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Federal Regulation of the Biotechnology Industry: The Need to Prepare Environmental Impact Statements for Deliberate Release Experiments

Donald J. Pagel Jr.

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FEDERAL REGULATION OF THE BIOTECHNOLOGY INDUSTRY: THE NEED TO PREPARE ENVIRONMENTAL IMPACT STATEMENTS FOR DELIBERATE RELEASE EXPERIMENTS

I. INTRODUCTION

In 1973, a technique for manipulating the genetic composition of bacteria was disclosed to the public.1 During the ensuing fourteen years, the development of the biotechnology industry has made the widespread use of genetically engineered products imminent.2 The federal government has responded to that growth by implementing policies to ensure the safety of genetically engineered products. This comment focuses on the regulation of the genetic engineering process known as a deliberate release experiment. In a deliberate release experiment, a genetically engineered microorganism is released into the environment to evaluate its potential for accomplishing a particular purpose. For example, genetically engineered bacteria may be used to prevent frost damage to crops and to eradicate harmful insects.3

The first deliberate release experiment was conducted in April of 1987.4 Before that, concerns about the safety of deliberate release experiments had led a federal court to enjoin proposed experiments.5

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1. The disclosure was made by Herbert Boyer at the Gordon Conference on Nucleic Acids. See Note, The EPA and Biotecnology Regulation: Coping with Scientific Uncertainty, 95 YALE L.J. 553 (1986) (describing the impact of the Boyer-Cohn technique).
3. Genetic engineering is a technology used to alter the hereditary apparatus of a living cell so that the cell can produce more or different chemicals or perform completely new functions. These altered cells are then used in industrial production. Id. See also infra notes 12-15 and accompanying text.
4. See Diamond v. Chakrabarty, 447 U.S. 303 (1980) (holding that genetically engineered organisms are patentable); Wall St. J., Dec. 6, 1985, at 38, col. 1 (Monsanto Company develops a genetic engineering technique to increase plant resistance to viruses); Abramson, Genentech's Drug Problem, NEWSWEEK, Nov. 25, 1985, at 70 (Genentech projects $30-40 million first year sales for Protropin, a genetically engineered human growth hormone).
5. See infra notes 62-63 and accompanying text.
7. See infra notes 60-63 and accompanying text.
This comment examines the federal regulatory processes affecting this area of the biotechnology industry. Section II analyzes relevant regulations and two judicial decisions concerning deliberate release experiments. Section III evaluates the adequacy of the Environmental Protection Agency's review process for approving deliberate release experiments. Finally, Section IV proposes preparation of initial environmental impact statements for all deliberate release experiments.

II. THE DEVELOPMENT OF GENETIC ENGINEERING EXPERIMENTS

A. Technical Background

Many useful biological products such as drugs, hormones, enzymes and pesticides, are composed of a class of chemical compounds known as proteins. Proteins are synthesized in nature inside of cells by segments of deoxyribonucleic acid (DNA) called genes. In a typical genetic engineering experiment, a gene within a microorganism, which controls the production of a certain protein, is modified. This gives the engineered microorganism the ability to produce (or sometimes not produce) a different protein than the original microorganism produces. The new gene is often referred to as recombinant DNA (rDNA), a name also applied to the whole genetic engineering process.

Throughout the development of rDNA processes, scientists have been aware of both the enormous potential and the equally


11. Environmental impact statements (EIS) are detailed studies of the effects a proposed federal action will have on the quality of the human environment. Their preparation is mandated by NEPA, 42 U.S.C. § 4332(C) (1982). See infra text accompanying notes 39-45 for a more complete discussion.


13. A microorganism is an organism that is a fungus, prokaryote, protist or virus. 49 Fed. Reg. 50,906 (1984). Bacteria are microorganisms.

14. See R. Old & S. Primrose, PRINCIPLES OF GENE MANIPULATION 5-6 (3d ed. 1985). Animal cells (eukaryotic cells) can also be modified by genetic engineering techniques. Id. at 12.

15. Guidelines, supra note 9, at 27,903-04.
enormous danger of that technique. The danger is that alteration of genetic material in microorganisms could create life forms with unknown properties. Released into the environment, these new microorganisms could disrupt or destroy existing ecosystems. On the other hand, when properly contained, the process has great humanitarian and commercial potential. For example, it allows previously scarce materials, such as insulin, to be produced in large amounts.

The great challenge for regulatory agencies is to insure that the exploitation of this new found technology takes place safely. An explanation of the regulatory background of this area and the method of judicial review of administrative decision making is essential to understanding the current status of this important technology.

B. Regulatory Background

1. Early Regulation

The National Institutes of Health (NIH) initiated federal oversight of genetic engineering research in 1976 by issuing its Guidelines for Research on Recombinant DNA Molecules (Guidelines). Under the Guidelines, only carefully controlled laboratory experiments involving rDNA were permitted. Deliberate release experiments and five other types of rDNA experiments were prohibited. The Guidelines, however, were directed only at institutions receiving NIH funds and the only sanction for their violation was loss of NIH funding. The NIH had no direct control over institutions or companies not receiving NIH funds, although most parties conducting rDNA research complied voluntarily with the Guidelines.

In 1978, NIH revised the 1976 Guidelines. The 1978


17. For example, in one laboratory experiment, a fungus was genetically modified to enhance the nitrogen fixing capability of pine trees. While the original fungus was harmless, the recombinant fungus turned out to be pathogenic and one isolate killed the tree seedlings to which it was applied. Id. at 19.


20. Guidelines, supra note 9, at 27,915.


22. Id. at 469 n.37.

Guidelines permitted much greater freedom in genetic engineering research. Subsequently, NIH approved three deliberate release experiments—none of which were ever conducted.24

The fact that the 1978 NIH Guidelines were only applicable to NIH funded institutions and the accelerated pace of commercial biotechnology activity, mandated that the scope of federal regulation be expanded.26

2. Current Regulation

The federal government now regulates all areas of biotechnology activity including commercial applications. The comprehensive policy statement describing the regulatory system of the biotechnology industry (the "Coordinated Framework") became effective in 1986.26 Under the Coordinated Framework, six federal agencies27 use their existing statutory authority to regulate various areas of biotechnology research and industry.28 This approach was chosen because the existing health and safety laws provided an immediate and familiar regulatory system for industry and because the broad spectrum of genetically engineered products defies a unitary statutory approach.29

Under the Coordinated Framework, the Environmental Protection Agency (EPA) became the lead agency in regulating the release of genetically engineered microbial pesticides into the environment.30 The EPA is allocated this duty because the Federal Insecticide,


24. See Heckler, 756 F.2d at 150. These three experiments involved: (1) improving the dietary value of corn plants containing rDNA; (2) the spread of pollen from tobacco and tomato plants containing rDNA; and (3) increasing the frost resistance of potato, tomato and bean plants. Id.


27. These are: the United States Department of Agriculture, the Environmental Protection Agency, the Food and Drug Administration, the National Institutes of Health, the National Science Foundation and Occupational Safety and Health Administration. See supra note 9, at 23,302.

28. This regulatory approach was first described in the Office of Science and Technology Policy's Proposal for a Coordinated Framework for the Regulation of Biotechnology, 49 Fed. Reg. 50,856 (1984) [hereinafter 1984 Proposal]. A table listing the agencies which regulate various biotechnology products is given in Coordinated Framework, supra note 9, at 23,304.

29. Coordinated Framework, supra note 9, at 23,303.

30. Coordinated Framework, supra note 9, at 23,315.
Fungicide and Rodenticide Act (FIFRA)\textsuperscript{31} and the Toxic Substance Control Act (TSCA)\textsuperscript{32} already provide the EPA authority over conventional microbial products. Because the scope of the EPA's authority under FIFRA extends to the review and registration of new conventional pesticides, the EPA asserts that it has control over genetically engineered microbial pesticides.\textsuperscript{33} The TCSA gives the EPA the authority to assess and control exposure to "chemical substances."\textsuperscript{34} Since DNA is a chemical substance, the EPA asserts that TSCA also gives the Agency control over genetically engineered microorganisms used for certain nonpesticidal purposes.\textsuperscript{35}

The expansion of the EPA's existing FIFRA and TSCA authority to cover genetically engineered microorganisms is interesting in two respects. First, it raises the issue of whether this is a legitimate expansion of statutory authority. In passing FIFRA and TSCA, Congress never contemplated genetic engineering processes.\textsuperscript{36} Second, and most important for purposes of this comment, is whether the policy announced in the Coordinated Framework is consistent with the judicial scrutiny that has prevented previous deliberate release experiments. In this respect, it is necessary to consider the provisions of the National Environmental Policy Act (NEPA)\textsuperscript{37} and the manner in which the NEPA has been applied to

\begin{itemize}
\item 33. Coordinated Framework, supra note 9, at 23,319. See also 49 Fed. Reg. 50,881 (1984). Genetically engineered microbial pesticides (GEMPs) are microorganisms that have been modified by genetic engineering techniques and are used as pesticides.
\item 34. TSCA defines chemical substances to mean "any organic or inorganic substance of a particular molecular identity including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature..." 15 U.S.C. § 2602(2)(A) (1976).
\item 35. 1984 Proposal, supra note 28, at 50,886-87. For example, under TSCA, the EPA would regulate genetically engineered microorganisms used for the conversion of biomass to energy, the enhancement of oil recovery, the extraction of metals and for some agricultural applications such as nitrogen fixation. Genetically engineered microorganisms used as or to produce foods, foodstuffs, food additives, drugs, cosmetics or medical devices would be regulated by the FDA or the USDA. Coordinated Framework, supra note 9, at 23,324. See also Schiffbauer, Regulating Genetically Engineered Microbial Products Under the Toxic Substances Control Act, 15 ENVTL. L. REV. 10,279, 10,281 (1985) [hereinafter Schiffbauer].
\item 36. The EPA acknowledges that the expansion of its statutory authority has been questioned by many commentators on the 1984 Proposal. However, the EPA maintains that FIFRA and TSCA furnish adequate authority for the regulation of biotechnology products. See Coordinated Framework, supra note 9, at 23,315. Contra Schiffbauer, supra note 35, at 10,288 (concluding that Congress did not expressly exclude genetically engineered products from TSCA jurisdiction).
\end{itemize}
previously proposed deliberate release experiments.


NEPA was enacted to ensure that environmental concerns were injected into the federal decision making process. NEPA was enacted to ensure that environmental concerns were injected into the federal decision making process. The major "action-forcing" provision of NEPA is section 4332. Specifically, section 4332(C) requires that all agencies of the federal government prepare a detailed statement discussing the environmental impact of all "major federal actions significantly affecting the quality of the human environment. . . ." That detailed statement is known as an environmental impact statement (EIS).

Pursuant to section 4332, federal agencies must consider, as a threshold matter, whether an EIS should be prepared. If the agency decides against preparing an EIS, it must prepare an environmental assessment providing the "evidence and analysis" for its negative decision. If an EIS is to be prepared, the agency must decide what information will be required in the document. The basic requirements of the EIS are set out in section 4332(C)(i)-(v) and can be summarized as requiring the agency to consider both the impacts of and alternatives to the action. Once the EIS is prepared, NEPA imposes a duty on the agency to include the finding of the EIS in the decision making process.

The courts have assumed an important role in policing NEPA's

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39. See, e.g., Heckler, 756 F.2d at 146.
41. "Environmental assessment: (a) Means a concise public document for which a Federal agency is responsible that serves to (1) Briefly provide sufficient evidence and analysis for determining whether to prepare an environmental statement or a finding of no significant impact." 40 C.F.R. § 1508.9 (1986).
42. See 40 C.F.R. § 1501.4(b) (1986). See also ANDERSON, supra note 38, at 698.
43. Section 4332(C) states:

(C) include in every recommendation or report on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment, a detailed statement by the responsible official on —

(i) the environmental impact of the proposed action,
(ii) any adverse environmental effects which cannot be avoided should the proposal be implemented,
(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 could be involved in the proposed action should it be implemented.

44. ANDERSON, supra note 38, at 753.
requirements. A plaintiff wishing to challenge a proposed federal action can raise three arguments in federal court. First, an NEPA plaintiff can argue that an EIS needs to be prepared for the action. Second, if an EIS was prepared, the plaintiff can argue that it is inadequate. Third, the plaintiff can challenge the merits of the agency’s ultimate decision.\textsuperscript{45} Judicial review of NEPA issues is generally treated under the “substantial inquiry” test of \textit{Citizens to Preserve Overton Park v. Volpe}.\textsuperscript{46} Under the substantial inquiry test, a reviewing court will be less deferential to administrative agency decisions than under the “arbitrary and capricious” test of the Administrative Procedure Act.\textsuperscript{47} The substantial inquiry test requires that an agency at least adhere strictly to procedural requirements of NEPA, carefully explain its decision-making and not reach plainly indefensible results.\textsuperscript{48}

Deliberate release experiments have been blocked in the past by challenging NIH’s decision not to prepare an EIS for the experiments. More recently, one court held that the EPA’s approval of a deliberate release experiment under the Coordinated Framework was not subject to the strict requirements of NEPA.\textsuperscript{49} The case histories of these challenges lays the foundation for evaluating future regulation of deliberate release experiments.

C. Recent Case History

1. \textit{Foundation on Economic Trends v. Heckler}

The first attempted deliberate release experiment of a genetically engineered microbial pesticide was blocked in February of 1985. In \textit{Foundation on Economic Trends v. Heckler},\textsuperscript{50} the court of appeals affirmed a temporary injunction prohibiting approval of the experiment by NIH. In arguing the case, both sides\textsuperscript{51} agreed that

\textsuperscript{45} A challenge on the merits of an agency’s decision is very difficult to win because the EIS is only one factor in reaching an ultimate decision. To be successful, a challenge on the merits must demonstrate that the ultimate decision was arbitrary in view of the EIS. See Anderson, supra note 38, at 753.


\textsuperscript{47} See Anderson, supra note 38, at 101.


\textsuperscript{50} Heckler, 756 F.2d 143 (D.C. Cir. 1985).

\textsuperscript{51} Appellants were Margaret Heckler, Secretary of the Department of Health and Human Services, and the Regents of the University of California. Respondents were three
NIH approval of a deliberate release experiment was a major federal action within the meaning of NEPA. Thus, the parties conceded that the environmental review procedure mandated by NEPA applied to the approval of this experiment. The disagreement in Heckler arose over what constituted an adequate environmental assessment for this experiment. The court's concern was that NIH only superficially considered the issue of dispersion before deciding not to prepare an EIS. Thus, the court upheld the injunction and stated that until an adequate environmental assessment was completed on the issue of dispersion, the question of whether an environmental impact statement should be prepared for deliberate release experiments remained open.

The problem of dispersion is an issue common to all deliberate release experiments. After Heckler, it seemed reasonable to expect that future federal approval of deliberate release experiments would include an environmental assessment sufficient for either determining whether to prepare an EIS or a finding of no significant impact. However, that was not the case. In December of 1985, acting under its newly announced policy of regulating deliberate release experiments under FIFRA, the EPA announced that it had approved a new deliberate release experiment. In approving this experiment, the Agency concluded that there would be no adverse effects on humans or the environment, but did not formally prepare an environmental assessment. Subsequently, a district court upheld the EPA's approval of the proposed experiment. This experiment was conducted in the April of 1987.

environmental groups and several individuals.

52. 756 F.2d at 153.
53. See supra text accompanying notes 41-44.
54. See supra note 41 for a definition of environmental assessment.
55. Dispersion is the process by which genetically engineered microorganisms move outside of the test area. Because of the novelty of deliberate release experiments, very little is actually known about dispersion. Experience with more familiar organisms, however, like the Gypsy Moth, has shown the serious consequences of inadequate containment measures. See Report, supra note 16, at 5.
56. 756 F.2d at 154.
57. These are simply the requirements imposed by the definition of an environmental assessment. See supra note 41.
58. 50 Fed. Reg. 49,760 (1985). The approval of this experiment marked the shift of regulatory authority over deliberate release experiments from NIH to EPA. See supra text accompanying notes 30-35.
60. See Thomas, 16 ENVTL. L. REP. (ENVTl. L. INST.) 20,632 (1986).
61. See San Jose Mercury News, April 25, 1987, at 1A, col.1. Within a week of this first deliberate release experiment, a second experiment was conducted by the University of
2. Foundation on Economic Trends v. Thomas

In the April 1987 deliberate release experiment, Advanced Genetic Sciences (AGS), a commercial biotechnology company sprayed a 0.1 acre strawberry patch in California with an aqueous solution of bacteria. These bacteria had been genetically altered to prevent the secretion of an ice-nucleating protein. The purpose of this procedure is to control frost damage to the strawberry plants by replacing the bacteria that secrete the ice-nucleating protein with genetically engineered bacteria that do not secrete the protein.

This experiment is basically the same experiment that was enjoined in the Heckler case discussed above. In light of the similarity to Heckler, the question arises as to why the AGS experiment was approved. In Heckler, the injunction was issued because NIH had not complied with the procedural requirements of NEPA. In the AGS case, approval of the experiment was given by the EPA under the auspices of FIFRA. Apparently, the EPA believed that the procedures adopted under the Coordinated Framework for reviewing proposed deliberate release experiments either obviated formal compliance with the NEPA standards articulated in Heckler, or that the Coordinated Framework procedures are the equivalent to NEPA compliance.

The latter position was adopted in Foundation on Economic Trends v. Thomas, where the District of Columbia District Court held that a preliminary injunction should not be issued to enjoin the AGS experiment. The court found that plaintiffs had not sufficiently shown they would succeed on the merits in proving the EPA violated provisions of NEPA, FIFRA and the Administrative Procedure Act (APA). Furthermore, there was no showing of irreparable injury to plaintiffs because the parties stipulated that the deliberate release experiments were not imminent. In reaching this decision, the court applied a two-step judicial review procedure to the EPA’s process for approving the AGS deliberate experiment. First, the court reviewed
the procedural requirements for issuing an experimental use permit. Second, the court deferred to the EPA on plaintiffs' substantive challenges to issuance of the experimental use permit, noting that in light of the "arbitrary and capricious" standard of review, plaintiffs were not entitled to injunctive relief. The court then noted that plaintiffs' case was further weakened because the stringent substantive and procedural NEPA standards did not apply to the EPA's approval of the AGS experiment. The EPA's review policy, as stated in the Coordinated Framework, was found to be the "functional equivalent" to NEPA compliance.

In applying the doctrine of functional equivalence to the EPA's Coordinated Framework review procedure, the court has established the legal standard which governs the development of deliberate release experiments in the immediate future. If the court's decision in Foundation on Economic Trends v. Thomas stands, it is likely that many more deliberate release experiments will be approved by the EPA under the Coordinated Framework. The next section of this comment analyzes the procedural requirements of the Coordinated Framework and discusses the propriety of classifying the Coordinated Framework review as the functional equivalent to NEPA.

III. Regulation of Deliberate Release Experiments Under the Coordinated Framework

A. Obtaining FIFRA Registration

Under the Coordinated Framework, genetically engineered...
microbial pesticides (GEMPs) are regulated under FIFRA and must be registered with the EPA Administrator prior to sale or distribution.\textsuperscript{74} In order to register a pesticide, a manufacturer must collect specific supporting data and information and submit it for EPA review prior to registration.\textsuperscript{75} Under FIFRA, manufacturers who are required to collect information necessary for pesticide registration may apply to the EPA for an experimental use permit.\textsuperscript{76} The application must contain certain preliminary data about the pesticide.\textsuperscript{77} With respect to conventional pesticides, the EPA has a policy of waiving the requirement of obtaining an experimental use permit.\textsuperscript{78} However, under the Coordinated Framework, manufacturers desiring to conduct small-scale field studies\textsuperscript{79} with GEMPs prior to FIFRA registration, must first notify the EPA of this intention.\textsuperscript{80} The EPA will then conduct an abbreviated review process to decide if an experimental use permit will be required.

The EPA has determined that certain types of genetically engineered microorganisms are more likely to cause adverse environmental effects than others. Under the Coordinated Framework, the EPA gives special regulatory attention to genetically engineered microorganisms that are likely to display new traits.\textsuperscript{81} Specifically, the EPA has determined that inter-generic GEMPs,\textsuperscript{82} as opposed to intra-generic GEMPs,\textsuperscript{83} are most likely to display new traits and hence merit special attention. In order to account for the inter-generic/intra-generic distinction and to minimize the regulatory bur-

\textsuperscript{74} 7 U.S.C. § 136a (1978).

\textsuperscript{75} See Coordinated Framework, supra note 9, at 23,319. The regulations governing the specific types of data information required for registration are detailed in 40 C.F.R. §§ 158.65, 158.170 & 162.163 (1986).

\textsuperscript{76} See 7 U.S.C. § 136c(a) (1978).

\textsuperscript{77} 40 C.F.R. Part 158 (1985) specifies the data required to be submitted before the EPA will issue an experimental use permit.

\textsuperscript{78} See 1984 Proposal, supra note 28, at 50,885. This waiver is allowed provided that the pesticide is only being tested to evaluate its potential as a pesticide and that the testing is conducted on a terrestrial field of less than 10 acres. Id.

\textsuperscript{79} Small-scale field studies are terrestrial field studies involving 10 acres or less of land or aquatic field studies involving one surface acre or less of water. Coordinated Framework, supra note 9, at 23,320.

\textsuperscript{80} Coordinated Framework, supra note 9, at 23,320.

\textsuperscript{81} Id. at 23,317.

\textsuperscript{82} An inter-generic GEMP is a genetically engineered microbial pesticide in which the new microorganism (GEMP) is formed by the deliberate combination of genetic material from organisms of different genera. See id. at 23,307, 23,332.

\textsuperscript{83} An intra-generic GEMP is a genetically engineered microbial pesticide in which the new microorganism is formed by the deliberate combination of genetic material from organisms of the same genus. Id. at 23,317.
den on GEMP producers in complying with the review process, the EPA has implemented a two-level review system for determining if an experimental use permit must be obtained.

Under the two-level system, Level II reporting requires that more extensive information be supplied to the EPA than Level I reporting. The more rigorous Level II reporting applies to small-scale field testing which involves inter-generic GEMPs or GEMPs derived from source organisms that are pathogenic. Contemplated small-scale field testing involving GEMPs which is not covered by Level II notification (i.e., intra-generic GEMPs) are subject to the less rigorous Level I reporting process. Once the GEMP producer provides the EPA with the information required under Level I or Level II notification, the EPA has 30 or 90 days respectively, to notify the applicant of the need to prepare an experimental use permit. If a Level I applicant does not receive notice to prepare an experimental use permit within the 30 day period, he is free to proceed with the small-scale field test. Level II applicants, however, must await receipt of a decision document before proceeding with the experiment.

If either a Level II or a Level I applicant is required to prepare an experimental use permit, the additional data and information necessary to support the permit application must be provided to the EPA. The EPA then has 120 days to review the use permit application and determine whether to grant a permit. If an experimental use permit is issued, the applicant may proceed with the small-scale field test. Thus, an applicant is entitled to proceed with the deliberate release experiment if the use permit requirement is waived or an experimental use permit is granted. The data generated during the small-scale field test is subject to further review by the EPA before

84. See id. at 23,321-22.
85. A pathogen is a virus or microorganism that has the ability to cause disease in other living organisms. See id. at 23,307, 23,333.
86. Id. at 23,321. The EPA has also determined that inter-generic GEMPs in which the added genetic material consists only of well-characterized, non-coding regulatory regions, are subject to Level I reporting. Id. at 23,317.
87. Id. at 23,321-23.
88. Id. at 23,323.
89. See supra note 77.
90. As an alternative to applying for an experimental use permit, a Level I applicant can comply with the Level II reporting requirements. The additional information will be considered by the EPA in deciding if an experimental use permit is required. Coordinated Framework, supra note 9, at 23,321.
91. 40 C.F.R. § 172 (1986). See also Coordinated Framework, supra note 9, at 23,323.
the GEMP in question is granted FIFRA registration. For purposes of this comment, the issue of whether or not a GEMP is ultimately registered is irrelevant. This comment focuses on whether the review process for approval of the small-scale field test prior to registration should be subject to the NEPA standards.

B. Application of the Doctrine of Functional Equivalence in Foundation on Economic Trends v. Thomas

The preceding summary of the EPA's policy for regulating deliberate release experiments demonstrates that the EPA has at least made a good faith attempt to formulate a comprehensive approach to that complex area. In spite of this apparently rational approach to regulating deliberate release experiments, however, the question remains as to the wisdom and legality of allowing a major new technology, to slip into routine regulation by a federal agency without being subjected to the full scrutiny of NEPA. After all, it is one of the express purposes of NEPA to insure that full and adequate consideration is given to all major federal actions significantly affecting the environment. Compounding this apparent anomaly is the fact that the EPA had to stretch its statutory authority to bring genetic engineering processes under the ambit of FIFRA.

The court in Thomas addressed the new technology aspect of deliberate release experiments by noting that the court is "at its most deferential" when reviewing administrative decisions concerning frontier technology. Curiously, in taking this approach, the court ignored the issue of the EPA's questionable authority to regulate deliberate release experiments. Even more curious was the cursory manner in which the court found the EPA's approval of the AGS deliberate release experiment to be the functional equivalent to

93. By this, it is not implied that all GEMPs are dangerous. However, the possibility exists that a genetically engineered microorganism could spread in an environmental niche with unexpected results. In considering the first applications for deliberate release experiment use permits, the EPA has already experienced regulatory problems. After initially approving AGS's experimental use permit, the EPA was forced to temporarily suspend the permit when it was learned that AGS conducted unauthorized experiments. See Wall St. J., Feb. 28, 1986, at 8, col. 2; San Jose Mercury News, March 23, 1986, at 20A, col. 1.
94. See supra note 40 and accompanying text.
95. See supra note 36 and accompanying text.
96. Id. at 20,633 (citing Baltimore Gas & Elec. Co. v. NRDC, 462 U.S. 87, 103 (1983)).
NEPA compliance. The court repeatedly recited that functional equivalence will be found where the five core NEPA issues\footnote{98} are carefully considered.\footnote{99} In \textit{Thomas}, the court apparently found that the experimental use permit review procedure satisfies the five core issues and is the equivalent of EIS preparation. This approach completely begs the question of whether experimental use permit review is in fact the functional equivalent to EIS preparation. In order to determine if the EPA’s decision to issue a use permit was arbitrary, capricious or an abuse of discretion, the court must also determine, at a minimum, if the underlying procedural framework is arbitrary and capricious. With the Coordinated Framework, where EPA has formulated an entirely new regulatory framework, the court should adopt a “hard look” approach to the arbitrary and capricious standard.\footnote{100}

Examination of the Coordinated Framework reveals that the EPA has formulated its biotechnology regulatory policy around the increased risks inherent in genetically engineered microorganisms.\footnote{101} This formulation is the basis of the inter-generic/pathogenic classification scheme discussed in section III (A) above.\footnote{102} The issue that demands judicial review is whether or not the inter-generic/pathogenic scheme evinces the concern for the environment demanded by NEPA. In this respect, there are significant questions about the EPA’s risk assessment\footnote{103} procedures. First, the EPA’s basic premise concerning deliberate release experiments is new, untested and

\footnote{98} The five core NEPA issues are: (1) the environmental impact of the action; (2) possible adverse environmental effects; (3) possible alternatives; (4) the relationship between short term use of the environment and long-term productivity; and (5) any irreversible commitments of resources. National Environmental Policy Act of 1969, 42 U.S.C. § 4332(C)(i-v) (1982).


\footnote{101} For example, the EPA states: “The alternative [risk potential] that EPA has chosen gives particular attention, under both FIFRA and TSCA, to microorganisms that (1) are used in the environment, (2) are pathogenic or contain genetic materials from pathogens or (3) contain new combinations of traits.” Coordinated Framework, supra note 9, at 23,315.

\footnote{102} See supra notes 82-85 and accompanying text.

\footnote{103} Risk assessment refers to the process of identifying risks. See \textit{Anderson}, supra note 38, at 451-58.
incomplete. The EPA recognizes that potentially significant risks are caused by the absence of physical restraints in deliberate release experiments. However, the Agency’s current position is that some deliberate release experiments are safe because of biological restraints. Thus, during the two-level FIFRA review procedure, the EPA examines data provided by the GEMP manufacturer and determines if the proposed release of the GEMP will be adequately controlled by biological constraints. Remarkably, the EPA admits that it has issued experimental use permits without finalizing the guidelines used to evaluate testing methodology and risk assessment. Secondly, many scientists doubt that adequate risk assessment techniques are presently available for evaluating the safety of deliberate release experiments. Finally, the EPA’s inter-generic/pathogenic classification scheme is barely two years old and is noticeably slanted toward allowing deliberate release experiments.

In view of these factors: the absence of an explicit Congressional mandate, the novelty of the technology, the possibility of catastrophic consequences, the absence of a scientific consensus on risk assessment methodologies and the relative infancy of the EPA’s policy for regulating deliberate release experiments, it is irresponsible to waive compliance with NEPA procedures as summarily as the Thomas court did. The more responsible approach, as discussed in section IV below, would be to require preparation of an EIS for each proposed deliberate release experiment that the EPA reviews. Such an
approach might be overly cautious, however, it would insure that deliberate release experiments will be properly documented before routine commercial development of this powerful technology is allowed.

IV. CONTROLLING DELIBERATE RELEASE EXPERIMENTS

A. An EIS Should be Prepared for Individual Deliberate Release Experiments

The two most serious questions concerning deliberate release experiments are whether genetically engineered microbial pesticides (GEMPs) can be contained within a test site and whether the consequences of containment failure can be predicted. In the absence of Congressional action, any administrative pronouncements on these issues will be met with skepticism and repeated judicial challenges. Accordingly, a public record directly addressing the issues of containment and the consequences of containment failure is necessary. The preparation of an environmental impact statement (EIS) for all initially approved deliberate release experiments would satisfy this need. First, the preparation of an EIS would create a public record, in language as plain as possible, addressing all of the environmental factors associated with a particular deliberate release experiment. Second, the large body of NEPA case law would provide a reference system which courts could use to orient themselves in addressing the novel aspects of genetic engineering technologies. Third, and most importantly, preparation of an EIS would force the EPA to crystallize its position concerning risk assessment in each experiment. If, over time, the EPA demonstrated that its risk assessment methodologies were applicable to classes of experiments (such as intra-generic, inter-generic and pathogenic GEMPs), then perhaps applications to conduct deliberate release experiments could be routinely reviewed in the manner that the EPA

111. See supra notes 40-44 and accompanying text for a discussion of EISs.
112. 40 C.F.R. § 1502.8 (1986) states: "Environmental impact statements shall be written in plain language . . . so that decision makers and the public can readily understand them." Id.
113. The courts have already seized on this reference point. The court in Thomas stated that because the case law on experimental use permit review was sparse, it would utilize a review procedure comparable to that used in EIS review. Thomas, 16 ENVTL. L. REP. (Envtl. L. Inst.) at 20,633 (1986).
REGULATION OF BIOTECHNOLOGY

proposes in the Coordinated Framework.\textsuperscript{114}

The Council on Environmental Quality’s (CEQ)\textsuperscript{115} regulation for incomplete or unavailable information\textsuperscript{116} would trigger a detailed discussion of risk assessment in an EIS for a deliberate release experiment. This regulation is ideally suited for dealing with the issues that have caused concern about the safety of deliberate release experiments. The stated goals of the regulation are: “[d]isclosure of the fact of incomplete or unavailable information; acquisition of that information if reasonably possible; and evaluation of reasonably foreseeable significant adverse impacts even in the absence of all information.”\textsuperscript{117} Compliance with this regulation means that any uncertainty (unavailable information) concerning the issue of dispersion would have to be disclosed and an evaluation of the consequences of dispersion would have to be discussed in the EIS for a particular deliberate release experiment. The discussion of the consequences of dispersion would then have to be considered by the EPA before reaching a final decision on approval of a particular experiment. If a private party still wished to challenge the EPA’s treatment of these issues, the adequacy of the EIS could be challenged before the deliberate release experiment was conducted.\textsuperscript{118}

The exact content of an EIS adequately addressing issues of incomplete or unavailable information is not well defined.\textsuperscript{119} However, the regulation, and CEQ commentary on the regulation, indicate the contours of what is expected. Initially, if an agency pre-

\textsuperscript{114} See supra notes 73-92 and accompanying text.

\textsuperscript{115} The CEQ is an executive agency which issues regulations covering NEPA. This includes regulations governing the preparation of EISs. See ANDERSON, supra note 38, at 687.

\textsuperscript{116} 40 C.F.R. § 1502.22 (1986). In this regulation, the term “incomplete information” refers to information which is unobtainable because of exorbitant costs. “Unavailable information” refers to information which cannot be obtained because there is no known method for obtaining it.

\textsuperscript{117} Coordinated Framework, supra note 9, at 15,620.

\textsuperscript{118} A challenge to the adequacy of the EIS would be reviewed under the “substantial inquiry” standard. See supra notes 46-48 and accompanying text. This review would be significantly different from the review in Thomas because in Thomas, the court was concerned with verifying compliance with FIFRA not NEPA. See supra notes 67-72 and accompanying text. Also, in Thomas the court deferred to the EPA’s FIFRA procedures. In an EIS review, the court would be free to evaluate the risk assessment data supplied to satisfy 40 C.F.R. § 1502.22 (1986).

\textsuperscript{119} This is because the relevant CEQ regulation, 40 C.F.R. § 1502.22 (1986), was recently subject to extensive revision. The “old” section 1502.22 regulation required preparation of a worst case analysis for incomplete or unavailable information. For a discussion of the “old” regulation, see Note, Scientific Uncertainty and the National Environmental Policy Act — The Council on Environmental Quality’s Regulation, 40 C.F.R. Section 1502.22, 60 WASH. L. REV. 101 (1984).
paring an EIS encounters incomplete information relevant to reasonably foreseeable significant adverse impacts on the environment, and the incomplete information is essential to a reasoned choice among alternatives, the agency must obtain the information if the costs of obtaining it are not exorbitant.\textsuperscript{120} Secondly, if the relevant incomplete information cannot be obtained then the EIS must include a statement discussing each of the following points: 1) the fact that such information is incomplete or unavailable; 2) the relevance of the incomplete or unavailable information to the task of evaluating reasonably foreseeable significant adverse impacts; 3) a summary of existing scientific evidence concerning reasonably foreseeable adverse environmental impacts; and 4) the agency’s evaluation of the potential impacts based on sound scientific research methods.\textsuperscript{121}

With respect to deliberate release experiments, this regulation would compel the EPA to either develop a testing protocol which provides answers to all relevant dispersion questions, or to document the scientific reasoning which justifies allowing the deliberate release

\textsuperscript{120} The complete 40 C.F.R. section 1502.22 reads:

When an agency is evaluating reasonably foreseeable significant adverse effects on the human environment in an environmental impact statement and there is incomplete or unavailable information, the agency shall always make clear that such information is lacking.

(a) If the incomplete information relevant to reasonably foreseeable significant adverse impacts is essential to a reasoned choice among alternatives and the overall costs of obtaining it are not exorbitant, the agency shall include the information in the environmental impact statement.

(b) If the information relevant to reasonably foreseeable significant adverse impacts cannot be obtained because the overall costs of obtaining it are exorbitant or the means to obtain it are not known, the agency shall include within the environmental impact statement: (1) A statement that such information is incomplete or unavailable; (2) a statement of the relevance of the incomplete or unavailable information to evaluating reasonably foreseeable significant adverse impacts on the human environment; (3) a summary of existing credible scientific evidence which is relevant to evaluating the reasonably foreseeable significant adverse impacts on the human environment; and (4) the agency’s evaluation of such impacts based upon theoretical approaches or research methods generally accepted in the scientific community. For the purposes of this section, “reasonably foreseeable” includes impacts which have catastrophic consequences, even if their probability of occurrence is low, provided that the analysis of impacts is supported by credible scientific evidence, is not based on pure conjecture, and is within the rule of reason.

(c) The amended regulation will be applicable to all environmental impact statements for which a Notice of Intent (40 C.F.R. 1508.22) is published in the Federal Register on or after May 27, 1986. For environmental impact statements in progress, agencies may choose to comply with the requirements of either the original or amended regulation.

\textsuperscript{121} 40 C.F.R. § 1502.22 (1986), \textit{supra} note 121.
experiment to proceed in spite of incomplete or unavailable dispersion information. The issue of dispersion must not be dismissed solely because the likelihood of its occurrence is remote. The regulation specifically states that low probability/catastrophic impact events are included within the definition of reasonably foreseeable impacts. Furthermore, CEQ commentary specifies that the requirement to disclose scientific evidence concerning reasonably foreseeable adverse impacts extends to responsible opposing views supported by generally accepted research methods.

Under the Coordinated Framework, the EPA has developed a regulatory scheme which classifies genetically engineered microorganisms as being inter-generic, pathogenic or intra-generic microorganisms. The EPA then evaluates proposed deliberate release experiments involving these classes of microorganisms according to different, newly promulgated, FIFRA regulation. Implicit in this regulatory scheme are many assumptions about the traits that newly created life forms will display, about the possibility of dispersion and about the ability of genetically engineered microorganism to cause adverse effects on the environment. All of these assumptions should be considered incomplete or unavailable information and should be addressed in an EIS pursuant to 40 C.F.R. section 1502.22. While preparing an adequate EIS on these issues would take some time and effort, that is precisely the duty that NEPA, through the CEQ regulations, imposes on federal agencies. It is inconceivable that an administrator could make an informed decision about a technological process like genetic engineering without thoroughly considering the effects of releasing genetically altered bacteria into the environment.

Finally, it is important to note that delaying deliberate release experiments until an adequate EIS is prepared does not mean that the genetic engineering industry must be shut down. Many of the

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122. Impacts not supported by credible scientific evidence do not have to be discussed in the EIS. 40 C.F.R. § 1502.22(b)(4) (1986). However, the EPA recognizes that dispersion is a credible potential impact. See Coordinated Framework, supra note 9, at 23,317. The regulation incorporates the "rule of reason" test for determining what type of impacts must be analyzed in the EIS. See 51 Fed. Reg. 15,621. The rule of reason means that an EIS need not analyze unforeseeable impacts, but impacts requiring some degree of forecasting cannot be ignored. Scientists' Inst. for Pub. Information, Inc. v. Atomic Energy Comm'n, 481 F.2d 1079, 1092 (D.C. Cir. 1973); see also 51 Fed. Reg. 15,621.

123. 51 Fed Reg. 15,621.

124. See supra notes 81-92 and accompanying text.

125. See supra notes 81-92 and accompanying text.

126. See, e.g., Coordinated Framework, supra note 9, at 23,317.
commercially important genetic engineering processes do not involve release of microorganisms into the environment. Rather, with these processes, the genetically engineered microorganisms are contained in the laboratory and the chemical products which the microorganisms produce are extracted before use.\textsuperscript{127}

V. CONCLUSION

Genetic engineering processes have the potential to greatly improve the quality of life. The power of genetic engineering techniques, however, demands that development in this field proceed with extreme caution.

In the past, rDNA research was loosely regulated by the NIH. The early NIH guidelines, however, suffered from many problems such as not being applicable to industrial researchers.\textsuperscript{128} The new EPA regulations are a great improvement over the NIH guidelines. However, the new regulations fail to adequately consider the unique dangers of genetic engineering processes, such as dispersion.\textsuperscript{129}

A more rational approach to regulating the biotechnology industry during its current rapid growth phase is to incorporate the established safeguards of NEPA into the current regulatory framework. This means that environmental impact statements should be prepared for deliberate release experiments before they are approved. The preparation of a statement discussing incomplete or unavailable information associated with a particular deliberate release experiment, in conjunction with the environmental impact statement, would ensure that the potential benefits of deliberate release experiments are adequately weighed against the possible catastrophic consequences associated with this new technology.

Donald J. Pagel, Jr.

\textsuperscript{127} See id. at 23,324.
\textsuperscript{128} See supra text accompanying note 22.
\textsuperscript{129} See supra note 55.