

# Deliberate Release of Genetically Altered Frost Inhibiting Bacteria: Judicial Intervention in the Genetic Age

What hope can there be for mankind, when there are such men to give such playthings as ice-nine to such short-sighted children as almost all men and women are?<sup>1</sup>

## HISTORY

The environmental concerns generated by recombinant DNA research began in 1974 when a group of scientists issued a warning on the uncertainty of impacts from genetically altered microorganisms that might escape from laboratory experiments. In the ensuing decade, the initial concerns that spawned National Institute of Health (NIH) guidelines for recombinant DNA research have been tempered, and once-prohibited deliberate release experiments are now under active consideration. These experiments involve intentional introduction of genetically altered microorganisms into the environment to test their effectiveness under actual conditions, rather than in a laboratory simulation. The ramifications from dispersion of these microorganisms can be conjectured, but there have been only conclusory concessions to worst-case environmental scenarios in proposals for these experiments. Inadequate environmental assessments have resulted in a lessening of confidence in scientific research which may be alleviated to some extent by full public disclosure of the risk involved in this type of experimentation. Such well-researched environmental assessments and impact statements are within the scope and requirements of the National Environmental Policy Act (NEPA).<sup>2</sup> For federally funded scientific experiments that engender any potential environmental hazards, these environmental assessments and impact statements constitute the minimum NEPA standards.

In compliance with NEPA, the only Environmental Impact Statement (EIS) that has been prepared by NIH on genetic engi-

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1. K. VONNEGUT, *CAT'S CRADLE* (1972).  
2. 42 U.S.C. §§ 4321-4370 (1982).

neering clearly identified dispersion of genetically altered microorganisms as a serious potential consequence of genetic research.<sup>3</sup> In describing the sequence of events that would result in the manifestation of an adverse environmental impact, the EIS stated that:

Current knowledge permits no more than speculation that such [hazardous] agents may be produced and an equally speculative assessment of the nature and extent of hazards associated with a particular recombinant DNA experiment. This is the underlying reason that the thrust of the Guidelines is to minimize contact of organisms containing recombinant DNA with other organisms or the environment.<sup>4</sup>

The stringent containment requirements upon which NIH relied to minimize dispersion became irrelevant when the prohibition on deliberate release experiments was lifted in 1978. NIH has an obligation with regard to these experiments to require the preparation of environmental assessments (EA) and/or an EIS that are responsive to the enhanced likelihood for dispersion outside the release area. Without data to support a finding of no significant impact, an EA is inadequate and whether the more in-depth EIS is necessary is impossible to determine. If the agency does not fulfill that obligation, judicial intervention is clearly mandated in order to implement Congressional intent as embodied in NEPA. As deliberate release experiments become reality, courts may have to remind researchers of their obligations to disclose the potential adverse environmental consequences of their experiments.

### THE PRESENT

Judicial intervention on behalf of environmental protection proved quite timely in a recent case, *Foundation on Economic Trends v. Heckler*,<sup>5</sup> involving deliberate application of genetically manipulated, frost inhibiting bacteria onto crops in California. The experiment had been approved by NIH and was nearly implemented<sup>6</sup> when three environmental groups and two individuals sought an injunction in September, 1983. The experiment was to be

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3. U.S. DEP'T OF HEALTH, EDUCATION AND WELFARE, NATIONAL INSTITUTE OF HEALTH, ENVIRONMENTAL IMPACT STATEMENT ON NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT DNA MOLECULES, 99-100 (1977).

4. *Id.* at 99.

5. *Foundation on Economic Trends v. Heckler*, 756 F.2d 143 (D.C. Cir. 1985).

6. After the D.C. Circuit Court of Appeals released the opinion on February 27, 1985, the University of California-Berkeley attorney David Dorinson was quoted as stating that: "I'm hopeful the experiment can be conducted this spring." L.A. Daily Journal, Mar. 1, 1985, at 3, col. 4.

the first deliberate release of genetically manipulated bacteria into the environment; the previous two experiments approved by NIH had been aborted after technical problems. A research team at the University of California at Berkeley had received NIH approval to apply genetically altered bacteria to plots of potatoes in northern California.<sup>7</sup> NIH approval was obtained because the University receives federal funds for recombinant DNA research and has stated a commitment to abide by the binding conditions of the NIH guidelines.<sup>8</sup>

The experimental bacteria has been stripped of genetic coding that initiates ice crystal formation on many types of crop plants. The researchers anticipated that application of the bacteria to the foliage, much like application of chemical pesticides, would overwhelm harmful, naturally occurring bacteria and reduce crop damage from untimely frost occurrence.<sup>9</sup> While this particular technological advancement may seem purely beneficial and benign, there was no information contained within the NIH approval that might support that conclusion. The researchers contended that bacteria similar to the test forms already occur in the natural environment, and that experiments with *chemically* manipulated bacteria have not resulted in adverse environmental impacts. The court

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7. *Foundation on Economic Trends*, 756 F.2d at 156.

8. Private laboratories are not bound by NIH guidelines since they do not receive federal funding. In 1980, NIH distributed "Physical Containment Recommendations for Large-Scale Uses of Organisms Containing Recombinant DNA Molecules" to private laboratories and had arranged to provide consultation on safety procedures. McGarity & Bayer, *Federal Regulation of Emerging Genetic Technologies*, 36 *VAND. L. REV.* 461, 502 (1983). Indications are that the private firms working in this field have voluntarily adhered to the NIH Guidelines thus far. Teichmann, *Regulation of Recombinant DNA Research: A Comparative Study*, 6 *LOY. L.A. INTL. & COMP. L.J.* 1, 6 (1983). Much has been written on possible regulatory schemes for private industry. Since no deliberate release experiments have yet been conducted by a private company, the question of governmental regulation has not been answered definitely. Many existing regulatory programs, while theoretically adequate for controlling marketing, distribution and use of genetically altered organisms, do not address the experimentation phase. Some provisions of the Toxic Substances Control Act (TSCA) could be interpreted to include regulation of biotechnology research and development, but NIH may offer the most comprehensive regulation of experimentation at present. Letter from Don R. Clay, Acting Assistant Administrator of the Office of Pesticide and Toxic Substances to Representative Albert Gore, Jr. in *Environmental Implications of Genetic Engineering, Hearing before the Subcomm. on Investigations of Genetic Engineering, Hearing before the Subcomm. on Investigations and Oversight and the Subcomm. on Science, Research and Technology of the Comm. on Science and Technology*, 98th Cong., 1st Sess. 153-54 (1983) [hereinafter cited as *Environmental Implications of Genetic Engineering*].

9. OFFICE OF TECHNOLOGY ASSESSMENT, *COMMERCIAL BIOTECHNOLOGY: AN INTERNATIONAL ANALYSIS*, OTA-BA-218, 184 (1984).

rejected this reasoning because the experiment was predicated on the hypothesis that these genetically altered bacteria were more stable and competitive than either of the two existing forms.<sup>10</sup>

It is foreseeable that the frost inhibiting bacteria might be successful colonizers, and would find a favorable ecological niche outside the fields where application occurred. In that case, environmental, and even climatic changes, might result. It is difficult to predict whether such novel genotypes would ultimately change the environment for better or worse. Data on introduced exotic species is not even conclusive on the net damage done by the vilified gypsy moth, which was brought into this country as an experimental substitute for the silk-worm. Defoliation by these moths, for example, allows understory trees to receive more sunlight, thereby increasing the growth and survival rates of those varieties.<sup>11</sup> On the other hand, the chestnut blight fungus, which was unintentionally introduced, produced an "ecological perturbation of great magnitude", causing the disappearance of an entire tree species that had provided a significant wildlife food and timber resource.<sup>12</sup>

Given the potential for such profound impacts from novel genotypes, it is obviously vital that proposals for specific experiments seriously address these environmental consequences. Without data to support a finding of no significant impact to the environment, NEPA becomes merely a procedural hoop through which researchers must jump to receive their funding and approvals. The court in *Foundation on Economic Trends*<sup>13</sup> introduced its opinion by emphasizing its commitment to advancing Congressional intent for the Act as demonstrated by its previous holdings on similar cases:

Almost 14 years ago, soon after passage of the National Environmental Policy Act . . . , this court faced the challenge of ensuring that the Act's "important legislative purposes, heralded in the halls of Congress [were] not lost or misdirected in the vast hallways of the federal bureaucracy." This case poses a no less formidable challenge: to ensure that the bold words and vigorous spirit of NEPA are not similarly lost or misdirected in the brisk frontiers of science.<sup>14</sup>

In the NIH review of the Berkeley experiment, the single conces-

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10. *Foundation on Economic Trends*, 756 F.2d at 154.

11. Sharples, Spread of Organisms With Novel Genotypes: Thoughts From an Ecological Perspective in *Environmental Implications of Genetic Engineering*, *supra* note 8, at 177.

12. *Id.* at 167.

13. 756 F.2d at 145.

14. *Id.* at 145 (quoting Calvert Cliffs' Coordinating Committee v. USAEC, 449 F.2d 1109, 1111 (D.C. Cir. 1971)).

sion to potential adverse impacts from dispersion of the frost inhibiting bacteria was found in the NIH reviewing committee's minutes: "Although some movement of bacteria toward sites near treatment locations by insect or aerial transport is possible, the numbers of viable cells transported has [sic] been shown to be very small; and these cells are subject to biological and physical processes limiting survival."<sup>15</sup> The NIH Director subsequently stated that there was no significant risk involved in the project, and approved it with no further documentation to support his conclusions. This conclusory approach did not constitute an adequate EA since it provided no basis for a finding of no significant impact. Without that finding, NEPA requires that an EIS be prepared before further experimentation occurs. Since NIH did not fulfill its NEPA obligations, the Court of Appeals properly affirmed the District Court's injunction against the experiment until an adequate EA is prepared.

### THE FUTURE

When NIH submits the EA for the Berkeley experiment, the court will be setting new standards for recombinant DNA research because it will be deciding the degree of detail that adequately addresses environmental concerns. The court also suggested that the NIH seriously consider undertaking a programmatic EIS that would encompass deliberate release experiments generally. In making this recommendation, the court reversed the District Court's holding that all future experiments be enjoined until such an EIS is prepared. However, the opinion included a caveat to the effect that NIH's failure to at least consider the need for a programmatic EIS could jeopardize subsequent approvals of individual experiments if they came up for judicial review.<sup>16</sup>

The requirement of an EA for specific experiments, as opposed to a programmatic EIS, is a good compromise. Scientists are understandably reluctant to engage in "crystal-ball inquiry" when sufficient details of an experiment are unavailable. This is particularly true in recombinant DNA research where each experiment involves unique organisms and applications. Conversely, when a deliberate release experiment is imminent, many details should be available on the organism's potential for survival and likelihood of competition with naturally occurring genotypes.<sup>17</sup> With this detailed informa-

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15. *Id.* at 153.

16. *Id.* at 160.

17. *See supra* note 3, at 99.

tion, researchers can "brain-storm" to consider every possible hazardous impact on the existing ecological balance from release of the organism.

If NIH meets its responsibilities to the environment, judicial intervention may be infrequent as this technology matures. NIH is well qualified to review such experiments, so it is somewhat curious that they did not use their considerable expertise to examine the deliberate release experiments in accordance with federal environmental legislation.

Within the NIH, the Recombinant DNA Advisory Committee studies proposals for deliberate release experiments and makes recommendations to the Director. This committee is composed of 25 voting members appointed by the Secretary of Health and Human Services, and nonvoting representatives of federal agencies. The committee is a mixture of different professions and viewpoints, and members have included a lawyer, a former state legislator, an occupational safety expert, practicing physicians, and the executive director of a state department of health. The federal agencies represented in a nonvoting capacity include most of those concerned with health and the environment.<sup>18</sup> Legal, regulatory, and scientific concerns should be well represented in such a group, provided that enthusiasm for this fascinating field of research does not obscure the preeminent need for environmental protection.

The court in *Foundation on Economic Trends v. Heckler* intervened to remind the NIH that they owe the public more than a perfunctory statement on environmental impacts from a new and rather awe inspiring technology. Certainly, they possess the expertise necessary to evaluate these consequences, and for the sake of future experimentation, it is in their own best interests to do so.

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18. *Environmental Implications of Genetic Information*, *supra* note 8, at 111.