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An Agricultural Law Research Article

Biotechnology and the United States Department of Agriculture: Problems of Regulation in a Promotional Agency

by

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Originally published in ECOLOGY LAW QUARTERLY
17-2 ECOLOGY L.Q. 413 (1990)

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INTRODUCTION

In the past fifteen years, advances in molecular biology, biochemistry, and cell biology have spurred dramatic growth in the biotechnology industry. Scientists can now directly manipulate cellular machinery to produce a whole range of new products and processes. Genes are routinely transferred from one microorganism to another, producing pharmaceuticals and other specialty chemicals at low cost.[1] Genetically engineered microbes can decompose toxic wastes[2] and leach minerals from the soil.[3] Researchers are also using new techniques to alter plants and animals for agricultural use.[4] These and other new processes will have an enormous commercial impact on the production of drugs, chemicals, and agricultural products.

Many of these applications of biotechnology will require the deliberate release of genetically altered organisms into the environment,[5] a practice that may threaten human health as well as the environment.[6] Unfortunately, scientists do not understand enough about the dynamics of ecosystems to predict confidently the environmental effect of releasing millions of genetically engineered microbes. Without natural population

* Associate, Townsend & Townsend, San Francisco. J.D. 1989, School of Law (Boalt Hall), University of California, Berkeley; M.A. 1982, San Jose State University; A.B. 1978, University of California, Berkeley.

1. U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, COMMERCIAL BIOTECHNOLOGY: AN INTERNATIONAL ANALYSIS 3, 119 (1984) [hereinafter COMMERCIAL BIOTECHNOLOGY].

2. *See id.* at 217-25. Oil-eating bacteria were at issue in Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980), where the Supreme Court held that a live, human-made microorganism is patentable subject matter.

3. COMMERCIAL BIOTECHNOLOGY, *supra* note 1, at 226-28.

4. *See generally* Shepard, Bidney, Barsby & Kemble, *Genetic Transfer in Plants Through Interspecific Protoplast Fusion,* 219 SCI. 683 (1983) [hereinafter *Genetic Transfer*]; *infra* notes 126-42 and accompanying text.

5. *See infra* notes 135-36 and accompanying text.

6. *See infra* notes 143-53 and accompanying text.

controls, novel organisms could sweep across the landscape, causing serious environmental damage.[7] In addition, a genetic manipulation may inadvertently introduce harmful characteristics into an organism that cannot be detected until after the organism is released.[8]

The federal government has attempted to deal with these risks by splitting the responsibility for regulating the products of biotechnology between the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the Department of Agriculture (USDA).[9] FDA regulates recombinantly produced foods, food additives, human drugs, and animal drugs, while EPA oversees the environmental release of recombinant microorganisms. The Department of Agriculture is responsible for genetically engineered plants and animals as well as animal drugs.[10] EPA and USDA both review the release of recombinant microorganisms that are plant pests.[11]

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7. *See* Sharples, *Spread of Organisms with Novel Genotypes: Thoughts from an Ecological Perspective,* 6 RECOMBINANT DNA TECH. BULL. 43, 45 (1983).

8. For instance, unexpected changes in altered organisms that had received well-characterized DNA might lead to subtle changes that would influence the ecology and population dynamics of the organisms. Stotzky & Babich, *Fate of Genetically Engineered Microbes in Natural Environments,* 7 RECOMBINANT DNA TECH. BULL. 163 (1984). The mechanisms that control expression of genes in higher organisms are extremely complex. For example, different parts of a chromosome undergo different rates of expression. This presents a problem because most methods used to produce recombinant organisms introduce DNA randomly into the host's chromosomes. There frequently is no way to predict accurately where on the chromosome the introduced DNA will insert. Expression is also controlled at a number of later stages of constructing a living cell with the information in DNA. *See generally* T. WATSON, N. HOPKINS, J. ROBERTS, J. STEITZ & A. WEINER, MOLECULAR BIOLOGY OF THE GENE (4th ed. 1987). Thus, simply inserting a well-characterized gene into an organism does not ensure that the function of that gene in the organism can be predicted.

9. Some federal regulation of biotechnology is needed because of the risks inherent in releasing genetically engineered organisms into the environment. *See generally 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. (1983) [hereinafter *Environmental Implications*]; *see also* McChesney & Adler, *Biotechnology Released from the Lab: The Environmental Regulatory Framework,* 13 Envtl. L. Rep. (Envtl. L. Inst.) 10,366 (1983). In 1986, the White House Office of Science and Technology Policy (OSTP) published a notice that established federal policy for the regulation of biotechnology. Coordinated Framework for the Regulation of Biotechnology, 51 Fed. Reg. 23,302 (1986) [hereinafter Coordinated Framework]. The notice included policy statements of the agencies that would be overseeing the biotechnology industry: USDA, EPA, FDA, the National Institute of Health (NIH), and the Occupational Safety and Health Administration (OSHA). *Id.* at 23,309-50. It discussed how these agencies would coordinate their scientific policies and regulatory activities.

The Coordinated Framework pieced together existing federal regulatory powers. According to OSTP, existing statutes provide a network of agency jurisdiction to cover all uses of biotechnology. Coordinated Framework, *supra,* at 23,302. OSTP expects that new products can be reviewed for safety and efficacy in essentially the same manner as products from other technologies. *Id.* at 23,303.

10. Coordinated Framework, *supra* note 9, at 23,304.

11. *Id.* EPA, however, is the lead agency in the joint review.

This Comment focuses on the Department of Agriculture's role in this structure, especially as it relates to the environmental release of recombinant organisms. For most of its past, USDA has been primarily a "promotional" agency, one whose mission was largely to encourage and support socially desirable private activities.[12] It has seldom taken on the role of a purely "regulatory" agency, which would protect the public against potentially harmful activities.[13] As USDA attempts to regulate biotechnology, it will face problems that inevitably arise out of the conflict between promotional and regulatory goals.

This Comment argues that the Department of Agriculture is a poor choice to regulate agricultural biotechnology because of this conflict. Part I presents a general theoretical framework that distinguishes regulatory from promotional policymaking. Part II uses this theoretical framework to examine the history of the Department of Agriculture, particularly its attempts at regulation. The theoretical framework provides a basis for understanding why the Department has failed in its efforts to regulate agriculture, its client industry.

Part III shifts the focus from the past to the future. After summarizing the development, risks, and benefits of agricultural biotechnology, Part III considers the challenges inherent in the regulatory decisions that must be made with respect to biotechnology. Part IV then uses the analysis developed in the first three parts to argue that the Department is ill-equipped to regulate biotechnology because its inherent promotional orientation biases its evaluation of biotechnology risks. The conclusion offers some tentative solutions to this problem.

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12. *See infra* notes 31-57 and accompanying text. Arguably, not all sectors of the industry have benefited equally from departmental activities. USDA's bias in favor of promoting large agribusiness interests has been, in the opinion of some, deleterious to smaller operations and laborers. *See* Scher, Catz & Mathews, *USDA: Agriculture at the Expense of Small Farmers and Farmworkers*, 7 U. TOL. L. REV. 837 (1976).

13. Some of the Department's activities, such as price supports, are often referred to as "regulation" of agriculture. *See, e.g.*, Roberts, *Deregulating the Agricultural Industry: A Wise Policy Choice?*, 12 J. CONTEMP. L. 49 (1986). Under the analysis presented here, however, these activities are more properly referred to as "promotional." *See infra* notes 25-30 and accompanying text.

USDA has occasionally been given regulatory duties. For example, at one point it enforced pure food and drug and pesticide laws. However, the Department has not been successful with such regulatory responsibilities. *See infra* notes 70-116 and accompanying text. Other USDA programs promote the interests of both agricultural producers and the general public. Thus, the Department inspects and grades agricultural products to insure "that agricultural products may be marketed to the best advantage, that trading may be facilitated, and that consumers may be able to obtain the quality product which they desire." 7 U.S.C. § 1622(h) (1988).

I
THEORETICAL ASSUMPTIONS: THE PROMOTIONAL/REGULATORY CONFLICT

The role and effect of organized interest groups in governmental decisionmaking has long been a matter of debate among political scientists.[14] Some theorists placed great emphasis on the importance of pressure groups and saw Congress largely as a neutral, passive referee that ratified the policy victories of shifting political alliances.[15] Others saw the government as anything but a neutral arbiter of conflict. To them government was biased in favor of more privileged interest groups.[16] A third and more recent view challenges as too simplistic the traditional analyses of the relationship between government and private interest groups. It attempts to reconcile other theories by identifying certain types of policymakers that are more or less susceptible to influence by pressure groups.[17] This Comment adopts such an integrative approach, particularly the argument that pressure groups are particularly influential where "subgovernments" prevail.

Subgovernments are small groups of individuals, both governmental and nongovernmental, that specialize in a particular issue and make all of the routine policy decisions in that area.[18] They typically include members of legislative committees or subcommittees, administrative agency officials, and representatives of private interests affected by the decisionmaking.[19] Subgovernments arise partly out of the sheer number and complexity of issues that must be resolved by government.[20] Since no one can understand all or even most of the issues facing the government, subgovernments fill a need for specialization.

Participants in a subgovernment form a subculture within the government, accepting each other as insiders and friendly adversaries in the decisionmaking process.[21] Consequently, subgovernment policymaking tends to be dominated by a narrow range of participants who enjoy relatively stable political alignments and who make decisions with very little

14. For a general discussion and review of this debate, see M. HAYES, LOBBYISTS AND LEGISLATORS 1-6 (1981).

15. *See, e.g.*, Latham, *The Group Basis of Politics: Notes for a Theory*, 46 AM. POL. SCI. REV. 376, 390 (1952).

16. *See, e.g.*, E. SCHATTSCHNEIDER, THE SEMISOVEREIGN PEOPLE: A REALIST'S VIEW OF DEMOCRACY IN AMERICA (2d ed. 1975).

17. *See, e.g.*, M. HAYES, *supra* note 14.

18. R. RIPLEY & G. FRANKLIN, CONGRESS, THE BUREAUCRACY, AND PUBLIC POLICY 4-7 (4th ed. 1987). The term "subgovernment" was first coined in D. CARTER, POWER IN WASHINGTON: A CRITICAL LOOK AT TODAY'S STRUGGLE TO GOVERN IN THE NATION'S CAPITAL (1964).

19. R. RIPLEY & G. FRANKLIN, *supra* note 18, at 6.

20. *Id.* at 4.

21. P. BOSSO, PESTICIDES AND POLITICS 6 (1987).

public scrutiny.[22] Decisions typically result from accommodations in which all parties involved tend to gain.[23] Because mutual dependence is an important part of the way subgovernments function, clientelism pervades subgovernment policymaking.[24]

Randall Ripley and Grace Franklin argue that subgovernments are primarily associated with promotional rather than regulatory bodies[25] because promotional agencies tend not to have high profile policing roles. Rather, they are intended to encourage socially desirable, usually private activities through direct governmental support, such as subsidies.[26] Consequently, public awareness of the issues tends to be low, and policymaking is done primarily by administrative agencies and legislative subcommittees that remain out of the public eye. The cooperative nature of promotional policymaking is highly conducive to the proliferation of subgovernments.[27]

Regulatory policy, in contrast, attempts to protect the public by putting limitations on various private activities. According to Ripley and Franklin, regulatory policymaking tends to be more visible to the public and attracts a wider array of interests than does promotional policymaking.[28] The debate over regulatory issues often reaches farther up the governmental hierarchy. The entire Congress and high-level agency officials are frequently involved, rather than the subcommittees and mid-level officials that predominate in promotional issues.[29] According to this model, although the regulated industry may have a strong impact on decisions, its influence is weakened because subgovernments and clientelism play a much more limited role in policymaking.[30]

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22. *Id.* at 9.

23. *Id.*

24. *Id.* "Clientelism" is a term political scientists use to describe the cooperative relationship that develops between interest groups, congressional committees, and administrative agencies. M. HAYES, *supra* note 14, at 12.

25. R. RIPLEY & G. FRANKLIN, *supra* note 18, at 73-74.

26. Examples of promotional policymaking dominated by subgovernments include water resources policy under the Army Corps of Engineers, *id.* at 100, agricultural price support programs, *id.* at 102-03, and veterans benefits, *id.* at 106-07.

27. *Id.* at 73-74.

28. *Id.* at 96-97. The regulation of strip mining is an example of regulatory policymaking. *Id.* at 129.

29. *Id.* at 97. In the case of strip-mining legislation, bills were proposed by both Houses as well as by President Nixon. *Id.* at 129.

30. *Id.* at 97. With respect to the case of strip-mining legislation, a wide variety of interests were represented at committee hearings, so the regulated industry's interest had no clear influence on the ultimate outcome. *Id.* at 131.

Obviously, regulatory policymaking is not immune from the influence of pressure groups and subgovernments. The benefits of regulatory policy are usually widely distributed and individual benefits tend to be small. The costs, on the other hand, are concentrated in the regulated industry. As a result, the industry has a large interest in influencing policymaking. Regulated industries may face stiff opposition in Congress because of the high visibility of the legislative process. When the law is handed to the responsible agency for implementation,

Although the line between promotional and regulatory policymaking is sometimes difficult to draw, the distinction helps explain why a promotional agency may not be successful as a regulator. As a result of the mutual accommodation and clientelism that flow from subgovernment-dominated promotional policymaking, the promoted industry and the administrative agency develop common interests. Where that common interest and the public interest conflict, the agency will tend to make decisions that protect its client industry's interests, rather than public interests.

The next section examines the promotional history of the Department of Agriculture and applies this analytical model to evaluate the Department's regulatory efforts. The analysis illustrates how subgovernment-dominated promotional decisionmaking fails when it is given regulatory responsibility.

II
THE DEPARTMENT OF AGRICULTURE: A PROMOTIONAL HISTORY

A. The Department of Agriculture as a Promotional Agency

Although the early American economy was almost exclusively agricultural, neither state nor federal governments initially provided direct support for agriculture. Innovation and improvement were left entirely to individual farmers.[31] Early in the 19th Century, however, private agricultural societies formed to encourage new agricultural practices. Members conducted experiments, held fairs, and published periodicals.[32] These organizations also put pressure on Congress and state legislatures to provide support for agricultural education.[33] The federal government made its first appropriation for agriculture in 1839, when Congress gave $1,000 to the Patent Bureau to collect agricultural statistics and to distribute seed.[34] By 1860, four states had adopted legislation to create agricultural colleges that would conduct research and other activities to promote local farming.[35]

Ultimately, these societies succeeded in lobbying for permanent federal support for agriculture. President Lincoln, in his first address to Congress, urged that an agricultural and statistical bureau be organized to prepare reports on the "condition of our agriculture, commerce and

however, industry may successfully short circuit the law through accommodation and clientelism. *See, e.g., id.* at 129-34.

31. E. MOORE, THE AGRICULTURAL RESEARCH SERVICE 3-4 (1967).

32. *Id.*

33. W. RASMUSSEN & G. BAKER, THE DEPARTMENT OF AGRICULTURE 4-5 (1972).

34. *Id.* at 5.

35. Carstensen, *An Overview of American Agricultural History,* in FARMERS, BUREAUCRATS, AND MIDDLEMEN 8, 15 (T. Peterson ed. 1980).

manufactures."[36] Congress responded by passing the Act to Establish a Department of Agriculture, which President Lincoln signed into law on May 15, 1862.[37] The Act instructed the Department to "acquire and diffuse among the people of the United States useful information on subjects connected with agriculture in the most general and comprehensive sense of that word, and to procure, propagate, and distribute among the people new and valuable seeds and plants."[38]

During its early history, USDA's primary means of promotion was agricultural research. The Department conducted experiments through specialized bureaus that focused on various research areas.[39] USDA also helped to fund agricultural research conducted at the state level. State land grant colleges established under the Morrill Land Grant Colleges Act[40] operated agricultural experiment stations that examined practical farming problems.[41] Under the Hatch Act,[42] the Department became more directly involved with these stations by administering grants that provided direct federal funding. The agricultural research supported by land grant colleges, experiment stations, and USDA helped to double American agricultural output from 1910 to 1970.[43]

USDA's basic mission underwent a major change during the Depression as Congress added a variety of new agencies to the Department.[44] The majority of these agencies were intended to promote

36. J. RICHARDSON, 6 A COMPILATION OF THE MESSAGES AND PAPERS OF THE PRESIDENTS 53 (1897).

37. Act of May 15, 1862, ch. 72, § 1, 12 Stat. 387 (codified as amended at 7 U.S.C. § 2201 (1988)).

38. *Id.* The section was later amended to read, "to acquire and diffuse among the people of the United States useful information on subjects connected with agriculture, rural development, aquaculture, and human nutrition, in the most general and comprehensive sense of those terms." Pub. L. No. 92-419, § 603(a), 86 Stat. 657, 675 (1972); Pub. L. No. 95-113, § 1502(a), 91 Stat. 913, 1021 (1977).

39. E. MOORE, *supra* note 31, at 20-42. The most visible of these research agencies was the Bureau of Chemistry, which concentrated on identifying potentially useful chemical constituents of agricultural products. *Id.* at 21. The Bureau of Soils investigated ways to improve and conserve soil nutrients. *Id.* at 25. Research at the Bureau of Entomology focused on insects, both beneficial and harmful, *id.* at 30-31, while the Bureau of Dairy Industry strove to improve the quality of dairy products and to promote the pasteurization of raw milk. *Id.* at 35. The Bureau of Plant Industry helped breed new varieties of crop plants. *Id.* at 28. Eventually, in 1953, the Department consolidated these various research bodies into a single organization, the Agricultural Research Service (ARS). *Id.* at 43.

40. Ch. 130, 12 Stat. 503 (1862) (codified as amended at 7 U.S.C. §§ 301-329 (1988)).

41. E. MOORE, *supra* note 31, at 11.

42. Ch. 314, 24 Stat. 440 (1887) (codified as amended at 7 U.S.C. § 361(a)-(i) (1988)).

43. Heady, *The Agriculture of the U.S.*, SCI. AM., Sept. 1976, at 106, 108. Many advances in agricultural techniques were made through the auspices of USDA. For example, an entomologist with the Department was the first to show that insects could be controlled through biological means. W. RASMUSSEN & G. BAKER, *supra* note 33, at 66. Department entomologists were also the first to release sterilized insects to control insect pests. E. MOORE, *supra* note 31, at 95. In addition, plant breeders at the Department made significant advances in developing new disease-resistant crops. *Id.* at 113.

44. W. RASMUSSEN & G. BAKER, *supra* note 33, at 30-31.

American agriculture by stabilizing the farm industry and improving rural areas.[45] These new responsibilities gave the Department a major role in the economic life of the country.

The Agricultural Adjustment Act of 1933,[46] which was intended to protect farmers against price drops, prompted the most dramatic change at USDA. For the first time, the Department was called upon to subsidize farmers directly in order to keep the industry going. The Act created the Agricultural Adjustment Administration (AAA), which was authorized to make direct payments to farmers who voluntarily reduced their production of basic crops.[47] In 1934, the first year that the Act was operative, AAA distributions amounted to four times USDA's entire budget in 1933.[48] Although the Agricultural Adjustment Act was held unconstitutional by the Supreme Court in 1936,[49] Congress revived voluntary production adjustment and price support programs under the Department's Agricultural Stabilization and Conservation Service (ASCS).[50] These price support programs were designed to protect the incomes of growers and producers through a combination of acreage allotments, target prices, government loans, direct payments to growers, and government purchases of crops.[51]

Most of the other USDA agencies that were created in the 1930's and 1940's continue to function today, and the Department's focus remains largely promotional.[52] Some programs indirectly assist farmers by promoting rural and small community development.[53] The majority of the Department's agencies, however, directly support agriculture. For instance, the Soil Conservation Service is responsible for developing soil

45. *Id.*

46. Ch. 25, 48 Stat. 31 (1934).

47. *Id.*, tit. I, § 8(1), 48 Stat. 34.

48. W. RASMUSSEN & G. BAKER, *supra* note 33, at 28.

49. United States v. Butler, 297 U.S. 1 (1936). The payments to farmers producing a particular commodity were made from a fund generated by the imposition of a tax on processors of that commodity. The Court held that although Congress had broad discretion and power under the taxation clause, U.S. CONST. art. I, § 8, cl. 1, the clause did not give Congress the authority to regulate agricultural production. 297 U.S. at 74-75.

50. U.S. GOVERNMENT PRINTING OFFICE, GOVERNMENT MANUAL 121 (1988) [hereinafter GOVERNMENT MANUAL]. The Commodity Credit Corporation (CCC) was created by the Commodity Credit Corporation Charter Act of 1948, ch. 759, 62 Stat. 1161 (codified at 15 U.S.C. §§ 714-714p (1988)). Implicit authorization for both the ASCS and the CCC is found in a variety of different acts codified at 7 U.S.C. §§ 1421, 1434, 1441, 1782-1787 (1988).

51. *See* L. TWEETEN, FOUNDATIONS OF FARM POLICY 493-519 (2d ed. 1979).

52. Some activities, such as the food stamp program and other food distribution programs, seem far removed from USDA's original mission. For example, the Department began to distribute food in the 1930's to dispose of price-deflating surpluses. W. RASMUSSEN & G. BAKER, *supra* note 33, at 135.

53. For example, the Rural Electrification Administration assists electric and telephone companies in providing service to rural areas, GOVERNMENT MANUAL, *supra* note 50, at 109-10, while the Farmer's Home Administration provides loans to people in rural areas who cannot get credit from other sources. *Id.* at 106.

and water conservation programs and assists in agricultural pollution control.[54] The Federal Crop Insurance Corporation provides crop insurance to farmers to cover unavoidable losses.[55] Agencies under the Assistant Secretary of Economics monitor agricultural economic activity and provide statistical and economic information to farmers, farm organizations, and agricultural policymakers.[56] Additionally, programs administered by the Under Secretary of International Affairs and Commodity Programs encourage the development of overseas markets for American agricultural products.[57]

B. The Department of Agriculture as Regulator

In addition to its promotional duties, the Department of Agriculture administers a variety of laws and programs that are more regulatory in nature. These regulatory functions are all under the purview of the Assistant Secretary for Marketing and Inspection Services.[58] Thus, for example, the Agricultural Marketing Service develops grade standards for agricultural commodities such as meat, eggs, and produce. It also administers the Plant Variety Protection Program, which grants developers of new plant varieties exclusive rights to sell, reproduce, import, and export their new varieties.[59] The Federal Grain Inspection Service establishes standards for grading American grain, whether bound for domestic or export markets.[60]

Two other USDA offices deal with the meat and poultry industries. The Food Safety and Inspection Service is responsible for ensuring that meat and poultry are safe for human consumption and accurately labeled. The Service inspects slaughtering and processing operations during various stages of production and handling.[61] In addition, the Packers and Stockyards Administration ensures effective competition and fair trade practices in that industry.[62]

Finally, the Animal and Plant Health Inspection Service (APHIS) conducts regulatory programs to protect and improve animal and plant health.[63] Programs administered by the agency include the Plant Protection and Quarantine Programs, which control plant pests and diseases,[64] and the Veterinary Services Program, which monitors diseases in live-

54. *Id.* at 132.
55. *Id.* at 110-11.
56. *Id.* at 134-36.
57. *Id.* at 104, 124-25.
58. *Id.* at 104.
59. *Id.* at 113-14.
60. *Id.* at 116.
61. *Id.* at 117.
62. *Id.* at 118.
63. *Id.* at 115.
64. *Id.*

stock.[65] APHIS is the agency responsible for regulating the products of agricultural biotechnology.[66]

Most of the regulatory programs administered by USDA are intended to protect the public against product misrepresentation, while at the same time guarding producers against unfair business practices. They are designed to ensure that "agricultural products may be marketed to the best advantage, that trading may be facilitated, and that consumers may be able to obtain the quality product which they desire."[67] Benefits, in theory, accrue to both farmers and consumers. Thus, it is anticipated that consumer and producer interests are not in direct conflict. In addition, these programs are entirely voluntary for the producer, especially to the extent that farmers are hurt by the requirements.[68]

This kind of oversight differs significantly from the regulation of biotechnology where conflicts between the public interest—in protecting the environment—and agricultural interests will necessitate oversight that is far closer to the purely regulatory activity described by Ripley and Franklin. The benefits of protecting the environment from biotechnology-related harm will accrue largely to the public in general, but the costs of regulation will be borne directly by industry through compliance expenditures and delayed introduction of new techniques.[69] The ensuing conflict between the agriculture industry's desire for limited regulations and the public's desire for environmental protection will force the Department to make difficult choices.

Unfortunately, as the Ripley and Franklin model employed by this Comment predicts, the Department has a poor record in such cases. As the discussion below indicates, two of the Department's most glaring failures have occurred when it tried to administer statutes regulating food quality and pesticide use, statutes under which the industry's interests and the public's interests came into conflict.

1. The Pure Food and Drug Act

In the late 19th century, the Department of Agriculture began to grow and change.[70] Although it retained its mission as a promoter of

65. *Id.* at 115-16.

66. *See infra* text accompanying note 210; *see also infra* text accompanying notes 211-30.

67. 7 U.S.C. § 1622(h) (1988).

68. *Id.*

69. These costs will also be felt indirectly by the general public, of course. However, the impact will be felt primarily by the agricultural industry.

70. In 1889, after over ten years of pressure to do so, Congress passed a bill elevating the Department to Cabinet status. Act of Feb. 9, 1889, ch. 122, 25 Stat. 659 (codified at 7 U.S.C. § 2202 (1988)). After achieving Cabinet status, the Department grew tremendously. From 1897 to 1912, the staff increased from about 2,500 to almost 14,000. The Department's yearly expenditures grew from $3.6 million to $21.1 million in that same period. W. RASMUSSEN & G. BAKER, *supra* note 33, at 14.

American agriculture, USDA also took on the role of regulating food purity with the passage of the Pure Food and Drug Act of 1906 (PFDA),[71] which forbade the manufacture, sale, or transport of poisonous or adulterated food and drugs. The PFDA covered, among other things, insecticide residues on fruit.[72]

The Department's Bureau of Chemistry was given the responsibility for enforcing PFDA.[73] The Bureau, however, was also responsible for enforcing the Insecticide Act of 1910,[74] a truth-in-labeling law designed to protect farmers against unscrupulous pesticide manufacturers.[75] Thus, the same agency was expected to protect consumers from pesticide residues while it facilitated the use of pesticides by farmers as part of its promotion of the agriculture industry.

This conflict of interest was not recognized until the mid-1920's when pesticide residues on produce became a subject of concern outside the agency and its client industry. In 1925, there was a public outcry in Britain when two cases of arsenic poisoning there were traced to pesticide residues on American apples.[76] To protect American apple growers, the Bureau developed a certification system to ensure that American apples met the British standards.[77] This standard applied only to exports, however, and the Bureau was slow to set standards for domestically consumed fruit.[78]

Indeed, concerned about negative publicity for the apple growers, the Bureau worked hard to keep the pesticide residue issue out of the public eye.[79] All of its work related to the British sanctions was conducted on a personal basis directly with the farmers; newspaper, magazine, and radio coverage was scrupulously avoided.[80] The Bureau believed that quiet persuasion and education, rather than publicity and punishment, were the best ways to prevent product adulteration. According to one official, the Bureau could accomplish more by acting in an advisory capacity to the farmers than by accumulating a record of prosecutions and fines.[81]

The Bureau came under increasing attack for its handling of the pesticide residue problem.[82] As a result, the Department dissolved the

71. Ch. 3915, 34 Stat. 768 (repealed 1938).
72. T. DUNLAP, DDT: SCIENTISTS, CITIZENS, AND PUBLIC POLICY 39-42 (1981).
73. *Id.* at 42.
74. Ch. 191, 36 Stat. 331 (repealed 1947).
75. P. BOSSO, *supra* note 21, at 48, 54.
76. T. DUNLAP, *supra* note 72, at 43.
77. *See id.* at 43-44.
78. *See id.* at 44-47.
79. *Id.* at 43.
80. J. WHORTON, BEFORE SILENT SPRING: PESTICIDES AND PUBLIC HEALTH IN PRE-DDT AMERICA 136 (1974).
81. P. BOSSO, *supra* note 21, at 49.
82. *Id.*

Bureau of Chemistry in 1927 and placed PFDA enforcement duties in the newly created Food and Drug Administration (FDA).[83] FDA had no responsibility for enforcing the Federal Insecticide Act and thus avoided any direct conflicts of interest over insecticide regulation.[84] Nonetheless, FDA was still subject to strong pressure from agricultural interests in the House Committee on Agriculture, which opposed strict standards for pesticide residues.[85] In 1940, FDA was moved into the Federal Security Administration (now the Department of Health and Human Services), free of the conflicts within the Department of Agriculture.[86]

2. *The Federal Insecticide, Fungicide, and Rodenticide Act*

World War II prompted many technological developments, including improvements in pesticide technology. Wartime research produced many new uses for DDT and other pesticides known as chlorinated hydrocarbons.[87] These agents were inexpensive, effective against a broad range of pests, had a long period of effectiveness, and were regarded as essentially nontoxic to humans.[88] The new products promised farmers both an edge in their battle against pests and increased yields at lower costs.[89]

In this atmosphere of technological promise, Congress passed the Federal Insecticide, Fungicide, and Rodenticide Act of 1947 (FIFRA).[90] FIFRA was nominally a regulatory statute, requiring manufacturers to submit the product's name and label, as well as a statement of its purported use, for registration and premarket clearance by the Department of Agriculture. However, the Act gave USDA very little power to keep products off the market. If the Department decided that a chemical agent was unsafe and denied it registration, its manufacturer could still register the product "under protest."[91] "Protest" classification meant only that the Department would negotiate with the manufacturer to alleviate any problems.[92] Thus, the registration system effectively left USDA powerless to deny an application. If USDA concluded that a label was misleading or that the product was fraudulent, its only recourse

83. *Id.*
84. *Id.* at 49-50.
85. *Id.* at 49-53.
86. *Id.* at 49. FDA, of course, is not without its own problems regarding the enforcement of protective legislation. The recent controversy over its regulation of generic drugs illustrates this point. *See* Hilts, *A Guardian of U.S. Health Is Buckling Under Stress,* N.Y. Times, Dec. 4, 1989, at A1, col. 1.
87. P. Bosso, *supra* note 21, at 30.
88. *Id.*
89. *Id.*
90. Ch. 125, 61 Stat. 163 (codified as amended at 7 U.S.C. §§ 136-136y (1988)).
91. *Id.* § 4(c), 61 Stat. 168; *see* P. Bosso, *supra* note 21, at 56.
92. P. Bosso, *supra* note 21, at 56.

was to take the manufacturer to court, where it had a heavy burden of proof to establish a lack of safety.[93]

FIFRA was a classic example of subgovernment policymaking. It was drafted by members of the House Committee on Agriculture, with technical advice from Department of Agriculture officials and industry representatives. In addition, only Department of Agriculture officials, state agriculture officials, and trade association representatives testified at the hearings.[94] The committee did not call any witnesses representing other perspectives, such as consumer interests. As a result, it did not consider outside concerns. Indeed, the purpose of FIFRA was "to protect the *users* of economic poisons by requiring that full and accurate information be provided as to the contents and directions for use."[95]

This period of USDA regulation was the heyday of pesticides. Total production rose from 100 million pounds in 1945 to approximately 650 million pounds by 1960.[96] At the same time, American agriculture flourished; average yields per acre of corn and wheat more than doubled, largely as a result of improved pest control and new hybrids developed by agricultural experiment stations.[97] However, as increased experience with pesticides brought to light various dangers, USDA policies came under attack.

The Department ultimately lost its control over pesticides regulation as the result of a backlash against two USDA programs, begun in the 1950's, to eradicate the gypsy moth and the fire ant.[98] Both of these pests were exotic species that thrived in the United States because they had no natural population controls.[99] The gypsy moth was widely acknowledged to be a threat to northeastern forests. The fire ant allegedly threatened agriculture in the South; however, its effects were probably exaggerated to encourage support for the USDA's pesticide program.[100] The two eradication programs involved broad application of DDT and other chlorinated hydrocarbons, including application by aerial spraying.[101]

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93. *Id.*

94. *Id.* at 54.

95. *Hearings on H.R. 4851 Before the House Comm. on Agriculture,* 79th Cong., 2d Sess. 1 (1946) (statement of S.R. Newell, Assistant Director, Livestock Branch, USDA).

96. P. BOSSO, *supra* note 21, at 63.

97. May, *Research in Land-Grant Universities: The Agricultural Experiment Station,* in FARMERS, BUREAUCRATS, AND MIDDLEMEN 177, 186, 189 (T. Peterson ed. 1980).

98. *See* P. BOSSO, *supra* note 21, at 81-90.

99. Gypsy moths were imported in the late 1860's by a French astronomer who wanted to use them to crossbreed with silk-producing caterpillars. T. DUNLAP, *supra* note 72, at 32. The fire ant migrated from South America in the 1920's and spread throughout the South by the mid-1950's. P. BOSSO, *supra* note 21, at 85.

100. Maney & Hadwiger, *Taking 'Cides: The Controversy over Agricultural Chemicals,* in FARMERS, BUREAUCRATS, AND MIDDLEMEN 200, 207 (T. Peterson ed. 1980); *see also* T. DUNLAP, *supra* note 72, at 90.

101. P. BOSSO, *supra* note 21, at 81-82, 87.

The gypsy moth campaign quickly drew opposition, largely because of the adverse environmental effects of DDT. Reported fish kills in several New York counties prompted the Governor of New York to protest to the Secretary of Agriculture.[102] On Long Island, residents sought an injunction to stop the spraying.[103]

The fire ant program was equally controversial. Critics, including the National Wildlife Foundation, the National Audubon Society, and academics, were concerned about the effects of the spraying on wildlife and other insects.[104] Eventually, some Southern states that had originally favored the spraying withdrew state funds from the program.[105]

These programs spawned a number of opposition groups. Growing evidence of the link between heavy pesticide use and bird mortality helped transform the Audubon Society from a "bird club" to an environmental protection organization.[106] Another group, the Environmental Defense Fund, emerged out of efforts to stop the spraying of DDT on Long Island.[107] Finally, the publication of Rachel Carson's *Silent Spring* in 1962 sparked a nationwide debate about the benefits of pesticide use.[108] Pesticide policy became a concern of society as a whole, not just an issue for a small group of agricultural interests.

Prompted by the debate surrounding Carson's book, President Kennedy ordered the President's Science Advisory Committee (PSAC) to study pesticide use.[109] The committee acknowledged the dangers of pesticides and recommended that all persistent toxic pesticides like DDT be phased out.[110] It also proposed tightening federal pesticide regulation and increasing research efforts on the effects of pesticides.[111] Additionally, it urged the President to transfer authority for registration of pesticides from USDA to the Department of Health, Education, and Welfare because of USDA's bias in favor of agriculture.[112]

The public exposure given the pesticide issue by the PSAC report and *Silent Spring* caused the pesticides policymaking community to expand beyond the subgovernments that had previously dominated decisionmaking. By the 1960's, reform of pesticide policy became a major

102. T. DUNLAP, *supra* note 72, at 87.

103. *Id.* at 87-89. The injunction was denied, however, because the scientific data available to support the plaintiffs' claims was too inconclusive to convince the judge of the dangers of DDT. *Id.*

104. *See id.* at 89-91.

105. *Id.* at 91.

106. *See* P. BOSSO, *supra* note 21, at 83-85.

107. *Id.* at 135.

108. *Id.* at 115-20.

109. *Id.*; *see also* PRESIDENT'S SCIENCE ADVISORY COMMITTEE, USE OF PESTICIDES (1963).

110. PRESIDENT'S SCIENCE ADVISORY COMMITTEE, *supra* note 109, at 4, 20.

111. *Id.* at 20-22.

112. *Id.* at 17.

debate in Congress, and the Department's regulation of pesticides came under increasing scrutiny.[113] In a report published in 1968, the General Accounting Office severely criticized the Department's registration and enforcement procedures.[114]

Finally, with the passage of the Federal Environmental Pesticides Control Act of 1972,[115] Congress transferred regulation of pesticides to the Environmental Protection Agency (EPA). EPA, unlike the Department of Agriculture, is a purely regulatory agency. Thus, it avoids USDA's dual purpose. In the words of William D. Ruckelshaus, EPA's first administrator, "EPA is an independent agency. It has no obligation to promote agriculture or commerce, only the critical obligation to protect and enhance the environment."[116]

USDA's history of enforcing the Pure Food and Drug Act and of regulating pesticides illustrates the dangers of regulation by a promotional agency. In both cases, the biases of the Department prevented it from adequately assessing the risks of the products it was regulating. The Department discounted the dangers of pesticide residues on food and in the environment because it focused on the benefits pesticides provided to the agricultural industry. Assessing the risks and benefits of agricultural biotechnology will put the Department in a similar bind between the interests of its client industry and the public's interest in environmental protection. The next section of this Comment presents a model for assessing biotechnology risks, and Part IV uses this model to evaluate USDA's experiences with the regulation of biotechnology.

III

RISK DECISIONMAKING IN BIOTECHNOLOGY REGULATION

A. Biotechnology: Technological Revolution or Silent Spring?

Biotechnology has been defined as "the application of biological systems and organisms to technical and industrial processes."[117] In this sense biotechnology is not new. For centuries, organisms have been used in such activities as plant agriculture, animal husbandry, baking, and brewing.[118] Originally, people simply selected and maintained particular plants or animals with desirable traits. Later, as our understanding of inheritance and genetics increased, breeders began to cross two or more

113. *See id.* at 125-28.

114. COMPTROLLER GENERAL OF THE U.S., NEED TO IMPROVE REGULATORY ENFORCEMENT PROCEDURES INVOLVING PESTICIDES (1968).

115. Pub. L. No. 92-516, 86 Stat. 973 (codified as amended at 7 U.S.C. §§ 136-136y (1988)).

116. *Federal Pesticide Control Act of 1971: Hearings Before the House Comm. on Agriculture,* 92d Cong., 1st Sess. 736 (1971).

117. Proposal for a Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. 50,856 (1984); *see also* COMMERCIAL BIOTECHNOLOGY, *supra* note 1, at 3.

118. COMMERCIAL BIOTECHNOLOGY, *supra* note 1, at 3.

individuals to create varieties that had not existed in nature.[119] Using this classic genetic technique, breeders have radically altered the characteristics of many commercially useful organisms. Most forest trees, garden plants, ornamentals, and high-yielding food crops are the products of traditional breeding techniques.[120]

The science of genetics has changed radically in the last thirty years. Researchers have greatly increased their understanding of the molecular basis for inheritance, particularly through discovery of the structure and function of deoxyribonucleic acid (DNA), the basic genetic material found in all organisms.[121] By the early 1970's, researchers had begun to manipulate DNA directly,[122] and today, genetic engineering has become a multi-billion dollar enterprise.[123] Researchers are investigating the use of genetically engineered organisms in many different areas, including pharmaceuticals, agriculture, specialty chemicals, environmental cleanup, and bioelectronics.[124] By one estimate, the new technologies eventually will be used in seventy percent of American industry.[125]

1. The Benefits of Agricultural Biotechnology

Most research today in agricultural biotechnology takes one of two general approaches to manipulating genetic material. Recombinant DNA techniques involve the "direct" introduction of genetic material

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119. NATIONAL RESEARCH COUNCIL, FIELD TESTING GENETICALLY MODIFIED ORGANISMS: FRAMEWORK FOR DECISIONS 10 (1989).

120. Brill, *Safety Concerns and Genetic Engineering in Agriculture,* 227 SCI. 381 (1985). For an overview of classical techniques, see NATIONAL RESEARCH COUNCIL, *supra* note 119, at 8-10.

121. Key to this development was the work of James Watson and Francis Crick, who first identified the structure of the DNA molecule. An interesting and highly personal account of their important research can be found in J. WATSON, THE DOUBLE HELIX (1968). After their discovery, researchers quickly determined the processes by which DNA replicates itself and encodes proteins. For a brief description of these developments, see U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, IMPACTS OF APPLIED GENETICS: MICROORGANISMS, PLANTS AND ANIMALS 33-39 (1981).

122. *See* COMMERCIAL BIOTECHNOLOGY, *supra* note 1, at 4. Most recombinant DNA experiments are carried out with a bacterium, *Escherichia coli,* that inhabits the human digestive tract. J. WATSON, J. TOOZE & D. KURTZ, RECOMBINANT DNA: A SHORT COURSE 14, 58-71 (1983). Some scientists became concerned about the dangers to laboratory workers and members of the public posed by the results of these experiments. *See generally Biotechnology and the Law: Recombinant DNA and the Control of Scientific Research,* 51 S. CAL. L. REV. 969 (1978). Much of the controversy over the health and safety risks of recombinant DNA technology has abated, in part because of controls imposed on government-funded recombinant DNA research. *See* Guidelines for Research Involving Recombinant DNA Molecules, 51 Fed. Reg. 16,958 (1986).

123. *See generally* COMMERCIAL BIOTECHNOLOGY, *supra* note 1, at 65-110.

124. *See generally id.* at 119-233, 253-57.

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

bearing the gene of interest into the host cell.[126] Using recombinant DNA techniques, scientists can insert into plant chromosomes genes that confer resistance to insect pests, thus avoiding the environmental hazards of chemical insecticides.[127] Other methods, using cells grown in culture, involve more indirect manipulation. For example, scientists can fuse specially prepared, genetically distinct plants called protoplasts to obtain crosses that would not occur in nature.[128] Plant cell culture is also useful in selecting resistance to disease, salinity, and other adverse environmental conditions.[129]

New varieties of existing plants can be developed much more quickly with these new techniques.[130] The new varieties can be used to help solve the problem of decreasing genetic variability of crop species.[131] Often the most heavily used varieties are descended from a few closely related lines. The lack of genetic variability in crop species combined with the widespread use of monoculture[132] means a disease can easily reach epidemic proportions. In the early 1970's, a single disease had a devastating effect on the U.S. corn crop because most of the corn planted was genetically identical.[133] Scientists can alleviate this kind of problem

126. *See* N. WADE, THE ULTIMATE EXPERIMENT: MAN-MADE EVOLUTION 23-26 (2d ed. 1979). This research has generally centered on the bacterial plant pathogen *Agrobacterium.* When infecting the plant, the bacterium transfers a small part of its DNA (known as t-DNA) into the chromosome of the plant. Scientists have taken advantage of this phenomenon to delete the genes that cause disease in the t-DNA and replace them with agronomically useful genes. When the genetically altered bacterium infects cultured plant cells, the gene of interest is transferred into the plant cell chromosomes. *See generally* Weising, Schelle & Kahl, *Foreign Genes in Plants,* 22 ANN. REV. GENETICS 421 (1988).

127. One of the most promising developments in this area is the isolation of a bacterial gene that contains the codes for an insect toxin that is not harmful to humans. *See generally* Held, Bulla, Ferrari, Hoch, Aronson & Minnich, *Cloning and localization of the lepidopteran protoxin gene of* Bacillus thuringiensis, *subsp.* kurstaki, 79 PROC. NAT'L. ACAD. SCI. 6065 (1982). The gene can be inserted directly into plant chromosomes, *see generally* Shields, *Towards Insect-Resistant Plants,* 328 NATURE 12 (1987), or into other bacteria that normally exist on the surface of plants. *See generally* Graham, Watrud, Perlak, Tran, Lavrick, Miller-Wideman, Marrone & Kaufman, *A Model Genetically Engineered Pesticide: Cloning and Expression of the* Bacillus thuringiensis *subsp.* kurstaki *delta-Endotoxin into* Pseudomonas fluorescens, in RECOGNITION IN MICROBE-PLANT SYMBIOTIC AND PATHOGENIC INTERACTIONS 385 (B. Lugtenberg ed. 1986).

128. *See generally Genetic Transfer, supra* note 4.

129. *See generally* Chaleff, *Isolation of Agronomically Useful Mutants from Plant Cell Cultures,* 219 SCI. 676 (1983). Cells carrying resistance genes can be selected from millions of individual cells in a culture. The cells are exposed to the disease toxins or to high salt concentrations. Surviving cells then are identified by their continued growth after these normally lethal exposures. This procedure holds great promise for isolating rare cells that have acquired resistance to a particular disease or adverse environmental condition.

130. COMMERCIAL BIOTECHNOLOGY, *supra* note 1, at 174.

131. *See, e.g.,* Sprague, *Germplasm Resources of Plants: Their Preservation and Use,* 18 ANN. REV. PHYTOPATHOLOGY 147, 150 (1980).

132. Monoculture is the use of farmland for only one crop.

133. J. DOYLE, ALTERED HARVEST 12-15 (1985).

by using genetic engineering to increase variability at a much faster rate than was previously possible.[134]

Genetically engineered bacteria and fungi can also be useful. The best known agricultural example is the "ice minus" bacteria developed at the University of California at Berkeley. Certain naturally occurring bacteria cause frost damage to plants by enhancing the formation of ice crystals on the leaf surface.[135] Researchers identified the gene encoding the proteins that initiate the ice crystals and deleted them from the bacteria's DNA. Altered bacteria, sprayed on plants early in the growing season, will crowd out the natural, harmful bacteria and prevent ice crystal formation.[136] It is thought that this approach could prevent up to $5 billion worth of damage to crops throughout the world.[137]

Animal husbandry is another area in which biotechnology offers promise. Monoclonal antibody technology can be used to diagnose, monitor, and understand disease better.[138] In addition, recombinant DNA technology can be used to develop better vaccines for animal diseases.[139] Animal health products, such as natural growth hormones and synthetic steroids, are also being developed. For example, the U.S. Food and Drug Administration has recently approved for experimental use a genetically engineered growth hormone that enhances lactation in dairy cows.[140] Animals, unlike plants, cannot be regenerated from a single cell. Transferring genes between animals is possible, however, by injecting foreign DNA into embryo cells and implanting the embryos in surrogate mothers.[141] This technology could be used to supplement breeding programs aimed at increasing disease resistance and other desirable traits.[142]

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134. *See* Brill, *supra* note 120, at 381.

135. *See* Pendorf, *Regulating the Environmental Release of Genetically Engineered Organisms:* Foundation on Economic Trends v. Heckler, 12 FLA. ST. U.L. REV. 891, 903-05 (1985).

136. *Id.*

137. Miller, *Microbial Antifreeze: Gene Splicing Takes to the Field,* 124 SCI. NEWS 132 (1983). However, the experiments have not been without controversy. *See generally* Pendorf, *supra* note 135; Sun, *Local Opposition Halts Biotechnology Test,* 231 SCI. 667 (1986); *"Ice-Minus": A Case Study of EPA's Review of Genetically Engineered Microbial Pesticides: Hearing Before the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology,* 99th Cong., 2d Sess. (1986).

138. Monoclonal antibodies are protein molecules that are useful primarily for diagnostic purposes. For a brief discussion of monoclonal antibody techniques, see COMMERCIAL BIOTECHNOLOGY, *supra* note 1, at 38-41.

139. *See id.* at 136. Recombinant vaccines for a number of animal diseases are being investigated. *Id.* at 164. Some of these vaccines, for example the vaccine for foot and mouth disease, could have huge economic impact. *Id.* at 163.

140. The use of this hormone is not without controversy. *See* Schneider, *5 Big Chains Bar Milk Produced with Aid of Drug,* N.Y. Times, Aug. 24, 1989, at A18, col. 1.

141. COMMERCIAL BIOTECHNOLOGY, *supra* note 1, at 167-68.

142. *Id.*

2. *The Risks of Agricultural Biotechnology*

The potential benefits of using genetically altered organisms in agriculture are numerous and easily identified, but the risks involved are not well defined. While many scientists agree that the probability of a release of genetically engineered organisms causing harm is small,[143] the damage, if it occurs, could be catastrophic.[144] It would be difficult to locate and kill recombinant microorganisms after they have become established in the environment.[145] Furthermore, organisms, unlike chemical pollutants, can grow, reproduce, and evolve. Their impact on the environment is thus harder to predict.[146]

Our limited understanding of how ecosystems function is a major obstacle to assessing the effects of releasing recombinant organisms into the environment.[147] However, the experience with the ecological disruption caused by the introduction of exotic species into new environments serves as a useful lesson to be applied to the release of recombinant organisms.[148] The majority of these introductions are not successful and do not cause ecological dislocations. However, some introductions, such as chestnut blight, gypsy moths, and starlings, have been disastrous.[149]

Our incomplete understanding of genetics also hinders assessment of the risks of recombinant organisms. The complexities of gene expression make it very difficult to predict the characteristics of an organism solely on the basis of its genetic makeup. Researchers have found that unexpected alterations in recombinant organisms have led to subtle changes that might influence the ecology and population dynamics of the organ-

143. *See* SUBCOMM. ON INVESTIGATIONS AND OVERSIGHT, HOUSE COMM. ON SCIENCE AND TECHNOLOGY, 98TH CONG., 2d SESS., THE ENVIRONMENTAL IMPLICATIONS OF GENETIC ENGINEERING 9 (Comm. Print 1984) [hereinafter IMPLICATIONS OF GENETIC ENGINEERING] (testimony of Dr. Martin Alexander); *see also* Shapiro, *Biotechnology and the Design of Regulation,* 17 ECOLOGY L.Q. 9-12 (1990).

144. IMPLICATIONS OF GENETIC ENGINEERING, supra note 143, at 14-16 (testimony of Dr. Martin Alexander).

145. One of the main problems would be determining where the organism had established itself. While many organisms would not survive, others could thrive and spread. "For example, microorganisms in a short period of time may be transported for tens, hundreds, or thousands of miles, and farmers noting the spread of weeds and allergic humans also can attest to the capacity of plant seeds and pollen to move for considerable distances." *The Potential Environmental Consequences of Genetic Engineering: Hearing Before the Subcomm. on Toxic Substances and Environmental Oversight of the Senate Comm. on Environment and Public Works,* 98th Cong., 2d Sess. 70 (1984) [hereinafter *Potential Environmental Consequences*] (testimony of Dr. Martin Alexander). *See also id.* at 115 (statement of Thomas McGarity).

146. *See* McChesney & Adler, *supra* note 9, at 10,367. The effect would be greater if "natural control features," which are present for native organisms (e.g., predators and competitors), do not control newly introduced organisms. IMPLICATIONS OF GENETIC ENGINEERING, *supra* note 143, at 19 (testimony of Dr. Frances E. Sharples).

147. Sharples, *supra* note 7, at 45.

148. *Id.* 44-45.

149. *Id.*

isms.[150] In some instances, there is a very thin line between the helpful and harmful qualities of an organism. A single mutation can turn a benign organism into a serious threat. For example, the naturally occurring bacterium responsible for the Florida citrus canker once existed in a largely benign state. It underwent a slight mutation and now threatens the Florida citrus industry.[151]

Engineered microorganisms might also transfer novel genes to other microorganisms in the environment.[152] Engineered plants might cross with closely related weeds in the field.[153] The cross might introduce herbicide resistance or other novel traits into the weed, creating pests that are impossible to control. Thus, even if the genetic structure of the engineered organism is very well understood, gene transfer adds another level of complexity that makes predicting the effects of a release almost impossible.

Ideally, regulators should strike a balance between the benefits to be realized and the risks to the environment and human health. However, this task is made difficult when the risks are uncertain. The remainder of this section considers the problems inherent in making regulatory decisions in the face of the uncertainties posed by biotechnology.

B. Risk Decisionmaking in Biotechnology

It is usually difficult to determine appropriate responses to hazards created by new scientific developments because risk determination is fraught with complicated and value-laden technical issues. Experts often cannot agree about the level of environmental risk created by a given activity. Even if the level of danger is not disputed, decisionmakers must still balance risks against benefits. Thus, making rational decisions about what constitutes an acceptable risk is a difficult process.[154]

When faced with a decision about the risks of a new technology, regulatory agencies generally do not require the regulated industry to eliminate all the risks before approving any use of that technology. Instead, the agencies usually must decide what level of risk is acceptable.[155] The decision whether to adopt a new technology is complicated by at

150. Stotzky & Babich, *supra* note 8, at 163.

151. *Potential Environmental Consequences, supra* note 145, at 88 (statement of Daniel S. Simberloff, Dep't of Biological Science, Florida State University).

152. Strauss, Hattis, Page, Harrison, Vogel & Caldart, *Genetically Engineered Organisms: Survival Multiplication and Genetic Transfer,* 9 RECOMBINANT DNA TECH. BULL. 69, 85 (1986).

153. Hauptli, Newell & Goodman, *Genetically Engineered Plants: Environmental Issues,* 3 BIO/TECH. 437, 439 (1985).

154. For a critical analysis of the possible approaches to making risk decisions, see B. FISCHOFF, S. LICHTENSTEIN, P. SLOVIC, S. DERBY & R. KEENEY, ACCEPTABLE RISK (1981) [hereinafter ACCEPTABLE RISK]. The discussion in the text is drawn from the ideas presented in this book.

155. *Id.* at 3-4.

least two factors. First, alternatives to the technology have their own risks and costs.[156] Second, the marginal cost of risk reduction may increase dramatically as the level of risk approaches zero.[157]

Properly balancing risks and benefits depends upon three factors, each of which is affected by the decisionmaker's values. First, the way in which the problem is framed shapes the scope of analysis. Second, the extent to which the scientific community understands the technology affects the depth with which it can analyze the problem. Third, public perception of the risks involved determines whether the decision will be politically acceptable. This section will consider each of these factors, and then discuss how values in turn alter the evaluation of each factor.[158]

1. Framing the Problem

There are two important aspects to framing the analysis of risk in a new technology: (1) the alternatives considered by the decisionmaker and (2) the definitions the decisionmaker applies to key terms.

An agency's decision will be influenced by the regulatory options it considers. The agency may not recognize the full range of possible options, or it may be limited by its legislative mandate. The Atomic Energy Commission (AEC) demonstrates a classic example of an agency whose regulatory decisionmaking was severely limited by the options it considered. The AEC's mandate from Congress was to promote the use of nuclear energy while simultaneously protecting public safety.[159] Thus, regulatory options such as complete elimination of nuclear power were not considered because they were contrary to the AEC's promotional goals. This conflict lead to many inadequacies in the regulatory scheme promulgated by the AEC. In pursuing its promotional objective it was often accused of ignoring its duties to protect public safety.[160] In particular, the process for granting operating licenses was criticized as largely perfunctory and lacking adequate consideration of environmental consequences.[161]

The decisionmaking process when considering new forms of biotechnology will be influenced by a complex range of options, including

156. *See id.* at 2-3. For example, the decision not to use nuclear power may be tied to increased pollution from coal- or oil-burning plants.

157. *Id.* at 5-7; *see also* Dwyer, *The Pathology of Symbolic Legislation,* 17 ECOLOGY L.Q. 242 (1990).

158. While these issues are common to all risk decisionmakers, the next section shows that USDA, as a promotional agency, is prone to potential pitfalls.

159. Atomic Energy Act of 1954, §§ 1, 2(d), 3(d), 42 U.S.C. §§ 2011, 2012(d), 2013(d) (1982).

160. Moore, *The Environmentalist and Radioactive Waste,* 49 CHI.-KENT L. REV. 55, 65 (1972).

161. Bronstein, *The AEC Decision-Making Process and the Environment: A Case Study of the Calvert Cliffs Nuclear Power Plant,* 1 ECOLOGY L.Q. 689 (1971).

accepting or rejecting the technology, making no choice, making incremental trial and error choices, or waiting until more information is available.[162] For example, OSTP's Coordinated Framework states that one goal of regulating biotechnology is to "avoid impeding the growth of an infant industry."[163] OSTP would thus limit regulatory options to possibilities that are generally consistent with this goal. Clearly, rejection of the technology has already been discounted. The Framework also implies that agencies will not consider alternatives that impose heavy compliance costs on biotechnology companies.

The framing of decisions will also be affected by the way an agency defines key terms.[164] The definition of key terms under the Coordinated Framework is illustrative. The Coordinated Framework devotes one section to defining key terms such as "intergeneric organism," "pathogen," and "release into the environment."[165] The definitions are critical because they establish the types of organisms that are subject to review. If they are given broader meanings, more activities will be subject to regulation. For instance, if placing genetically engineered plants into greenhouses is considered a "release into the environment," federal regulation will be required at an earlier stage in the development of new products.

Because these definitions were so important, they drew a heavy response from both opponents and proponents of biotechnology. Jeremy Rifkin, a vocal critic of biotechnology, filed a suit challenging the legality of the definitions used in the Coordinated Framework.[166] The lawsuit charged that the use of these definitions "cannot be attributed to agency expertise and reflects a failure of the defendants to consider important aspects of the regulatory issues facing them."[167] On the other hand, the biotechnology industry was unhappy with certain USDA definitions, such as the one adopted for "pathogen."[168] Under this definition, regulations would come into effect any time DNA in a recombinant organism is derived from a pathogenic (disease-causing) organism.[169] Industry representatives felt that the definition was "not based on current knowledge" and that the issue should be determined, not by whether the recombinant organism receives genes from a pathogen, but by whether the recombinant organism itself is a pathogen.[170]

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162. ACCEPTABLE RISK, *supra* note 154, at 12-13.

163. Coordinated Framework, *supra* note 9, at 23,303.

164. *See* ACCEPTABLE RISK, *supra* note 154, at 13.

165. Coordinated Framework, *supra* note 9, at 23,306-08.

166. *See generally 12 Federal Officials Sued Over Policies; Definitions of Organisms Covered Challenged,* 10 Chem. Reg. Rep. (BNA) 504 (1986).

167. *Id.* The suit was eventually dismissed because the plaintiff lacked standing. Foundation on Economic Trends v. Johnson, 661 F. Supp. 107, 110 (1986).

168. *Industry Group Pleased with Framework, But Finds Pathogen Definition Unacceptable,* 10 Chem. Reg. Rep. (BNA) 818 (1986) [hereinafter *Industry Group*].

169. Coordinated Framework, *supra* note 9, at 23,307.

170. *Industry Group, supra* note 168, at 818. The Department ultimately kept its defini-

2. *Factual Uncertainty*

Assessing the risks of a new technology is also difficult because the risks may be clouded with uncertainty.[171] In the case of releasing genetically engineered organisms into the environment, factual uncertainty is a critical issue. Our lack of understanding about ecosystem dynamics and gene expression hinders our ability to assess the risks.[172]

There is a sharp dispute in the scientific community about the effects of releasing recombinant organisms.[173] Some scientists argue that organisms altered by classical genetic techniques have been used without harm for centuries.[174] They claim that genetic engineering should be even safer than traditional methods because it allows for more precise transfer of DNA between organisms.[175] Scientists who question the safety of releases, on the other hand, focus more on environmental questions than on the organism itself.[176] They point out that so many variables affect survival in the environment that it is hard to predict what will happen.[177] The dispute shows that respected and competent scientists can take widely divergent views on the facts. Thus, it is difficult to determine the "objective" facts needed to make a risk decision.

3. *Public Perception of Risk*

Risk decisions are not based solely on quantitative data; public perception of the risk is an important element of the decisionmaking process. Those who study risk decisionmaking are often puzzled by public attitudes about risks.[178] For example, the extreme adverse reaction of the public to nuclear power does not appear to be justified in terms of the quantitative measures of the risk.[179] Similarly, the carcinogenicity of aflatoxin, a naturally occurring chemical in peanuts, is about the same as dioxin, yet public concern about dioxin is much higher.[180]

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tion of "pathogen," despite industry disapproval. Although this Comment argues that USDA rulemaking is biased in favor of agriculture, the Department obviously will not take the industry position on every issue.

171. *See* ACCEPTABLE RISK, *supra* note 154, at 15.

172. *See supra* notes 147-53 and accompanying text.

173. *See, e.g.*, Brill, *supra* note 120 (arguing for the safety of genetic engineering); Letter from Colwell, Norse, Pimentel, Sharples & Simberloff, 229 SCI. 111 (1985) (criticizing Brill's article from the "ecologist's" perspective).

174. Davis, *Bacterial Domestication: Underlying Assumptions*, 235 SCI. 1329 (1987).

175. *See id.* at 1332-35.

176. *See, e.g.*, Sharples, *supra* note 7.

177. *See* Sharples, *Regulation of Products from Biotechnology*, 235 SCI. 1329, 1330-31 (1987).

178. *See* Slovic, *Perception of Risk*, 236 SCI. 280 (1987).

179. *See* Cohen, *Criteria for Technology Acceptability*, 5 RISK ANALYSIS 1 (1985).

180. *See* Wilson & Crouch, *Risk Assessment and Comparisons: An Introduction*, 236 SCI. 267, 269 (1987).

In the past ten years, social scientists have attempted to determine how the public perceives risks.[181] Researchers have identified fifteen qualitative characteristics that influence lay persons' perception of risk: whether the risk is (1) uncontrollable, (2) dreaded, (3) globally catastrophic, (4) likely to result in fatalities, (5) inequitably distributed, (6) likely to affect large groups as opposed to individuals, (7) high for future generations, (8) not easily reduced, (9) increasing, (10) involuntary, (11) nonobservable, (12) unknown to those exposed, (13) delayed, (14) new, or (15) unknown to science.[182]

The researchers found that many of these risk characteristics correlated with each other across a wide range of hazards. Using complex mathematical analysis, the characteristics were condensed down to two factors. The first of these factors, labeled "dread risk," applies to hazards characterized by "perceived lack of control, dread, catastrophic potential, fatal consequences, and the inequitable distribution of risks and benefits."[183] Not surprisingly, the risks posed by nuclear weapons and nuclear technology have a high "dread risk" rating.[184] The second factor, called "unknown risk," applies to "hazards judged to be unobservable, unknown, new, and delayed in their manifestation of harm."[185] Chemical technologies score high on the "unknown risk" factor.[186]

This research should be of special interest to those who must make risk decisions about releasing recombinant organisms into the environment because recombinant DNA technology scores high in both factors.[187] By taking these factors into account, decisionmakers can better understand and anticipate the public reaction to the risks of agricultural biotechnology. Once technical experts and the lay public reach an understanding, there should be better communication of risk information between experts and the public.[188]

Scientists have not always appreciated the impact of risk perception on biotechnology, as illustrated by the public reaction to the release of ice-minus bacteria in Monterey County, California.[189] Researchers were secretive about some of the details of the experiment and failed to keep local community members informed.[190] As a result, the county board of supervisors delayed approval of the experiment for an indefinite period of

181. *See, e.g.*, Slovic, *supra* note 178; Slovic, Fischhoff & Lichtenstein, *Why Study Risk Perception?*, 2 RISK ANALYSIS 83 (1982).
182. Slovic, *supra* note 178, at 282-83.
183. *Id.* at 283.
184. *Id.*
185. *Id.*
186. *Id.*
187. *Id.*
188. *See* Slovic, Fischoff & Lichtenstein, *supra* note 181, at 89-92.
189. *See supra* notes 135-37 and accompanying text.
190. Sun, *supra* note 137, at 667-68.

time.[191] The adverse public reaction could have been anticipated and residents' fears allayed had decisionmakers taken into account the way that the public perceives risks. Had local residents felt involved in the decisionmaking process, they might have been more cooperative.

4. *The Effect of Values on Risk Decisions*

Finally, it is important to remember that risk decisions are not made in an ideological vacuum. Factual determinations are often colored by values.[192] Even technical experts are subject to partisanship and may misuse facts to advance an outcome they think is correct. For instance, at congressional hearings on lead toxicity, government and industry scientists aligned themselves in predictable camps over the importance of lead in automobile exhaust.[193]

Many observers feel that experts should restrict their input to purely technical questions. Indeed, at least one writer has suggested that risk decisions be divided into two separate inquiries. The first step would be a purely scientific assessment of the risks involved. Political decisionmakers would then make a policy decision about how society should deal with the risk.[194]

However, this proposal does not take into account the unavoidable intermingling of facts and values in risk assessments. Values enter purely technical aspects of risk decisionmaking in many ways. First, they affect the quality and quantity of information used to make decisions.[195] Information is sought only if the decisionmaker feels that it is worth knowing. This judgment can have political as well as technical roots. For example, it has been suggested that the risks of uranium mining have not been adequately considered because the responsible policymakers have been less concerned about miners than about a steady supply of uranium.[196]

Second, theoretical models for analyzing risks are necessarily value-laden because they depend upon the values and assumptions of the person devising the model.[197] For example, in quantitative cancer risk assessment, dose response functions are used to estimate the likelihood of cancer occurring in individuals exposed to low doses of a carcinogen.[198]

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191. *Id.* at 668.

192. *See generally* Mazur, Marino & Becker, *Separating Factual Disputes from Value Disputes in Controversies Over Technology,* 1 TECH. IN SOC'Y 229 (1979).

193. *See* Marshall, *The Politics of Lead,* 216 SCI. 496 (1982).

194. *See* Ramo, *Regulation of Technological Activities: A New Approach,* 213 SCI. 837, 841-42 (1981).

195. *See* Whittemore, *Facts and Values in Risk Analysis for Environmental Toxicants,* 3 RISK ANALYSIS 23, 26 (1983).

196. *See* ACCEPTABLE RISK, *supra* note 154, at 44.

197. Whittemore, *supra* note 195, at 26.

198. *See, e.g.,* Ricci & Molton, *Regulating Cancer Risks,* 19 ENVTL. SCI. & TECH. 473, 475 (1985).

Different response functions are based on different assumptions about the biology of cancer induction.[199] Thus, estimation of cancer risk from the same set of data varies tremendously depending upon which dose response function is used.[200]

Third, interpretation of experimental results can be influenced by scientists' prejudices and values. An extreme example is a 19th century scientist's conclusions regarding racial differences in cranial capacity. His experimental results appeared to support the belief that Caucasians were superior to other races. However, his conclusions were skewed because they were based on manipulations, unconscious or otherwise, of the data.[201]

Risk evaluations cannot be made independent of the values of the decisionmaker. Every aspect of what appears to be an objective analysis of risks may be subject to subtle biases and prior assumptions. Although it is difficult to separate issues of value from issues of fact, recognizing the distinction between the two helps prevent differences in values from masquerading as factual disputes. Given these observations on the risk decisionmaking enterprise, the next section discusses how USDA has allowed its biases to affect the way it has dealt with risk decisions about biotechnology.

IV
THE DEPARTMENT OF AGRICULTURE AND RISK DECISIONS ABOUT BIOTECHNOLOGY

From the beginning, the Department of Agriculture's regulation of biotechnology has exhibited the conflict between promotional and regulatory duties. The Department's first published policy statement on the regulation of biotechnology showed its lack of concern about the environmental and public health risks of biotechnology. The Department stated that "agriculture and forestry products developed by modern biotechnology will not differ fundamentally from conventional products."[202] In addition, the Department pointed out that "no unique safety problems have been associated with products of genetic engineering."[203] As a result, the Department played down the need for special regulation of the environmental release of recombinant organisms. The Department

199. *Id.*

200. *Id.* at 475-76. Since little is known about cancer induction, a variety of models might suffice. A researcher may subconsciously choose a dose response function that best fits her predisposed notion of the experimental outcome.

201. *See* Gould, *Morton's Ranking of Races by Cranial Capacity,* 200 SCI. 503, 509 (1978).

202. Proposal for a Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. 50,856, 50,898 (1984) (Department of Agriculture, Statement of Policy for Regulations, Biotechnology Processes and Products).

203. *Id.* at 50,897.

stated that no new laws needed to be written for biotechnology and that the guidelines promulgated by NIH would be adequate.[204]

The Department's approach quickly drew criticism. The House Committee on Science and Technology requested that the U.S. General Accounting Office (GAO) examine the Department's regulatory system. GAO's report was released in March of 1986.[205] Although acknowledging USDA's expertise in agricultural research, the GAO report noted that the Department had few programs or activities that related exclusively to biotechnology.[206] The report was especially critical of the Department for failing to clarify the roles that different agencies within the Department would play in biotechnology regulation.[207] As a result of this failure, GAO concluded that agencies advanced conflicting policies and struggled with each other over who would have primary responsibility for biotechnology.[208] The report found that intradepartmental policy coordination was especially poor. The Agriculture Recombinant DNA Research Committee (ARRC), which was supposed to coordinate biotechnology policy within the Department, lacked authority and direction. Its members served only on a part-time basis and did not appear to give top priority to their ARRC duties.[209]

The Department's problems, however, go deeper than turf battles and poor coordination. As discussed in the previous section, risk assessment is the critical part of regulating environmental hazards. The policy statements and regulations issued by USDA and APHIS reveal the biases evident in the way the Department has assessed the risks of agricultural biotechnology.[210]

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204. *Id.* at 50,898.

205. U.S. GENERAL ACCOUNTING OFFICE, BIOTECHNOLOGY: AGRICULTURE'S REGULATORY SYSTEM NEEDS CLARIFICATION (1986); *see also* Sun, *USDA Biotechnology Review Criticized and Defended,* 232 SCI. 316 (1986).

206. U.S. GENERAL ACCOUNTING OFFICE, *supra* note 205, at 3.

207. *Id.* at 38.

208. *Id.*

209. *Id.* at 41. The Department eventually established the Committee on Biotechnology in Agriculture to coordinate regulatory and research activities within the Department and to "foster public awareness of the scientific issues in biotechnology." Final Policy Statement for Research and Regulation of Biotechnology Processes and Products, 51 Fed. Reg. 23,336, 23,344 (1986) [hereinafter Final Policy Statement].

210. The Department published its final policy statement for biotechnology regulation at the same time that the Coordinated Framework was published. *See* Final Policy Statement, *supra* note 209. APHIS, the agency responsible for actual regulation of biotechnology, published its final regulations in 1987. Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which are Plant Pests or Which There is Reason to Believe are Plant Pests, 52 Fed. Reg. 22,892 (1987) (codified at 7 C.F.R. pt. 340 (1989)) [hereinafter Final Rule].

A. Framing the Problem

The Department of Agriculture frames risk decisions primarily in terms of agricultural interests, not societal or environmental interests. In its policy statement, the Department expresses confidence that recombinant organisms will play a major role in increasing crop yields for American farmers.[211] It also states that it must "prevent the introduction of genetically engineered organisms that pose a threat to agriculture."[212] Thus, USDA appears to be primarily concerned with the risks and benefits of biotechnology only as they affect the agricultural industry.

Changes in APHIS's definition of critical terms in its regulations has further narrowed USDA's regulatory scope. Its original regulations were quite comprehensive, prohibiting any person from "introducing" a "regulated article" without a permit.[213] APHIS defined "introduction" as "to move into or through the United States, to release into the environment, to move interstate," or to attempt to do so.[214] A "regulated article" was defined as "[a]ny organism or product which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent" is a plant pest or if APHIS "has reason to believe" that it is a plant pest.[215] In response to public comments, however, APHIS stated that it "agrees with commentators expressing the view that the proposed regulations were too broad and inclusive and has made several revisions to narrow the scope of the regulations."[216] Two examples illustrate these revisions.

The original definition of "genetic engineering" included protoplast fusion techniques as well as recombinant DNA techniques.[217] APHIS received a number of comments expressing the view that protoplast fusion was really a classical genetic technique and should not be included in the definition of genetic engineering.[218] It agreed and dropped reference to techniques other than recombinant DNA in its definition of genetic engineering.[219] As a result, the agency currently regulates only those organisms that are produced by recombinant DNA techniques. In fact, however, protoplast fusion and regeneration is a relatively new technique and allows gene transfers that could never occur through classical

211. Final Policy Statement, *supra* note 209, at 23,342.

212. *Id.*

213. Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which are Plant Pests or Which There is Reason to Believe are Plant Pests, 51 Fed. Reg. 23,361 (1986) (proposed rule).

214. *Id.*

215. *Id.*

216. Final Rule, *supra* note 210, at 22,894.

217. *Id.*

218. *Id.*

219. *Id.*

techniques.[220] Consequently, plants that have been dramatically altered can be released into the environment without significant notice or review.

Other commentators expressed concern that the definition of "regulated article" was too broad because it included organisms that APHIS only had "reason to believe" were plant pests.[221] In response to these comments, APHIS stated that the "reason to believe" provision would apply only where there are "*demonstrated* plant pest risks."[222] Since our understanding of ecosystems is limited, this interpretation could exclude from regulation a large number of potentially risky organisms.

B. Scientific Uncertainty

Scientific uncertainty about the effects of environmental release also allows USDA to interject its values into the decisionmaking process. It has enabled the Department to take a more optimistic approach than other, more skeptical agencies. The regulatory effect of the Department's values is evident from the permit requirements APHIS has imposed on environmental releases. APHIS estimates that a permit application for environmental release of recombinant plants and animals should take a maximum of two weeks for the applicant to prepare and should cost the applicant at most $5,000.[223] In comparison, the information required by EPA to obtain a permit to use a microbial pesticide (genetically engineered or naturally occurring) on an experimental basis is much more extensive than the APHIS requirements.[224]

Under the National Environmental Policy Act of 1969 (NEPA),[225] APHIS must evaluate the environmental impact of each release before issuing a permit.[226] The information required by APHIS, however, focuses on the molecular biology of the organisms involved in the experi-

220. *See generally Genetic Transfer, supra* note 4.

221. Final Rule, *supra* note 210, at 22,896.

222. *Id.* (emphasis added).

223. *Id.* at 22,906.

224. The permit requirements include mobility studies, studies to assess hazards to humans, domestic animals, and nontarget organisms, and tests to evaluate the genetic stability of an altered organism. 40 C.F.R. § 158.740 (1988). EPA has yet to propose rules regarding the regulation of biotechnology, although it has circulated drafts reviewed by subpanels of two agency advisory committees. *EPA Should Expedite Proposed Rules Issued Under FIFRA, TSCA, BSAS Urges,* 12 Chem. Reg. Rep. (BNA) 1526 (1989). EPA has submitted draft rules under FIFRA (7 U.S.C. §§ 136-136y (1988)) and the Toxic Substance Control Act (15 U.S.C. §§ 2601-2629 (1988)) for public comment. Microbial Pesticides; Request for Comment on Regulatory Approach, 54 Fed. Reg. 7026, 7027 (1989).

225. 42 U.S.C. §§ 4321-4361 (1982).

226. Section 102(2)(C) of NEPA requires that every recommendation or report of a "major Federal action[] significantly affecting the quality of the human environment" include a detailed statement on the environmental impact of the proposed action. 42 U.S.C. § 4332(2)(C) (1982). USDA regulations implementing NEPA are codified at 7 C.F.R. pt. 1b (1989). The APHIS Guidelines Implementing NEPA were published in 1979. Implementation of NEPA Procedures, 44 Fed. Reg. 50,381 (1979).

ment (that is, the donor, recipient, and vector organisms).[227] There is no explicit requirement for the applicant to address possible ecological consequences of the release beyond detailing the safeguards that will be used to prevent the spread of the modified organism.[228] The EPA rules for release of microbial pesticides, in contrast, have extensive requirements for protection of the environment.[229] Despite the NEPA requirements, the Department does not seem to be concerned with the ecological consequences of a release.

Since there is scientific uncertainty about the level of risk posed by the release of recombinant organisms,[230] it is difficult to determine whether APHIS properly considers the risks of a given release. It is clear, however, that ecological concerns do not weigh heavily in the balance.

C. *Public Perception of Risk*

USDA has been open about its concern with improving public perceptions of biotechnology. In 1988, it sponsored four conferences devoted to agricultural biotechnology and the public. The conferences were held in Raleigh, North Carolina; Reno, Nevada; New Brunswick, New Jersey; and Minneapolis, Minnesota.[231] At these meetings, panels including representatives of industrial and environmental groups discussed the Department's regulatory policies.[232]

According to the Department, the purpose of these "information meetings" was to "discuss publicly the latest developments in agricultural biotechnology."[233] The meetings were largely devoted to extolling the virtues of agricultural biotechnology.[234] The Department apparently felt that any problem of public perception was due to insufficient information. In fact, however, and as the public response to "ice-minus" experiments illustrates, biotechnology poses the kind of risk that causes great public concern.[235] Recombinant DNA technology is one of the few

227. *See* 7 C.F.R. § 340.3(b) (1989).

228. *Id.*

229. *See* 40 C.F.R. § 158.740 (1989).

230. *See supra* notes 143-53 and accompanying text.

231. *Over Regulation Will Stifle Innovation, Slow Development, Ciba Geigy Official Says,* 11 Chem. Reg. Rep. (BNA) 1840 (1988) [hereinafter *Over Regulation*].

232. Agricultural Biotechnology and the Public, Final Program, Reno, Nev. (Mar. 28-30, 1988).

233. Department of Agriculture, Agricultural Biotechnology and the Public (Promotional Pamphlet).

234. The author attended the meeting in Reno, Nevada. *See also* USDA STAFF REPORT, AGRICULTURAL BIOTECHNOLOGY AND THE PUBLIC (Summary of the Southern Regional Conference, Raleigh, N.C., Feb. 22-24, 1988).

235. Slovic, *supra* note 178, at 282.

technologies that scores high in both "dread" and "unknown" risk factors.[236]

The Department does not appear to be sensitive to these problems. Instead of trying to understand public perception of the risks of biotechnology, it tries to sway public opinion by presenting "information meetings" to extol the virtues of biotechnology. The Department's response to public reaction reflects its long-standing commitment to promoting agriculture and any technology that improves it.

V. CONCLUSIONS AND RECOMMENDATIONS

The Department of Agriculture may seem to be a logical choice for the regulation of agricultural biotechnology because of its expertise in agriculture. However, promotional agencies such as the Department of Agriculture are poor regulators when the policies they enforce conflict with the interests of industries that they promote. Given this assessment, the Department's experience in agriculture is more of a liability than an asset in making sound regulatory decisions. Because of its long-standing focus on promoting agriculture, the Department is poorly equipped to fairly evaluate the risks and benefits of agricultural biotechnology.

One obvious solution to this conflict of interest would be to remove regulatory responsibilities from the Department of Agriculture altogether. The Department's involvement in agricultural research for over 100 years and its immense accumulation of scientific knowledge and background, however, should not be overlooked.[237] It would be a mistake to regulate agricultural biotechnology without access to this expertise. Thus, if regulatory authority is removed from the Department, its resources should be made available to the new agency.

The Environmental Protection Agency is a good candidate to take over regulation of agricultural biotechnology. EPA already regulates en-

236. *See supra* notes 187-91 and accompanying text.

237. The Department's expertise in agricultural research, however, has been questioned in the last fifteen years. The first major criticism came in 1972 when the National Academy of Sciences released the Pound Report. NATIONAL ACADEMY OF SCIENCES, REPORT OF THE COMMITTEE ON RESEARCH ADVISORY TO THE U.S. DEPARTMENT OF AGRICULTURE (1972). The report was concerned that the majority of the research grants awarded by the Department are not awarded competitively but according to a fixed, state-by-state formula. The Winrock Report, sponsored by OSTP in conjunction with the Rockefeller Foundation, echoed many of the criticisms made in the Pound Report. SCIENCE FOR AGRICULTURE: REPORT OF A WORKSHOP IN CRITICAL ISSUES IN AMERICAN AGRICULTURAL RESEARCH (1982).

Another complaint in the Winrock Report was that the Department has ignored long-term basic research in favor of short-term, problem-oriented research. *Id.* at 9. The research is purposely fragmented among local research stations so that each station can respond to geographically particularized needs. A decentralized research system, however, makes a coordinated and comprehensive approach to agricultural science more difficult. Thus, the Department's research strategy does "not always stimulate the level of basic science required to address the most critical and complex research issues." *Id.*

vironmental releases of recombinant microorganisms. Adding responsibility for other agricultural products such as plants and animals would not be overly burdensome. It might make sense to consolidate regulation of all environmental aspects of biotechnology in one agency.

Furthermore, because EPA's mission is solely regulatory, it avoids the conflict of interest that plagues the Department of Agriculture. As an independent agency within the executive branch,[238] it should be less susceptible to the subgovernments that influence USDA decisions.[239] Without a clear position of authority within the executive branch, however, EPA may be vulnerable to external manipulation by the regulated industry. Many observers have commented on capture of independent agencies such as EPA.[240] Moreover, the difficulties of making risk decisions are no less troubling for EPA than USDA.[241] Despite these problems, however, EPA should be able to do a better job in setting a sound regulatory policy for biotechnology. Unlike USDA, it is not structurally and historically predisposed toward promoting agricultural interests.

In reality, such a transfer of regulatory duties is extremely unlikely. The Coordinated Framework has been in effect for over three years, and it would be disruptive to make such a major change in policy at this point. In addition, USDA, the biotechnology industry, and agricultural interests are likely to resist strongly any such move.

Although it is unlikely that regulation of biotechnology will be completely removed from USDA, less drastic changes might be possible. One solution is to separate regulatory and promotional duties within the Department. Regulators within USDA could be relatively insulated from the influence of the regulated industry.

APHIS, which regulates biotechnology, theoretically is just such an agency. It is ostensibly separate from other agencies whose missions are purely promotional. This separation, however, is not as complete as it appears. Although APHIS is a regulatory body, the bulk of the programs administered by APHIS do not conflict with agricultural interests. Generally, APHIS enforces laws that protect American agriculture

238. 40 C.F.R. § 1.1 (1989).

239. *See* Dwyer, *supra* note 157, at 309-10 (arguing that the visibility of both EPA and environmental issues ensures that EPA will remain accountable and escape capture).

240. For a summary of this position, see M. REAGAN, REGULATION: THE POLITICS OF POLICY 52-66 (1987); *see also* Stigler, *The Theory of Economic Regulation*, 2 BELL J. ECON. & MGMT. SCI. 3 (1971).

There is some concern that "final" rules promulgated by EPA are only the first round in a larger process in which regulations are finalized only after EPA and affected parties have privately negotiated their contents. Gaba, *Informal Rulemaking by Settlement Agreement*, 73 GEO. L.J. 1241 (1985).

241. *See, e.g.*, Note, *The EPA and Biotechnology Regulation: Coping with Scientific Uncertainty*, 95 YALE L.J. 553 (1986).

against new pests and diseases.[242] The goal of these regulations, like all the other regulatory programs in the Department, is to preserve the marketability of American agricultural products.

Moreover, there is no evidence that APHIS' regulatory philosophy differs from that of the rest of the Department. An analysis of the rules promulgated by APHIS[243] indicates that it is biased in favor of biotechnology. Indeed, the director of the Biotechnology and Environmental Coordination Staff in APHIS has stated that "the regulatory structure is here to help develop the industry."[244]

Thus, to overcome conflicts of interest, a new USDA agency that focuses solely on regulating agricultural biotechnology should be created. The officers of the agency should be hired from outside the Department to avoid any carryover of current USDA biases. Since the agency would be regulatory, the clientelism associated with subgovernments and promotional agencies should not develop to the same extent.

There is some precedent for the creation of an independent regulatory agency within the Department. As discussed above, FDA was formed after the Bureau of Chemistry's conflict of interest in pure food enforcement became apparent.[245] FDA, however, was overseen by the House Agricultural Committee, which allowed the agricultural subgovernment to maintain control of regulatory policy. To avoid this problem, the agricultural biotechnology regulatory agency should be overseen by a different committee, one which is not dominated by a sympathetic subgovernment. The House Committee on Science and Technology is a likely candidate because it has been concerned in the past with USDA's regulatory policies.[246]

USDA's experience with FDA will also be instructive in the event that any new regulatory agency is hindered by its relationship with the Department. If the new agency continues to be controlled by an agricultural subgovernment, Congress can always remove it from the Department, as it did FDA.[247] This two-step removal process toward creating an independent regulatory agency is less likely to cause controversy than complete removal in a single step.

Past experience suggests that any change is unlikely to occur unless some departmental activity or policy leads to major environmental damage. A disaster would expose the Department's regulatory policy to public scrutiny, just as the gypsy moth and fire ant eradication campaigns

242. GOVERNMENT MANUAL, *supra* note 50, at 115.

243. *See supra* text accompanying notes 213-30.

244. *See Over Regulation, supra* note 231, at 1839.

245. *See supra* text accompanying note 83.

246. The chairman of the House Committee on Science and Technology requested that the GAO prepare a report on USDA activities relating to biotechnology. The report was published in March 1986. U.S. GENERAL ACCOUNTING OFFICE, *supra* note 205.

247. *See supra* note 86 and accompanying text.

did in the 1960's. The resulting public outcry would prompt Congress to reform the current regulatory structure. Unfortunately, if responsibility for biotechnology is not removed from the sphere of agricultural subgovernments, the current conflict of interest will increase the likelihood of just such a disaster. Agricultural biotechnology will not be properly regulated until this conflict is removed.