when used in accordance with widespread and commonly recognized practice, [it] will not cause (or significantly increase the risk of) unreasonable adverse effects to humans or the environment."[99] The EPA has regulated naturally occurring microbial pesticides for years;[100] by 1985, fourteen microbial pesticides were registered under FIFRA requirements.[101] Under the Microbial Product Policy, the EPA

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[91] See Sun, EPA Approves Field Test of Altered Microbes, 230 Sci. 1015, 1016 (1985).

[92] Statement of Policy: Microbial Products Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic Substances Control Act, 51 Fed. Reg. 23,313 (June 26, 1986) [hereinafter 1986 Microbial Product Policy]. Earlier proposals were published at 49 Fed. Reg. 50,880 (proposed Dec. 31, 1984) [hereinafter 1984 Microbial Product Policy], and 49 Fed. Reg. 40,659 (proposed Oct. 17, 1984) [hereinafter Interim Microbial Product Policy].

[93] The assertion was made initially by the 1984 proposed policy and has been carried out in the final policy as well. Both policy statements have, however, recognized the overlapping jurisdiction of other federal agencies. See 1984 Microbial Product Policy, supra note 92, at 50,895; 1986 Microbial Product Policy, supra note 92, at 23,318.

[94] See 1986 Microbial Product Policy, supra note 92, at 23,318. The EPA has explained that it must strike "a balance between the restrictions and higher costs" of regulation. 1984 Microbial Product Policy, supra note 92, at 50,882.

[95] 7 U.S.C. §§ 136-136y (1982, Supp. I 1983, Supp. II 1984, Supp. III 1985).

[96] 15 U.S.C. §§ 2601-2629 (1982, Supp. I 1983, Supp. II 1984, Supp. III 1985).

[97] See 1984 Microbial Product Policy, supra note 92, at 50,882.

[98] See generally 1986 Microbial Product Policy, supra note 92, at 23,319-24 (discussing the applicability of FIFRA to microbial products).

[99] Id. at 23,319; see 7 U.S.C. § 136a(c)(5)(D), (c)(7) (1982); 40 C.F.R. § 162.2(d)(4) (1986).

[100] See 1986 Microbial Product Policy, supra note 92, at 23,320.

[101] Id.

will extend FIFRA to genetically engineered microorganisms[102] that are considered to be "pesticides" under FIFRA section 2(u).[103]

The EPA's registration requirements and testing procedures for non-rDNA microbial pesticides are designed to enable the agency to evaluate the risks of "infectivity, pathogenicity, toxicity, host range, virulence, and survivability."[104] RDNA microbial pesticides present many of the same risks as their non-rDNA counterparts, but may have greater survivability, enhanced virulence, and greater ability to compete with indigenous organisms.[105] In response to these risks, the EPA will apply the current microbial pesticide regulations to rDNA microbes,[106] but may require more detailed data for use in assessing the risks of particular rDNA microbial pesticides.[107]

The EPA requires producers of new non-rDNA pesticides to submit data sufficient to indicate the identity, molecular composition, potential harmful effects, and environmental fate of the pesticide.[108] For rDNA pesticides, the EPA may require certain additional data, including information on the specific gene sequence inserted in the microbe, the method used to insert that sequence, the regions in the gene that control its expression, the new traits that it expresses, and the likelihood that the gene will be transferred to other organisms in nature.[109]

After an applicant has submitted the required data for the new pesti-

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[102] See id. at 23,319-20.

[103] See id. at 23,319-24. Section 2(u) of FIFRA defines "pesticide" as "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or dessicant." 7 U.S.C. § 136(u) (1982); see 40 C.F.R. §§ 162.3 (ff), 162.4 (1986). Most nonmicrobial organisms considered to be biological control agents, on the other hand, are currently exempt from FIFRA because they are regulated by other agencies. See 1986 Microbial Product Policy, supra note 92, at 23,320; 40 C.F.R. § 162.5(c)(4) (1986). The EPA defines "biological control agent" as "any living organism applied to or introduced into the environment to control the population or biological activities of another life form which is considered a pest under section 2(t) of FIFRA." Id. § 162.5(c)(2).

[104] See 1984 Microbial Product Policy, supra noto 92, at 50,884.

[105] See id.

[106] See 1986 Microbial Product Policy, supra note 92, at 23,319-24.

[107] See id. at 23,321, 23,323.

[108] See 40 C.F.R. § 158.170 (1986). Specific data requirements vary depending upon the "general use patterns" of the pesticide. The uses are grouped into six categories: "terrestial, aquatic, greenhouse, forestry, domestic outdoor, or indoor." Id. Depending upon the general use pattern, data are required in four categories. First, data are required regarding product analysis to determine the identity of the pesticide and possible formation of unintentional by-products. Second, residue data are required to determine the amount and type of compounds that remain after application of the pesticide. Third, toxicology data are required to identify possible toxicity. Fourth, "non-target organism and environmental expression" data are required to assess the impact of the pesticide on the environment. See id.

[109] See 1986 Microbial Product Policy, supra note 92, at 23,321, 23,323.

cide, the EPA may then regulate its use under FIFRA.[110] Section 5 of FIFRA allows an individual to obtain an Experimental Use Permit (EUP) for limited uses of an unregistered pesticide.[111] The EUP allows an applicant to bypass the lengthy delays and expense of registration in the early development of a pesticide. Small-scale field testing of a pesticide may be conducted without even an EUP, however, so long as the principal purpose of the test is to establish the pesticide's effectiveness, rather than to provide actual pest control.[112]

The EPA has recognized that microbial pesticides have several characteristics that may make even small-scale field tests of such pesticides quite dangerous: replication, dispersion, and resistance to "natural control."[113] As a result, the EPA requires individuals to notify it before conducting any field studies, regardless of size or purpose, with microbial pesticides.[114] This notification process is designed to enhance the EPA's

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[110] The EPA will follow the same procedures for registering rDNA pesticides as those used in registering chemical pesticides and non-rDNA microbial pesticides. See id. at 23,321. These procedures are codified at 40 C.F.R. §§ 152 and 158 (1986). The expected time required for EPA review of submitted data under FIFRA currently varies from nine months to several years, and similar periods may be expected for rDNA microbial pesticides. See 1984 Microbial Product Policy, supra note 92, at 50,885. Once registered, microbial pesticides are regulated under 40 C.F.R. §§ 158.65 and 158.170 (1986).

[111] See 7 U.S.C. § 136c (1982). 40 C.F.R. § 172 (1986) establishes the procedures for issuance of EUPs.

[112] See 40 C.F.R. § 172.3 (1986). The exemption from EUP requirements applies only to field studies of not more than 10 acres if on land or one surface-acre if on water. See id. § 172.3(a)(1)-(2).

[113] See 1984 Microbial Product Policy, supra note 92, at 50,885. "Microbial pesticides . . . may replicate and spread beyond the site of application. Further, nonindigenous and genetically engineered microbial pesticides may not be subject to natural control or dissipation mechanisms; they may be capable of spreading beyond the site of application . . . ." Id.

[114] See 1986 Microbial Product Policy, supra note 92, at 23,320. The amount of information that the notice must include varies depending on how risky the EPA believes the microorganism to be. Level II microbes, which are considered more dangerous, include "[m]icrobial pesticides formed by deliberately combining genetic material from organisms of different genera, genetically engineered microbial pesticides derived from source organisms that are pathogens . . . and nonindigenous pathogenic microbial pesticides." Id. at 23,321. These microbes are subject to stringent reporting requirements. Level I microbes, for which less information must be submitted, include all other microbial pesticides. Information that must be submitted for Level I microbes is as follows:

> (1) Identity of the microorganism, including characteristics, and means and limits of detection.
>
> (2) Description of the natural habitat of the microorganism or its parental strains, including information on natural predators, parasites, and competitors.
>
> (3) Information on the host range of the parental strain(s) or nonindigenous microorganism.
>
> (4) Information on the relative environmental competitiveness of the microorganism, if available.

ability to restrict small-scale field tests of potentially hazardous microbes.

2. *Statutory Regulation Under TSCA*

The EPA will regulate *non*-pesticidal commercial microbes, DNA sequences, and their products under TSCA. The purpose of TSCA is "to provide a comprehensive mechanism for addressing the hazards to health and the environment of chemical substances."[115] Section 3(2) of TSCA defines "chemical substance" as "any organic or inorganic substance of a particular molecular identity, including . . . (i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature and (ii) any element or uncombined radical."[116] The definition specifically excludes mixtures, pesticides, tobacco and tobacco products, nuclear materials, and food, drug, or cosmetic devices.[117] The EPA will regulate most non-pesticidal rDNA gene sequences and microbes through TSCA, on the basis of their purported status as new chemical substances.[118] According to the EPA, the chemical substances definition applies to these microbes because "[a] living organism is a 'combination of such substances occuring [sic] in whole or in part as a result of a chemical reaction . . . or occurring in nature,' "[119] and DNA

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(5) If the microorganism is genetically engineered, information should be provided on the methods used to genetically engineer the microoranism(s); the identity and location of the rearranged or inserted/deleted gene segment(s) in question; a description of the new trait(s) or characteristic(s) that are expressed; information on potential for genetic transfer and exchange with other organisms, and on genetic stability of any inserted sequence.

(6) A description of the proposed testing program, including site location, crop to be treated, target pest, amount of test material to be applied, and method of application.

Id. The information required for Level II microbes is similar to that required for Level I microbes, but includes additional data about the location and parameters of the field test, as well as detailed data about any genetic alterations. See id. at 23,321-22.

[115] Senate Hearings on Environmental Consequences, supra note 1, at 122 (testimony of Prof. Thomas O. McGarity, Univ. of Texas Law School); see 15 U.S.C. § 2601(a)-(c) (1982).

[116] 15 U.S.C. § 2602(2)(A) (1982).

[117] Id. § 2602(2)(B).

[118] See 1984 Microbial Product Policy, supra note 92, at 50,886. This approach was reaffirmed in the final policy. See 1986 Microbial Product Policy, supra note 92, at 23,324. According to the EPA, most microorganisms produced for environmental, industrial, or consumer uses, including those that may be developed for "conversion of biomass for energy, pollutant degradation, enhanced oil recovery, metal extraction and concentration, and certain non-food and non-pesticidal agricultural applications," are potentially regulable under TSCA. See id. Specifically excluded from the scope of the statutue, however, are foods, food additives, drugs, cosmetics, medical devices, and pesticides, as well as plants and animals. See id.

[119] 1984 Microbial Product Policy, supra note 92, at 50,886.

sequences are "organic substances of a particular molecular identity."[120]

The EPA will regulate two types of microbes under TSCA—those that have been modified by the insertion of genetic material from organisms of different genera,[121] and those that are pathogenic or have received genetic material from organisms that are pathogens.[122] The former will be regulated by the premanufacture notification (PMN) requirements of TSCA section 5(a)(1)(A);[123] the latter by the significant new use report (SNUR) requirements of TSCA section 5(a)(1)(B), whenever they are released into the environment.[124]

TSCA provides the EPA administrator with power to require a premanufacture notification to EPA of the importation or manufacture of any chemical defined as a "new chemical substance."[125] "New" chemical substances are those that are not listed on the current EPA Inventory of all chemical substances currently being manufactured or processed in the United States.[126] The EPA considers all microorganisms deliberately formed to contain genetic material from different genera, except for those in which the added genetic material consists only of well-characterized, non-coding regulatory regions, to be new chemical substances subject to the PMN reporting requirements.[127] Once a microbe has been classified as a new chemical substance, section 5(a)(1)(A) requires commercial manufacturers to notify the EPA of their intention to import or produce it ninety days before beginning to do so.[128] The PMN must include a wide variety of known or reasonably ascertainable information about the

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[120] Id.

[121] See 1986 Microbial Product Policy, supra note 92, at 23,325. These microbes are called "inter-generic combinations." See id. at 23,332. The process for determining whether an organism is an inter-generic combination is outlined in id. at 23,332-33.

[122] See id. at 23,325. The process for determining whether an organism is pathogenic is outlined in id. at 23,333-35.

[123] See id. at 23,325.

[124] See id. ("Microorganisms other than inter-generic compounds that are . . . pathogenic or contain genetic material from pathogens will, in the future, if released into the environment, be subject to significant new use reporting requirements under TSCA section 5(a)(2).").

[125] See 15 U.S.C. § 2604(a)(1)(A) (1982).

[126] See 15 U.S.C. § 2602(9) (1982). TSCA directs the EPA to prepare and maintain a Chemical Substances Inventory. See 15 U.S.C. § 2607(b) (1982). This Inventory contains both manmade and naturally occurring substances. See 40 C.F.R. § 710.4(b) (1986).

[127] See 1986 Microbial Product Policy, supra note 92, at 23,325-26. The EPA has expressly reserved judgment, however, on whether microorganisms containing genetic material from other organisms in the same genus, called "intra-generic combinations," and those that are developed from a single source microorganism, should also be considered "new" and therefore subject to PMN requirements. See id. at 23,325.

[128] See 15 U.S.C. § 2604(a)(1)(A) (1982).

substance.[129]

The EPA recognized that organisms and compounds that do not fall within the statutory definition of new chemical substance—and thus within the PMN reporting requirements—may also present significant risks to health or the environment.[130] The Microbial Product Policy suggests that the SNUR provisions of TSCA section 5 may be used, as a supplement to the PMN requirements, to require notification to the EPA in these cases.[131] Section 5(a)(2) authorizes the EPA, upon consideration of all relevant factors, to issue a rule declaring that a particular use of a chemical substance already listed on the Inventory is a "significant new use."[132] Once the EPA has issued a SNUR, section 5(a)(1)(B) requires any individual planning to manufacture or process the substance for that use to notify the EPA ninety days before doing so, through a submission similar to a PMN.[133]

TSCA section 5(h)(3), however, provides a significant exemption from the PMN and SNUR requirements for chemical substances produced in small quantities solely for research and development purposes.[134] "Small quantities" have been defined by rule to be those not greater than reasonably necessary for research and development purposes.[135] Notification is not required under TSCA for deliberate release experiments meeting this definition, although the EPA can require data submissions where necessary.[136] The small quantities exemption created a much-discussed gap in the federal oversight of deliberate release microbes: whereas academic research—that is, research undertaken with the support of federal funds—required NIH approval,[137] the same research, if performed on a

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[129] See 15 U.S.C. § 2604(d)(1) (1982); 15 U.S.C. § 2607(a)(2) (1982). Data include the common name and molecular identity of the chemical substance, amount to be produced, any test data on the effect the substance has on human health and the environment, and other information. See 15 U.S.C. § 2607(a)(2) (1982). Implementing rules, to be codified at 40 C.F.R. § 720, were proposed in early 1983, see 48 Fed. Reg. 21,722 (May 13, 1983), and revised a few months later, see 48 Fed. Reg. 41,132 (Sept. 13, 1983). The EPA revised these regulations still further in the 1986 Microbial Product Policy. See infra note 190.

[130] See 1986 Microbial Product Policy, supra note 92, at 23,329.

[131] See id. at 23,328-29.

[132] See 15 U.S.C. § 2604(a)(2) (1982). The process for determining if a use is a significant new use is outlined in the 1986 Microbial Product Policy, supra note 92, at 23,329-30.

[133] See 15 U.S.C. § 2604(a)(1)(B) (1982).

[134] See 15 U.S.C. § 2604(h)(3) (1982).

[135] See 40 C.F.R. § 720.3(cc) (1986).

[136] The specific provisions of the small quantity exemption, 40 C.F.R. §§ 720.36, 720.78(b) (1986), are currently subject to agency stay. See 48 Fed. Reg. 41,132 (1983). In the interim, producers of small quantities must follow the general provisions of 15 U.S.C. § 2604(h)(3) (1982) and 40 C.F.R. § 710.2(y) (1986). See 1984 Microbial Product Policy, supra note 92, at 50,891.

[137] See supra notes 51-76 and accompanying text.

small scale by commercial enterprises, was exempt from both NIHRAC review and from TSCA's PMN requirements.[138]

The 1986 Microbial Product Policy fills this gap by a rulemaking that excludes from the small quantities exemption living microbes released into the environment.[139] Thus, biotechnology companies planning to release rDNA microbes into the environment will be required to submit substantial data before performing any field tests. Although this rule will close the commercial deliberate release gap, it will narrow the statutory definition of "small quantity" to "no quantity" in the case of deliberate release microbes. This rule is of dubious validity and likely to provoke litigation by the affected companies.[140]

In sum, the Coordinated Framework and the EPA's Microbial Product Policy comprise a complex attempt to sort out the "labyrinth"[141] of federal biotechnology regulation using existing statutes. The proposals also represent an attempt on the part of the federal government to strike a balance between promoting the biotechnology industry and protecting human health and the environment.

III. Criticisms of the Regulatory Framework

The underlying difficulty with the present system of biotechnology regulation is that biotechnology involves new processes that in many cases cannot be adequately dealt with by existing environmental statutes.[142] In

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[138] See 1984 Microbial Product Policy, supra note 92, at 50,891.

[139] See 1986 Microbial Product Policy, supra note 92, at 23,330 ("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.").

[140] A second problem exists. Because TSCA § 5(i) defines manufacturing and processing to mean "manufacturing or processing for commercial purposes," 15 U.S.C. § 2604(i) (1982), pure academic research conducted without federal funds would remain outside the regulatory purview of the NIH Guidelines and of the EPA under TSCA. See 1984 Microbial Product Policy, supra note 92, at 50,881; see also 1986 Microbial Product Policy, supra note 92, at 23,331 (discussing the exemption for noncommercial research and development).

[141] See Flaherty, A Brave New World for Biotech Lawyers, Nat'l L.J., Oct. 8, 1984, at 27, col. 1.

[142] Legislation designed to remedy some of the problems identified here has been introduced and is pending in both houses of Congress. On December 17, 1985, Sen. Durenberger (R-Minn.) and Sen. Baucus (D-Mont.) submitted S. 1967, entitled "A Bill to amend the Toxic Substances Control Act to protect the environment and human health from adverse effects caused by the release of genetically engineered micro-organisms into the environment, to promote the safe use of genetically-engineered micro-organisms, and for other purposes." S. 1967, 99th Cong., 1st Sess., 131 Cong. Rec. 17, 812-14 (1985). On March 19, 1986, Rep. Don Fuqua (D-Fla.) introduced H.R. 4452, entitled "The Biotechnology Science Coordination Act of 1986." H.R. 4452, 99th Cong., 2nd Sess., 132 Cong. Rec. 1433 (1986). For a

the absence of legislation specifically addressing biotechnology, however, agencies that have traditionally regulated similar activities have been tempted to extend their authority to biotechnology. Yet prior regulation of similar products or industries does not necessarily mean an agency has the ability to handle the complex problems associated with biotechnology. Although the potential risks of biotechnology resemble those addressed by existing environmental statutes, they are often more difficult to assess. Existing statutes may suffice in some cases, forestalling the need for new and potentially misguided legislation. But when questionable statutory interpretations are required to extend the reach of existing legislation, the inevitable court challenges—and the regulatory readjustments that follow—may stymie commercial development in an industry that relies upon constant innovation and clear guidelines.

A. Regulatory Uncertainty

1. Jurisdictional Confusion

The Coordinated Framework was developed to coordinate the federal oversight of biotechnology and to close regulatory gaps. Nevertheless, one commentator has called the federal agencies' attempts to divide responsibilities "a patchwork of conflicting regulatory policies."[143] The idea of the BSCC was to untangle jurisdictional problems, but to prevent the addition of a time-consuming layer in the regulatory process, the current Coordinated Framework gives the BSCC limited powers and membership, which severely restricts its ability to accomplish its mission. In fact, Senator Albert Gore (D-Tenn) has stated that "the council is toothless and just a kind of discussion group."[144] Although an actual evaluation of the success of the BSCC will require some experience with its operation, the chances of the BSCC operating effectively do not appear good.[145] Without some assurance of order in the regulatory structure, the strength of the biotechnology industry will be impaired.[146]

NIHRAC and the NIH Guidelines have been extremely successful in

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discussion of the provisions of both bills, see infra notes 220-34 and accompanying text.

[143] Pendorf, supra note 38, at 921.

[144] Sun, supra note 91, at 1016.

[145] Harvey Price, director of the Industrial Biotechnology Association, believes that neither the BSCC nor its parent committee resolves the confusion about jurisdictional control. See id.

[146] See Hilts, supra note 77, at A6, col. 1 (reporting that companies are uncertain about which agency to go to for approval); Comments on Cabinet Gene-Splice Plan, 127 Sci. News, May 4, 1985, at 280 (reporting statement of Jack Doyle, staff member of the Environmental Policy Institute, that there is "an increasing sense of confused responsibility in the federal establishment").

promoting academic research while allaying public fears about rDNA techniques, but because the Guidelines are not compulsory for commercial enterprises, a resurgence of public concern is occurring. Until 1985 no companies were prepared to perform deliberate release field tests of rDNA products.[147] In 1985, however, a private corporation—Advanced Genetic Sciences, Inc. (AGS)—sought and obtained EPA approval for the release of the ice-minus bacteria developed by Dr. Lindow.[148] Although the NIHRAC's approval of the release sponsored by Dr. Lindow was enjoined by a federal district court,[149] AGS, which as a private enterprise was not required to gain NIHRAC approval, was not affected by the injunction. Instead, it applied for and was granted EPA permission to field test the ice-minus bacteria,[150] triggering a second suit by the Foundation on Economic Trends.[151]

Months before the EPA approved the field test, AGS had performed its own unauthorized test, injecting the bacteria into trees growing on the two-acre roof of its Oakland, California headquarters.[152] Although AGS contended that the experiment was "contained" and therefore safe, the EPA later discovered that "a substantial number of the more than 45 trees leaked sap where the syringe was inserted,"[153] possibly permitting insects and birds to carry the bacteria beyond the roof and disproving the claim of containment. In addition, three trees developed cankers, indicating "an adverse reaction to the microbe,"[154] a reaction that AGS failed to report to the EPA.[155] When it learned of the unauthorized test, the EPA

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[147] See 1986 Microbial Product Policy, supra note 92, at 23,320; see also Karny, Regulation of Genetic Engineering: Less Concern About Frankensteins but Time for Action on Commercial Production, 12 U. Tol. L. Rev. 815, 831 (1981) (discussing why companies might voluntarily adhere to the Guidelines).

[148] See Boffey, Field Test of Gene-Altered Bacteria Is Approved, N.Y. Times, Nov. 15, 1985, at A17, col. 1.

[149] Foundation for Econ. Trends v. Heckler, 587 F. Supp. 753 (D.D.C. 1984), aff'd in part, vacated in part, 756 F.2d 143 (D.C. Cir. 1985); see supra notes 51-76 and accompanying text.

[150] See Boffey, supra note 148, at A17, col. 1.

[151] Foundation on Econ. Trends v. Thomas, 637 F. Supp. 25 (D.D.C. 1986). The court rejected a motion for a preliminary injunction against EPA approval of the experiment on the ground that the Foundation on Economic Trends was not likely to be able to establish that the EPA failed to follow the procedural requirements of FIFRA and NEPA or that the EPA failed to consider adequately the risks of the field test. See id. at 28-29. The court declined to grant summary judgment for the EPA, however, because the EPA was investigating allegations of wrongdoing by AGS, and the EPA's possible revocation of the permit "would moot any decision as to the permit's propriety." See id. at 29.

[152] See Hilts, Test of Altered Microbe Was Illegal, EPA Says, Wash. Post, Feb. 27, 1986, at A3, col. 5.

[153] See id.

[154] See id.

[155] See A Novel Strain of Recklessness, N.Y. Times, Apr. 6, 1986, at E22, col. 1.

responded by fining the company and withdrawing its permit to test the microbe.[156]

The absence of a clear federal regulatory policy and the perceived inadequacy of the existing policy has provoked not only an unauthorized test and lawsuits, but also state and local governmental actions to prevent rDNA microbial research and testing. For example, despite the lengthy NIH and EPA review and two court challenges of the ice-minus field test, the Monterey County, California, Board of Supervisors halted the field test sponsored by AGS in February 1986.[157] Many other local governments have passed restrictions on various forms of laboratory-based rDNA research.[158] In addition, the New Jersey legislature is considering a bill that would regulate biotechnology releases.[159] Given the growing public fear of rDNA deliberate releases, localities may produce even more extensive regulations in the future. State and local regulation will compound the time and expense required by biotechnology companies to gain approval for deliberate releases, with questionable environmental benefits. As these developments demonstrate, the Coordinated Framework and the NIH Guidelines alone are insufficient to allay the public concern about whether future deliberate releases by biotechnology companies will be adequately regulated.[160]

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[156] See id.

[157] See Foundation on Econ. Trends v. Heckler, 639 F. Supp. 25, 29 (D.D.C. 1986); Howard, Halting Designer Bacteria, Newsweek, Feb. 10, 1986, at 8. Several commentators have suggested that the tort system may provide the necessary incentive for companies to adhere to the Guidelines. See, e.g., Dworkin, Biocatastrophe and the Law: Legal Aspects of Recombinant DNA Research, *in* The Recombinant DNA Debate 222 (D. Jackson & S. Stich eds. 1979). These commentators assume that a court would find that the Guidelines establish the standard of care for biotechnological research and production. The Guidelines have become the customary practice in commercial biotechnology laboratories and compliance is mandatory for federally funded laboratories. See supra notes 51-77 and accompanying text. Although deliberate releases were once prohibited by the Guidelines, because the Guidelines have never been enforced against private industry, the standard of care in the event of a deliberate release misbap is uncertain.

[158] See generally Legislation—Recombinant DNA—Local Laws, 2 Biotech. L. Rep. (Liebert) 19 (Jan. 1983) (charting local laws).

[159] S. 1123, (prefiled for introduction in 202d Leg., 2d Annual Sess., 1986) (copy on file with Virginia Law Review Association).

[160] A second problem with NIH regulation of commercial rDNA activities is tbe traditional role of the NIH. The NIH is charged with identifying and promoting beneficial research, a role that is inconsistent with the regnlation of commercial biotechnology. See infra notes 206-10 and accompanying text for a description of similar problems within tbe nuclear power industry; see also Senate Hearings on Environmental Consequences, supra note 1, at 116 (testimony of Prof. Thomas O. McGarity, Univ. of Texas Law School) (comparing nuclear power to biotechnology promotion).

2. The Applicability of TSCA

The EPA monitors at least fourteen microbial pesticides under FIFRA[161] without difficulty, and the statute should be able to address rDNA microbial pesticides without significant problems. The proposed regulation of rDNA deliberate releases under TSCA, on the other hand, presents several problems. Although the legislative history indicates that Congress intended TSCA to serve as a "gap filler" for other environmental laws,[162] so that applying it to biotechnology would not contravene Congress' general purposes, there is no evidence that Congress ever considered the possibility that the statute would regulate biotechnology.[163] The technology was still in its infancy during this period,[164] and it is unclear whether Congress intended TSCA's gap-filling role to encompass only existing gaps, or also to include gaps that might arise in the future.

Because the legislative history does not address biotechnology, a court deciding whether TSCA can be used to regulate biotechnology must make its determination on the basis of other factors. A threshold question is whether TSCA's "chemical substance" definition[165] can be read to cover rDNA microbes. The regulation of nucleic sequences is uncontested under the definition, but the EPA's plans to extend its regulatory powers to the living microbes that contain these nucleic sequences have caused some controversy.[166]

The arguments for applying TSCA to living rDNA microbes rely on the literal terms of the chemical substance definition and on the general purpose of TSCA. Living organisms are clearly "a combination of [organic] substances occurring in whole or in part as a result of a chemical reaction or occurring in nature," as TSCA's definition of chemical substance requires.[167] The definition also requires, however, that a chemical substance be "of a particular molecular identity."[168] Living organisms are not of a particular molecular identity; in fact, their exact chemical composition is

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[161] See 1986 Microbial Product Policy, supra note 92, at 23,320.

[162] See, e.g., Staff Report, supra note 22, at 11. The legislation may have been intended, however, to fill contemporary, rather than future gaps.

[163] See House Hearing on Biotechnology Regulation, supra note 17, at 7 (statement of Rep. Dingell (D-Mich.)).

[164] The NIH Guidelines were not completed until July, 1976.

[165] See supra notes 116-17 and accompanying text.

[166] See Sun, EPA Revs Up to Regulate Biotechnology, 222 Sci. 823, 823 (1983) (quoting EPA official for the proposition that "[c]ompanies have already promised that they'll sue me" if authority is asserted under TSCA); see also Staff Report, supra note 22, at 123-26, 143-45 (concluding that although the arguments against applying TSCA are supportable, the arguments in favor of regulatory authority are stronger).

[167] See 15 U.S.C. § 2602(2)(A) (1982).

[168] See id.

constantly changing, through respiration and other processes.[169] For this reason, scientists have argued that living organisms are not chemical substances within the definition of TSCA. In the opinion of EPA Associate General Counsel Stanley H. Abramson, "commonly accepted scientific definitions [of chemical substances] both at the time of TSCA's enactment and today do not [include life forms]."[170]

Statements made by EPA officials just after passage of TSCA indicate that the EPA itself had some reservations about classifying life forms as chemical substances. As an EPA official stated in a 1977 letter to the chairman of a Senate subcommittee:

> [A]lthough there is a general consensus that recombinant DNA molecules are "chemical substances" within the meaning of section 3 of TSCA, it is not at all clear whether a host organism containing recombined DNA molecules fits—or was intended to fit—that definition. . . . If such organisms are subject to TSCA on the grounds that they are a "combination of . . . substances occurring in whole or in part as a result of a chemical reaction," the Agency might logically have to include all living things in the definition of "chemical substance"—an interpretation which I am confident the Congress neither contemplated nor intended.[171]

On the other hand, the EPA shortly thereafter rejected a comment suggesting that bacteria and fungi were not chemical substance with the statement that the chemical substances definition "does not exclude life forms which may be manufactured for commercial purposes and nothing in the legislative history would suggest otherwise."[172]

Another argument supporting the regulation of living organisms under TSCA is the all-inclusive nature of the statute's chemical substance definition. Because the definitional exclusions are made by explicit reference to other federal laws,[173] it can be argued that Congress would have explicitly excluded life forms if it had so intended.[174] In addition, there is at

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[169] See House Hearing on Environmental Implications, supra note 27, at 32 (statement of Geoffrey M. Karny, Senior Analyst, Biological Applications Programs, Office of Technology Assessment) (recognizing that "it is arguable whether a living organism has a particular moleculer [sic] identity").

[170] Staff Report, supra note 22, at 145 (memorandum of Stanley H. Abramson, Associate General Counsel, Pesticides and Toxic Substances Div., EPA) (arguing for TSCA applicability).

[171] Senate Oversight Report, supra note 40, at 88 (letter of Dec. 9, 1977, from Douglas M. Costle, Administrator, EPA, to Sen. Adlai Stevenson, Chairman of Subcomm. on Science, Technology, and Space of the Senate Comm. on Commerce, Science, and Transportation).

[172] Karny, supra note 147, at 847-48 (citing 42 Fed. Reg. 64,572, 64,584 (1977)).

[173] See 15 U.S.C. § 2602(2)(B) (1982).

[174] This broad interpretation of TSCA's chemical substance definition is supported by the

least one administrative precedent (predating the current attempts to regulate biotechnology) for applying TSCA to living organisms: substances labeled as of unknown or variable composition, complex reaction products, or biological materials—among which are included bacteria, fungi, yeasts, and microorganisms—are listed on the TSCA Chemical Substances Inventory.[175] In fact, the original Inventory instructions expressly required the reporting of bacteria, yeast, and fungi.[176]

Other elements of TSCA, however, support a determination that it is not applicable to biotechnology. TSCA refers to the "manufacture" of chemical substances,[177] and bioengineered life forms are not manufactured from whole cloth, though they may be altered. Similarly, the exemption for small quantities used in research and development indicates that Congress did not believe living microbes were covered by TSCA, because even small quantities of living organisms can create substantial environmental and human health problems when they multiply.[178] The threat of such microbial reproduction has led the EPA to exclude all rDNA deliberate release experiments from the TSCA exemption for small quantities, by issuing a rule that defines small quantities of deliberate release microbes as none whatsoever.[179]

Many questions exist concerning the applicability of TSCA to living organisms. These questions will almost certainly lead to court challenges of the EPA's proposed inclusion of living organisms in TSCA,[180] causing delays that will impede the development of the commercial biotechnology industry. Yet even if the proposed application of TSCA to living organisms withstands court scrutiny, as seems likely, other problems will surface. AGS's unauthorized testing of the ice-minus bacteria illustrates the private sector's impatience with regulatory and judicial delays. But it also points to a second flaw in the present regulatory system: the system does

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Supreme Court's opinion in Diamond v. Chakrabarty, 447 U.S. 303 (1980). In *Chakrabarty*, the Court held that a genetically engineered bacterium constituted a "manufacture" or "composition of matter" within the meaning of the federal patent statute, id. at 308-18, despite the fact that genetic technology was unforeseen at the time that statute was enacted, id. at 314-18. The *Chakrabarty* analogy was first suggested by Rep. Gore in the House Hearing on Environmental Implications, supra note 27, at 32.

[175] See Staff Report, supra note 22, at 125-26. Administrative precedents may be useful in construing a statute. See Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944).

[176] See Staff Report, supra note 22, at 125-26.

[177] See, e.g., 15 U.S.C. § 2604(a) (1982).

[178] See supra notes 29-37 and accompanying text (discussing potential hazards of microbial release).

[179] See 1986 Microbial Product Policy, supra note 92, at 23,330; supra notes 139-40 and accompanying text.

[180] See Sun, supra note 166, at 823.

not provide regulators with sufficient information on the risks posed by genetically engineered microbes.

B. Inadequate Data Accumulation and Evaluation

1. The Weakness of TSCA

The most important weakness of TSCA stems from the fact that it is not a "permitting" statute—a manufacturer of a new chemical substance need not secure a permit or a license before beginning production, so long as he submits a PMN report.[181] The PMN must contain a "full report" of any test data about the substance's health and environmental effects in the manufacturer's possession or control.[182] But there is no requirement that the manufacturer develop these data before submitting the PMN, and a PMN lacking the information is considered complete so long as the manufacturer is not in possession or control of any such data.[183] After the PMN has been submitted, the EPA can require the manufacturer to conduct any testing reasonably necessary to develop these data, if it finds the PMN itself insufficient to enable it to predict the health and environmental effects.[184] But the EPA must first determine that the substance may present an unreasonable risk of injury to health or the environment,[185] or that it will be produced in substantial quantities and either enter the environment in substantial quantities or result in substantial human exposure.[186] Thus, the burden of demonstrating that more data are required is on the EPA, not the manufacturer. Under such a regime,

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[181] See Senate Hearings on Environmental Consequences, supra note 1, at 126 (testimony of Prof. Thomas O. McGarity, Univ. of Texas Law School). FIFRA, on the other hand, is a permitting statute—that is, it forbids a manufacturer of a new pesticide to proceed with its sale or distribution until the new pesticide is properly registered. See 7 U.S.C. § 136a(a) (1982).

[182] See 40 C.F.R. § 720.50(a)(3) (1986). By definition, this report should include "experimental methods and materials, results, discussion and data analysis, conclusions, references, and the name and address of the laboratory that developed the data." Id. However, these items need only be included if they are in the PMN submitter's possession or control. See id.

[183] See id. For a description of this section, see 48 Fed. Reg. 41,132, 41,135 (Sept. 13, 1983) ("the absence of this information in the report submitted with the PMN will not make the PMN incomplete, because it is not in the submitter's possession or control").

[184] See 15 U.S.C. § 2603(a) (1982).

[185] See 15 U.S.C. § 2603(a)(1)(A)(i) (1982).

[186] See 15 U.S.C. § 2603(a)(1)(B)(i) (1982). If the EPA can make this showing, it can enjoin the manufacture or use of the substance pending completion of the testing. See id. § 2604(e)(1)(A) (1982). See generally Note, The EPA and Biotechnology Regulation: Coping with Scientific Uncertainty, 95 Yale L.J. 553, 564-65 (1986) (describing the data requirements of TSCA's PMN provisions).

manufacturers have little incentive to develop data on the risks of new rDNA products.

This apportionment of the burden is problematic, because the EPA may have insufficient data to determine whether more data are necessary to fully evaluate the risks of the new substance. The EPA may only demand more information, however, where it can establish, on the basis of the data submitted with the PMN, that an unreasonable risk exists or a substantial exposure will occur.[187] Moreover, the EPA must make this determination under substantial time pressure—if it fails to act within ninety days (extendable to 180 days) of the PMN's submission, the submitter may begin to produce the unevaluated substance.[188] Given these problems, the agency may fail to recognize the need to obtain additional data in many cases.[189] This is particularly likely to occur in the case of rDNA products, where the potential risks of a substance are far from obvious and the underlying biochemistry of genetic recombination is only partially understood.[190]

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[187] See supra notes 185-86 and accompanying text.

[188] See 1986 Microbial Product Policy, supra note 92, at 23,328; Note, supra note 186, at 565.

[189] The question remains whether the EPA has the expert staff and sufficient funding to adequately regulate biotechnology in general and deliberate releases in particular. The EPA Office of Pesticide Programs administers FIFRA and has regulated microbial pesticides in the past. See 1984 Microbial Product Policy, supra note 92, at 50,883; see also House Hearing on Environmental Implications, supra note 27, at 47 (statement of Geoffrey M. Karny, Senior Analyst, Biological Applications Program, Office of Technology Assessment) (reporting that the office administering FIFRA, the OPP, is "sophisticated" in its approach to evaluating the ecological impacts of genetically modified organisms). The Office of Toxic Substances, which administers TSCA, has less experience with microbial substances, cf. 1986 Microbial Product Policy, supra note 92, at 23,326 (biotechnology companies are not yet submitting under TSCA), and a 1980 Government Accounting Office study revealed that the toxic substances program was understaffed. See House Hearing on Environmental Implications, supra note 27, at 33 (statement of Geoffrey M. Karny, Senior Analyst, Biological Applications Program, Office of Technology Assessment). More recently, the EPA Office of Research and Development, which is responsible for developing many of the risk assessment techniques necessary to evaluate deliberate releases, has undergone massive budget cuts, prompting one congressman to remark that "there have been serious, damaging effects on the availability and quality of scientific information caused by inadequate public investment in ecological research." House Hearing on Biotechnology Regulation, supra note 17, at 9 (statement of Rep. Gerry Sikorski, D-Minn.).

[190] The 1986 Microbial Product Policy indicates that manufacturers planning environmental releases of regulated microbes "should assume, in the absence of data to the contrary, that the microorganisms may present a risk because of their potential to reproduce and exhibit new traits. Therefore, EPA will expect manufacturers to provide test and other data demonstrating the microorganisms' safety." 1986 Microbial Product Policy, supra note 92, at 23,327. It appears from this language that the EPA is attempting to make an across-the-board finding that rDNA releases present an unreasonable risk sufficient to trigger the

The most pressing question concerning TSCA and FIFRA is whether the statutes will enable the EPA to gather enough data to make rational decisions about the safety of deliberate releases. An earlier version of the Microbial Product Policy acknowledged that "our current data requirements would yield no information about the characteristics that the inserted genes are intended to express, and the potential for other characteristics to be unknowingly inserted and expressed."[191] Although the 1986 Microbial Product Policy states that the EPA "is likely to require" data on the new characteristics that the inserted genetic material is *intended* to express, manufacturers are not required to submit data bearing on the likelihood that it will actually express unknown characteristics, other than a general requirement of information on "[m]ethods used to manipulate source organisms."[192] Perhaps the most important data are those that indicate the impact of the released microbe on the environment. The effectiveness of TSCA and FIFRA in accumulating sufficient data on this issue in turn depends on the techniques used to predict the environmental impact of released microbes.

2. *The Limits of Modern Risk Assessment Techniques: The Nuclear Power Example*

Although there have been no reported injuries to human health or the environment arising from laboratory research or field testing of rDNA microbes,[193] the potential for harm presented by such organisms has led the staff of a House committee to conclude that assessment of the risks posed by their deliberate release is "essential."[194] Yet the lack of injuries produced by laboratory research on rDNA microbes may not be an accurate indication of these risks, because microbes designed for release may be able to survive in environments where escaped laboratory organisms would die.[195] Nor can regulators be certain that the lack of injuries from field tests of deliberate release microbes fairly reflects the risks presented

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right to demand extra testing. This would shift the burden of developing data regarding health and environmental risks to the manufacturer, a result that seems to contradict the current statutory scheme. See supra notes 184-88 and accompanying text.

[191] 1984 Microbial Product Policy, supra note 92, at 50,884.

[192] See 1986 Microbial Product Policy, supra note 92, at 23,327.

[193] See House Hearing on Environmental Implications, supra note 27, at 38 (statement of Geoffrey M. Karny, Senior Analyst, Biological Applications Program, Office of Technology Assessment).

[194] See Staff Report, supra note 22, at 1.

[195] See Senate Hearings on Environmental Consequences, supra noto 1, at 115 (testimony of Prof. Thomas O. McGarity, Univ. of Texas Law School).

by their commercial release, for commercial releases will undoubtedly occur at levels substantially greater than the field tests.[196]

To assess the potential hazards of deliberate release, scientists must develop the capacity to predict the impact that both field tests and large-scale commercial releases will have on the environment. This task, sometimes termed "predictive ecology,"[197] attempts to forecast the changes in an environment caused by a single modification, such as the introduction of a particular rDNA microbe. Yet current risk assessment techniques make it "extremely difficult, if not impossible" to accurately predict the probability, magnitude, or type of impact a particular rDNA microbe will have on the environment.[198] The principal reasons for this inability to assess the risks of deliberate release are the lack of a standard ecological methodology for evaluating the environmental consequences of rDNA organisms and the lack of a sound data base from which to extract principles useful in predicting future events.[199] Without an effective methodology in place, ready to catalog and analyze the effects of various deliberate releases, field testing will not significantly enhance regulators' ability to assess future risks.[200] And without a reliable data base, even the most sophisticated methodology will not enable regulators to make accurate predictions about the impact of future releases.[201]

In short, predictive ecology is an inexact science that falls short when asked to determine the environmental consequences of deliberately released rDNA microbes.[202] But the risks posed by these releases, which

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[196] See id. at 66-67 (testimony of Dr. Martin Alexander, Cornell University) (comparing deliberate release to the regulation of pesticides where small quantities posed no threat to ecological systems, but large-scale commercial use did cause problems).

[197] See id. at 151 (testimony of Jack Doyle, Director, Agricultural Resources Project, Environmental Policy Institute) (describing the field that attempts to determine the environmental fate of organisms as " 'predictive ecology' ").

[198] See Staff Report, supra note 22, at 20. This conclusion was based on the testimony of several ecologists and is supported by the testimony of ecologists at other congressional hearings. See generally House Hearing on Environmental Implications, supra note 27 (assessing present knowledge of the ecological impact of biotechnology and deliberate releases as well as suggestions for regulatory change).

[199] See House Hearing on Environmental Implications, supra note 27, at 20 (statement of Dr. Frances E. Sharples, Oak Ridge National Laboratory).

[200] See House Hearing on Biotechnology Regulation, supra note 17, at 35 (statement of Rep. John Dingell, D-Mich.) (stressing the need for research to ensure better predictions); Senate Hearings on Environmental Consequences, supra note 1, at 117, 123 (testimony of Prof. Thomas O. McGarity, Univ. of Texas Law School) (recognizing the need for a central data-gathering mechanism and proposing formation of a "central registry of hosts, vectors, industrially useful genetic sequences, products, and byproducts").

[201] See Weinberg, Science and Its Limits: The Regulator's Dilemma, Issues in Sci. & Tech., Fall 1985, at 59, 63.

[202] See Senate Hearings on Environmental Consequences, supra note 1, at 151 (testimony

may be termed "low probability/high consequence" risks,[203] present great challenges for modern risk assessors. Evaluation of hazards with a small chance of occurrence and a high degree of complexity is always difficult; as physicist A.M. Weinberg has suggested, risk assessment in these areas is more "trans-science" than science.[204] In fact, Weisberg suggests that the assessment of low probability/high consequence risks involves little more than a political judgment.[205]

Although the decision to permit a deliberate release may ultimately be political, by accumulating a sound data base of analogous experiences, regulators can assure that this political judgment is guided by the most accurate predictions possible within the intrinsic limits of modern risk assessment techniques. This data base must, however, preserve past experiences in a form that will enable regulators to use them to predict future events. As the nuclear power experience demonstrates, simply gathering large quantities of data is not enough.

The Nuclear Regulatory Commission (NRC) regulates an industry presenting the same sort of low probability/high consequence risks as biotechnology.[206] The NRC has created safety data requirements similar to those used by the EPA under the current scheme—that is, requirements that focus on situation-specific data not easily transferred to similar incidents arising in the future.[207] Although the NRC often received sufficient quantities of data, a 1979 Government Accounting Office (GAO) study found that it did not define clearly the scope or format of the information required,[208] but instead allowed each of its three headquarters offices and five regional offices to determine individually the reporting requirements for nuclear safety data.[209] Moreover, the lack of uniformity in the data

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of Jack Doyle, Director, Agricultural Resources Project, Environmental Policy Institute) (stating that "we especially lack a predictive ecology in microbiology"); Note, supra note 186, at 558.

[203] See Staff Report, supra note 22, at 9. The risks of deliberate release are termed "low probability/high consequence" because, while few rDNA microbes will actually harm human health or the environment, those that do may cause large-scale damage.

[204] Weinberg, supra note 201, at 61.

[205] Id. at 68.

[206] See generally N. Evans & C. Hope, Nuclear Power: Futures, Costs and Benefits (1984) (exploring the present state of nuclear power technology in the Western world and projecting its future).

[207] Cf. House Hearing on Biotechnology Regulation, supra note 17, at 18-19, 30 (statement of Dr. Frank E. Young, Commissioner, Food and Drug Administration) (defending this approach).

[208] See Energy and Minerals Div., Government Accounting Office, Reporting Unscheduled Events at Commercial Nuclear Facilities: Opportunities to Improve Nuclear Regulatory Commission Oversight 4 (1979) (recommending that the NRC define the scope of data gathered).

[209] See id. at 3-5.

generated by the disparate reporting measures made it difficult for regulators to determine the relevance of one event to another,[210] which made it difficult to identify general principles useful in estimating future risks.

The GAO study demonstrated the need for systematic data collection and assessment in the nuclear power industry. In the federal government's current scheme for regulating biotechnology, the weakened BSCC cannot prevent the agencies involved from committing the same mistake.[211] Under the current regulatory framework, for example, the NIH may develop data collection and assessment procedures inconsistent with those of the EPA, limiting the federal government's ability to make accurate risk assessments.[212]

Simply stated, the nuclear power example demonstrates that where risk data are not uniform, the usefulness of the data base to the industry as a whole is diminished. Because the BSCC lacks the authority to require uniform data collection, the current biotechnology regulatory scheme will not benefit from the nuclear industry's experience and will not promote accurate risk assessment as expeditiously as possible.

IV. Recommendations

The analysis of the federal government's attempts to regulate rDNA deliberate releases demonstrates four fundamental weaknesses in the regulatory scheme. First, the scheme has not reduced the confusion over agency jurisdiction.[213] The BSCC lacks the authority to settle jurisdictional questions and to compel agencies to coordinate activities such as the accumulation of data in a consistent form.

Second, applying TSCA to biotechnology without amending its provisions creates difficulties. The questionable application of the TSCA chemical substance definition to living organisms will result in further lit-

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[210] See id. at 19. Data from nuclear reactors also are inferior because the various designs of nuclear power plants in the United States do not produce consistent, comparable safety information. See Webb, The Accident Hazards of Nuclear Power Plants 65 (1976) (describing the negative effect of different plant designs on the ability to assess the possibility of meltdowns).

[211] One of the primary missions of the Working Group was to ensure that the various agencies involved developed consistent approaches to the biotechnology problem. See House Hearing on Biotechnology Regulation, supra note 17, at 11 (statement of Dr. Bernadine Bulkley, Deputy Director, Office of Science and Technology Policy, Executive Office of the President).

[212] Although under the current scheme the two agencies may cooperate, the likelihood that they will do so more frequently than the different offices within the NRC is slim.

[213] Cf. OECD Committee Reaches Accord on Document for Achieving Uniform Approach to Regulation, 9 Chem. Reg. Rep. (BNA) 1094, 1094 (Dec. 13, 1985) (noting " 'growing turf battles about who will regulate biotechnology in the U.S.' ").

igation, delays, and uncertainty in the regulated industry.[214]

Third, although risk assessment is admittedly difficult in low probability/high consequence fields, regulation under TSCA and FIFRA may fail to produce the data necessary to evaluate individual experiments or to increase the effectiveness of future risk assessment.[215] TSCA now places the burden on the already understaffed EPA to demonstrate that substances pose unreasonable risks before additional data may be required. But the scientific debate over the risks of rDNA technology constrains the agency's ability to determine whether unreasonable risks exist, thereby limiting its ability to demand additional information.[216] Moreover, the voluntary TSCA requirements for data submission prevent the EPA from requiring that data be developed in a consistent fashion. As a result, data developed for the EPA may be subject to the same lack of uniformity that may occur on the interagency level, where the BSCC lacks the power to compel consistent data gathering. As experience in the nuclear power area indicates, large amounts of data are most valuable when they add to a common, assessable base of experience. Disparate or inconsistent data are much less valuable to risk assessors.

Finally, the regulatory scheme will not accommodate the speed at which the field of biotechnology advances. The advances will include not only new techniques for genetic recombination, but also advances in understanding the fundamental processes that underlie biotechnology. For example, researchers only recently learned the frequency with which different species of organisms may exchange genes in nature.[217] The implications of this finding for biotechnology are immense. Because the addition of a harmful gene from another organism can render a seemingly innocuous microbe dangerous, regulators must now examine the likelihood that such exchange will occur when assessing the impact of a particular deliberate release.

The problems with the current regulatory scheme require both short-term and long-term responses. The first three problems—jurisdictional confusion, uncertainty about the application of TSCA to biotechnology,

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[214] Rifkin and Foundation for Economic Trends have tried to enjoin the 1986 Coordinated Framework. See Bennett, Government's New Biotechnology Guidelines Leave Some Issues Unresolved, 6 Genetic Engineering News, Sept. 1986, at 4, 10.

[215] Nor can NEPA serve as a safety net for the potential inadequacies of TSCA and FIFRA. NEPA requirements are satisfied by TSCA, see Twitty v. North Carolina, 527 F. Supp. 778, 781 (E.D.N.C. 1979), aff'd, 696 F.2d 992 (4th Cir. 1982), and FIFRA, see Environmental Defense Fund v. Blum, 458 F. Supp. 650, 661-62 (D.D.C. 1978).

[216] Particularly important is information regarding the potential for exchange of genetic material and the environmental fate of the organism.

[217] See K. Low & D. Porter, Modes of Gene Transfer and Recombination in Bacteria, *in* 12 Annual Review of Genetics 249-87 (1978).

and inadequate data requirements—call for immediate actions before the EPA approves further deliberate releases. The fourth problem—regulating a field in which both the technological processes and the underlying science are changing rapidly—should be addressed through long-term structural modifications.

A. Immediate Actions: Clarification of Agency Jurisdiction and Statutory Authority and Modification of Data Requirements

In the short term, with the impetus of international competition spurring federal policymakers to promote the domestic biotechnology industry,[218] a coherent regulatory scheme is essential to ensure that human health and the environment are protected. Clarification of agency jurisdiction and statutory authority will provide a degree of certainty to guide biotechnology industry actions, reduce duplicative agency efforts, close regulatory gaps, and produce more cost-effective regulation.

As a first step toward regulatory clarification, the Cabinet Council Working Group should strengthen and expand the authority of the BSCC, to enable it to untangle current and future jurisdictional disputes. Like the advisory mechanism first proposed in the 1984 Coordinated Framework,[219] the BSCC should focus much of its effort on clarifying agency authority. The strengthened BSCC should require that agencies gather and share data developed on the characteristics of DNA sequences in a consistent manner. This information should comprise a central data bank for risk assessment, to provide regulators with a functional base of information about rDNA research and specifically about the potential environmental effects of deliberately released rDNA microbes.

Second, Congress should amend TSCA to make clear that it applies to rDNA microbes. Congress is now considering two bills,[220] each of which attempts to improve the regulatory response to the biotechnology problem. The Senate bill,[221] cast in the form of an amendment to TSCA, is the superior medicine for biotechnology's regulatory ills, because it converts TSCA into a permitting statute for the purposes of rDNA regulation,[222] places the burden of demonstrating that a particular rDNA microorganism "will not cause an adverse effect on human health or the environment" on the producer,[223] and defines microbes subject to TSCA regula-

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[218] See 1986 Coordinated Framework, supra note 92, at 23,308.

[219] See 1984 Coordinated Framework, supra note 92, at 50,856-58.

[220] See supra note 142.

[221] S. 1967, 99th Cong., 1st Sess., 131 Cong. Rec. 17,812-14 (1985) [hereinafter Senate Bill].

[222] See id. § 32(a)(2), 131 Cong. Rec. at 17,812.

[223] Id. § 32(a)(4), 131 Cong. Rec. at 17,813.

tion in a broad fashion[224] that is consistent with the definition adopted by the EPA in the Microbial Product Policy.[225] Another positive feature of the Senate bill is its reformulation of the standard the EPA Administrator must satisfy before requiring a producer to provide more information. Whereas TSCA currently permits the Administrator to demand more information from a producer only upon a finding that the microbe "may reasonably" be harmful,[226] the Senate measure would authorize him to do so simply upon a determination that such information is "necessary."[227]

Although the House bill also converts TSCA into a permitting statute, it would eliminate the concurrent regulation of genetically engineered microbes under FIFRA.[228] Because FIFRA's current data requirements are closer to what is necessary to permit adequate assessment of the risks of rDNA microbial pesticides,[229] the Senate bill, which preserves the option of regulation under FIFRA,[230] is preferable.

Nor is the House bill's definition of the genetically engineered microbes that are subject to TSCA regulation satisfactory. The bill defines " 'genetically-engineered organism' " as "a bacterium, virus, fungus, plant cell, plant tissue, animal cell, or animal tissue which has been deliberately altered to contain genetic material derived from more than one taxonomic genus."[231] Predicating regulatory jurisdiction upon generic classifications may lead to unjustified loopholes in review, in which "intra-generic"[232] microorganisms escape regulation, although they may not necessarily pose fewer risks than inter-generic microbes. The definition offered in the Senate bill, which focuses on whether an organism's genetic structure has been altered by human intervention, rather than on whether it contains material from organisms of different genera, is far more useful.

Both the House and Senate measures take steps in the right direction

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[224] The Senate bill provides that "the term 'genetically engineered micro-organism' means a bacterium, virus, fungus, blue-green alga, or protist, the genetic material of which has deliberately heen altered by human intervention." Id. § 32(i), 131 Cong. Rec. at 17,813.

[225] See 1986 Microbial Product Policy, supra note 92, at 23,316.

[226] See 15 U.S.C. § 2603(a) (1982).

[227] See Senate Bill, supra note 221, § 32(e)(1)-(2), 131 Cong. Rec. at 17,813. One problem area in biotechnology regulation, the weakness of the BSCC, is left untouched by the Senate bill, which merely provides for the composition of BSCC membership, the announcement of meetings, and the status of meetings as either open or in some cases closed. See id. § 32(j), 131 Cong. Rec. at 17,813-14.

[228] H.R. 4452, 99th Cong., 2d Sess., § 505 (1986) [hereinafter House Bill].

[229] See supra notes 97-114 and accompanying text.

[230] See Senate Bill, supra note 221, § 32(g), 131 Cong. Rec. at 17,813.

[231] House Bill, supra note 228, § 301(b).

[232] Intra-generic rDNA microbes are produced by the transfer of genetic material between two organisms of the same genus. See 1986 Microbial Product Policy, supra note 92, at 23,326; supra note 127.

by subjecting deliberate releases to permit requirements.[233] The measures also resolve the controversial application of TSCA's chemical substance definition to rDNA microorganisms by the addition of a specific provision covering genetically engineered microorganisms. Most importantly, both measures shift the burden of proving relative safety from the regulatory agency to the producer.[234]

Finally, regulators should apply to the deliberate release problem a lesson learned from laboratory-bound rDNA research—the use of microbes that have been genetically crippled to survive only in particular environments. Much of the success of laboratory rDNA safety is the result of the use of microbes from which scientists have removed the gene for the production of an essential enzyme.[235] Because these microbes will survive only in laboratory environments to which scientists have added amounts of the missing enzyme, they die soon after they escape from the laboratory.[236] The use of microbes similarly designed to exist only in particular environments would reduce the risks of deliberate release significantly.

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[233] See House Bill, supra note 228, § 301(a); Senate Bill, supra note 221, § 32(a)(2), 131 Cong. Rec. at 17,812.

[234] See House Bill, supra note 228, § 301(a); Senate Bill, supra note 221, § 32(a)(4), 131 Cong. Rec. at 17,813.

[235] See Decision of the Director, National Institutes of Health to Release Guidelines for Research on Recombinant DNA Molecules, 41 Fed. Reg. 27,902, 27,904 (July 7, 1976) (noting that "*[b]iological* containment is the use of vectors or hosts that are crippled by mutilation so that the recombinant DNA is incapable of surviving under natural conditions").

[236] See id. Similarly, federal regulations could require scientists to remove the gene for an essential compound from field-tested rDNA microbes whenever possible. Carefully designed microbes would survive only if the investigator applied the missing compound to the microbes in the field. For example, the EPA could have required that the AGS investigators remove the gene for the production of a metabolite from the ice-minus bacterium. Then, when the bacterium was applied to the strawberry plants as proposed, the metabolite could be sprayed onto the plants in the field. The microbes would survive with the added compound, but if they began to have an adverse environmental impact the investigators could control them by halting application of the missing compound.

The advantages of this biological containment mechanism are that investigators can field test rDNA microbes with relative safety, even where predictive ecology is unable to determine the probable environmental fate of the microbe. Although the self-destructor mechanism will require some additional expense at the experimental stage, much of the expense will be compensated by savings on additional greenhouse and laboratory simulations that investigators might have to perform without the mechanism. If the microbe proves to be safe in field tests, scientists could reinsert the missing gene at the commercial production stage. Alternatively, the EPA could require commercially produced rDNA microbes to lack the ability to produce a compound so that the safety mechanism will operate in large-scale microbial applications as well as field tests.

B. Long-Term Response: Adapting the EPA to Biotechnology Regulation

A recurring problem with the EPA's regulation of biotechnology is the complex nature of the biological issues involved. To be effective, regulators must be well versed in the current understanding of fundamental biological concepts, as well as in biotechnological processes. A thorough and current understanding of scientific issues is also necessary if the EPA is to retain the respect and full cooperation of the regulated industry, which is composed of highly trained scientists equipped with the most advanced instruments. Regulators who are scientists themselves can ensure that the EPA receives the data necessary to evaluate adequately the risks of rDNA technology.[237]

The use of scientist-regulators would also permit more efficient data collection. Industries that produce biotechnological products can generate data about those products more efficiently than can independent consultants or agency scientists.[238] Yet fear of manipulated or incomplete studies makes federal regulators reluctant to rely on industry-generated data.[239] Regulators who maintained active research programs in the same general field as the regulated industry, however, would be able to spot faulty or incomplete industry data.

The Division of Biochemistry and Biophysics of the Center for Drugs and Biologics of the Food and Drug Administration (the Center) provides an excellent a model for the regulatory oversight of a rapidly evolving field like biotechnology. The Center employs over 300 scientists who spend the majority of their time on basic rDNA research and their remaining time on regulatory assignments for the Center.[240] Because the Center provides so much time for basic research, the program attracts eminent scientists with active research programs. These scientist-regulators have gained the respect of their peers in the biotechnology industry. In fact, one government official asserts that scientists with knowledge of the subject matter are able to perform as much regulatory oversight in twenty percent of their time as less informed regulators can working on a full-time basis.[241]

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[237] An immediate problem that must be studied is agency capture. See, e.g., Dworkin, supra note 157, at 231. This problem could be addressed in part by disallowing any consulting on the part of agency scientists.

[238] See Kates, Success, Strain, and Surprise, Issues in Sci. & Tech., Fall 1985, at 46, 53.

[239] See id. at 54 (suggesting that an agency guarantee of confidentiality of test data may be appropriate).

[240] Telephone interview with Dale Wilburn, Acting Division Director, Department of Administration, Center for Drugs and Biologics, Food and Drug Administration (Feb. 12, 1986).

[241] Id.

The Center's scientist-regulators provide the FDA with the benefits of efficiency, accurate regulatory supervision, and basic research. The EPA could use scientist-regulators in a similar fashion to improve its biotechnology regulatory strategy. By properly channeling industry research at an early stage, scientist-regulators could instruct biotechnology companies in efficient compliance with applicable regulations. Scientist-regulators could also supervise the production of safety data by the industry itself. With industry-submitted data subject to review by practicing scientists, regulatory supervision would be more accurate. Finally, the research generated by scientist-regulators would, of course, be of continuing value to society.

Although the EPA calls on research scientists in the final stages of its deliberate release review,[242] the success of the Center's scientist-regulators demonstrates the advantages of incorporating research scientists throughout the entire regulatory process. The EPA should evaluate the applicability of the Center's scientist-regulator program to its regulation of biotechnology generally and to deliberate releases in particular.

V. Conclusion

The biotechnology industry is a rapidly developing and highly competitive industry that has the potential to produce great benefits. Unfortunately, deliberate releases of rDNA microbes present significant risks as well. These low probability/high consequence risks differ from the risks presented by laboratory-based biotechnology and are difficult to evaluate with modern risk assessment techniques. As a result, the long experience of safety with laboratory rDNA research may not be indicative of the potential hazards of deliberate releases.

The current regulatory framework will not contribute to the improvement of risk assessment techniques. The federal government's current coordinating organization, the BSCC, lacks the authority to compel agencies to develop a central data bank. Yet without such a central storehouse of collective experience, assessment of the risks of rDNA research generally, and deliberate release in particular, will remain difficult. In addition, TSCA does not ensure that regulators will have enough information—or enough time—to make the initial finding necessary to permit them to require the submission of more data about a particular rDNA microbe. The EPA's attempts to graft biotechnology onto a statute primarily designed to control inert pollutants will result in delaying litigation, prolonging the uncertainty among biotechnology enterprises.

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[242] The EPA has provided for a Scientific Advisory Committee composed of research scientists and others to advise the agency, modeled on the NIHRAC. See 1986 Microbial Product Policy, supra note 92, at 23,318.

The weaknesses in the federal regulatory structure can be addressed in the short term by strengthening the BSCC to enable it to oversee the development of a central data bank for rDNA research and deliberate release information, and by congressional clarification of TSCA's applicability to biotechnology. To ensure that regulators obtain sufficient data to evaluate the risks of new rDNA microbes, the amended TSCA should place a FIFRA-type burden on manufacturers to demonstrate the safety of new organisms before proceeding with release experiments. In the long term, the EPA should study the feasibility of fully incorporating research scientists into the oversight of biotechnology. These actions will ensure that the biotechnology industry will prosper and that the rutabaga that eats Pittsburgh will not gain EPA approval.

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