

Biotechnology and the Design of Regulation

*Sidney A. Shapiro**

INTRODUCTION

Modern technology has brought wondrous benefits to society, but not without creating significant risks to people and the environment. Regulation can prevent, or at least mitigate, some of these dangers, but it can also inhibit innovation and product development. Choosing a regulatory scheme that neither overregulates nor underregulates new technologies is one of the most difficult tasks facing modern government.

Recent developments in biotechnology present the newest challenge to our ability to design effective and efficient regulatory structures. While these new technologies have the potential to revolutionize medicine, agriculture, and manufacturing, they could also generate products that are extremely dangerous. Unfortunately, a contentious debate between those who warn that strict regulation will destroy America's most promising new industry and those who warn that weak regulation will lead to environmental disasters has stymied the federal government's response to these potential risks. As Section I explains, two countervailing considerations exacerbate this debate and its consequent regulatory paralysis. First, many options that would make regulation less burdensome to industry would also reduce the government's ability to protect the public and the environment. Second, the lack of scientific consensus concerning the dangers posed by some biotechnology products makes it difficult to determine the proper scope of regulation. Those who advocate a minimum of regulation in the interest of a more efficient system generally believe the risks inherent in biotechnology are less than those who advocate maximum environmental and human protection.

Copyright © 1990 ECOLOGY LAW QUARTERLY

* John M. Rounds Professor of Law, University of Kansas; J.D. 1973, B.S. 1970, University of Pennsylvania.

This Article is based on a report prepared for the Administrative Conference of the United States. Additional support was provided by the University of Kansas Research Fund. The report was the basis for the Administrative Conference of the U.S. Federal Regulation of Biotechnology (Recommendation 89-7), 54 Fed. Reg. 53,493 (1989) (to be codified at 1 C.F.R. § 305.89-7). Publication of this Article is authorized by the Administrative Conference, but the author is solely responsible for its content. The author appreciates the comments of Richard Levy and Tom McGarity and acknowledges the assistance of Susana Namnum, Class of 1991, University of Kansas School of Law.

This Article considers how the federal government should redesign its system for regulating biotechnology, given that government policy-makers have chosen to adapt preexisting statutes rather than enact new legislation. The adaptation process presents four types of problems. First, the White House and Congress must confront the problem of incomplete and inadequate regulatory coverage. Presently, biotechnology is regulated under several different statutes that were enacted to prevent or reduce society's exposure to unsafe or harmful products or substances, including some statutes written for the regulation of chemicals. Second, the White House must take the responsibility for coordinating regulatory activities because several executive branch agencies are involved in regulating biotechnology. Third, these agencies must consider how to reduce regulatory delay. Finally, the agencies must adopt procedures that ensure public participation in their decisionmaking because participation is essential to public acceptance of biotechnology.

Section II analyzes the problem of incomplete and inadequate regulatory coverage. This problem was created when the White House rejected the suggestion that new legislation was needed to regulate adequately the research and production of new biotechnology products. The White House based its decision on the belief that existing statutory authority was sufficient for that task, although it admitted that additional regulations issued under existing authorities would be necessary. Section II concludes that this judgment was generally sound, but that legislation may be necessary to plug jurisdictional gaps and to give the Environmental Protection Agency (EPA) additional authority to regulate the environmental release of genetically engineered microorganisms.

Section III documents the collapse of White House efforts to coordinate biotechnology regulation caused by political infighting among the participating agencies. It explains that White House efforts to direct EPA's regulation of the environmental release of genetically engineered organisms have caused EPA to withdraw from current coordination activities. Section III concludes that White House efforts at coordination will remain moribund unless they are restructured to avoid the types of political disagreements that led to their demise.

Sections IV and V discuss which methods and procedures of regulation should be used. Section IV explores how current controversies concerning biotechnology risk assessment and management affect the ability of agencies to adopt more efficient methods of regulation. It concludes that agencies can regulate more effectively by improving their capacity for risk assessment and by relying on consensus-building approaches, such as advisory committees and regulatory negotiation.

Section V endorses the current use of notice and comment procedures to obtain public input, but recognizes the need for some changes to ensure the legitimacy and accuracy of agency decisionmaking. These

changes include providing additional notice of pending regulatory actions to citizens who live near proposed release sites, holding informal public hearings to supplement written procedures when a pending regulatory action is of unusual public interest, and seeking ways to meet the public's need for information about pending regulatory decisions while protecting the interests of those who submit confidential business information.

Designing an effective and efficient regulatory system is not the government's only challenge concerning biotechnology. Decisionmakers must consider other important issues not covered by this Article, such as what types of biotechnology research should receive government funding and how to address the ethical, economic, and social implications of biotechnology. At the present time, however, no issue is more pressing than restructuring the regulatory system to provide adequate protection for the public and the environment.

I

BIOTECHNOLOGY: AN OVERVIEW

Biotechnology, as well as its regulation, is in a process of evolution. Important biotechnology innovations have been developed, yet their commercial potential remains largely unrealized. Scientific knowledge about the possible dangers of these advances is also evolving. Although the existing data suggests that some products pose significant environmental dangers, the data is inadequate to judge the potential danger of many other products. Finally, the government is still developing its response to biotechnology. Though a few regulatory programs are in place, most have yet to be designed.

A. The Benefits of Biotechnology

While forms of biotechnology have existed for thousands of years, recent scientific advances have created innovative new techniques for manipulating the genes of living organisms.¹ Recombinant DNA (rDNA) was the first breakthrough in genetic manipulation.² Newer

1. Biotechnology began with the domestication of plants as much as 10,000 years ago. The prehistoric development of winemaking and the development of brewing in the 11th century are other early examples of biotechnology. Modern biotechnology was born with the discovery of the structure of deoxyribonucleic acid (DNA) in 1953. OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONG., *NEW DEVELOPMENTS IN BIOTECHNOLOGY — FIELD-TESTING ENGINEERED ORGANISMS: GENETIC AND ECOLOGICAL ISSUES* 34 (1988) [hereinafter *OTA, FIELD TESTING*]. The discovery of restriction enzymes in the early 1970's gave scientists the ability to move specific pieces of DNA within and between organisms. P. WHEALE & R. McNALLY, *GENETIC ENGINEERING: CATASTROPHE OR UTOPIA* 3-38 (1988).

2. This technique uses chemicals to break open a group of cells and remove DNA. Enzymes are then used to cut DNA molecules into segments that can be introduced into a host cell, which is induced to incorporate the desired segment of DNA. By this means, DNA from

techniques, such as direct transfer³ and cell fusion,⁴ have since been developed. These have the potential to create new organic pesticides⁵ and fertilizers,⁶ new methods of manufacturing food,⁷ and improved means of pollution control and oil recovery.⁸ Genetic engineering is also expected to produce new drugs, biologics, and diagnostic products for humans⁹

different organisms, or from the same organism, is recombined to form a new DNA sequence not found in nature. P. WHEALE & R. MCNALLY, *supra* note 1, at 25-38.

3. Direct transfer methods facilitate a cell's uptake of DNA from the surrounding medium without the use of recombinant techniques. Direct transfer can be accomplished by chemical poration (transfer by use of a chemical solution), electroporation (transfer by use of electrical impulses), projectile techniques (transfer by use of gun), and injection (transfer by use of microscopic glass needles). M. MELLON, *BIOTECHNOLOGY AND THE ENVIRONMENT: A PRIMER ON THE ENVIRONMENTAL IMPLICATIONS OF GENETIC ENGINEERING* 21-22 (1988) (Report for the National Wildlife Federation). The newest method of transfer uses sperm as the vehicle. Schmeck, *Simplified Gene Transplant Method Reported*, N.Y. Times, June 2, 1989, at 1, col. 2.

4. In this technique, two cells are fused through the use of chemicals or electricity. Although the process does not involve the transfer of pieces of DNA, the hybrid cell created by the fusion can have a novel genetic constitution. M. MELLON, *supra* note 3, at 22.

5. Biotechnology is expected to produce biodegradable microbial pesticides derived from bacteria, viruses, and fungi with the ability to synthesize toxins poisonous to specific insects. OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONG., *COMMERCIAL BIOTECHNOLOGY: AN INTERNATIONAL ANALYSIS* 183-84 (1984). It could also be used to transfer a pesticide-producing gene into a plant to improve the plant's natural defense system. M. MELLON, *supra* note 3, at 25.

6. Biotechnology can produce microorganisms that control soil pH and salinity. It can also endow bacteria with enhanced nitrogen-fixing capabilities such as those that now coexist symbiotically with certain legumes. McGarity, *Federal Regulation of Agricultural Biotechnologies*, 20 U. MICH. J.L. REF. 1089, 1092 (1987).

7. See Moshy, *Biotechnology: Its Impact on Traditional Food Processing*, in *BIOTECHNOLOGY IN FOOD PROCESSING* 8 (S. Harlander & T. Labuza eds. 1986). Products for food processing include bacterially grown enzymes for making saccharin, ethanol, fructose, red food color, and a yeast strain for increasing the alcohol percentage in beer production. Comment, *An Overview of FDA Regulation of Biotechnology Derived Products: Dealing With the Collision of Science and Society*, 11 RUTGERS COMPUTER & TECH. L.J. 501, 503-04 (1985) [hereinafter Comment, *An Overview of FDA*]. Microorganisms used to improve the texture or flavor of cheese are also being developed. McNamara, *FDA Regulation of Food Substances Produced by New Techniques of Biotechnology*, 42 FOOD DRUG COSM. L.J. 50, 59 (1987). Moreover, a single-cell protein that could serve as a possible substitute for traditional sources of animal and human protein is on the horizon. J. DOYLE, *ALTERED HARVEST* 294-97 (1985).

8. Bacteria engineered to generate carbon dioxide could be injected underground to create pressure to help recover oil from wells. M. MELLON, *supra* note 3, at 28. Industrial applications of microbes that degrade pollutants include dissolving oil in spills, cleaning up toxic landfills, and treating sewage. *Id.*; see also McGarity & Bayer, *Federal Regulation of Emerging Genetic Technologies*, 36 VAND. L. REV. 461, 471-72 (1983).

9. New or anticipated drugs include human insulin, human growth hormone, and hormones to treat infertility. New or anticipated biologics include interferon, vaccines (for diseases such as hepatitis B, influenza, and leprosy), coagulation factors and other blood components, and therapies for cancer. Comment, *An Overview of FDA*, *supra* note 7, at 503. New or anticipated diagnostic tools include *in vitro* diagnostic tests (for such conditions as glucose oxidase, AIDS, and pregnancy) and specific prenatal tests for blood disorders such as thalassemia and sickle-cell anemia. *Id.* In a related development, researchers are also breeding gene-altered mice for medical experimentation. See, e.g., *DuPont to Market Gene-Altered Mice for a Cancer Study*, N.Y. Times, Nov. 17, 1988, at A26, col. 1.

and animals.¹⁰ Finally, the new techniques are likely to improve the results of plant¹¹ and animal¹² breeding.

If the new methods of biotechnology are indeed used for such purposes, almost no area of the economy would remain untouched. Potential applications for biotechnology have been identified for industrial sectors now accounting for up to seventy percent of the annual American gross national product.¹³ Almost no country will remain unaffected. By the year 2000, annual worldwide sales of bioengineered products could reach \$40 billion.¹⁴ Beyond this economic influence, "it has been clear to all observers that biotechnology is a profoundly powerful new technical form that contains the possibility, indeed the probability, of transforming society in important ways."¹⁵ The changes that may be wrought range from potentially profound changes in human genetics¹⁶ to the alteration of who produces the foods we eat.¹⁷

10. Vaccines are being developed against such animal diseases as rabies, foot-and-mouth disease, and bovine leukemia. OTA, *FIELD TESTING*, *supra* note 1, at 128. See also McGarity, *supra* note 6, at 1092; von Oehsen, *The FDA's Regulation of Veterinary Biotechnology: Business as Usual or A New Era of Environmental Protection*, 43 *FOOD DRUG COSM. L.J.* 847, 851 (1988).

11. Major innovations anticipated in agriculture include: crops more resistant to diseases caused by viruses, bacteria, fungi, and insects; crops better able to absorb and use fertilizer; crops genetically modified to fix their own nitrogen; plants with increased photosynthetic efficiency; crops with greater resistance to stresses brought on by drought, salinity, chill, and frost; crops with higher ratios of edible to nonedible parts, fewer structural weaknesses, and higher yields of economically important plant constituents; plants with improved nutritional value; and regulation of plant growth to allow harvest of uniformly ripe fruits and vegetables. Kinney, *USDA Agricultural Research Service: Biotechnology in Farm Policy*, 3 *NOTRE DAME J.L. ETHICS & PUB. POL'Y* 145, 155 (1987).

12. New and anticipated developments in animal engineering include increasing the tolerance of striped trout and bass to cold by inserting genes derived from winter flounder. OTA, *FIELD TESTING*, *supra* note 1, at 131; Thornton, *Superfish: Coming Soon to a Lake Near You?*, *SPORTS ILLUSTRATED*, Mar. 7, 1988, at 14. Growth hormone genes are being transferred from trout to carp to create a faster growing fish. M. MELLON, *supra* note 3, at 28-29. The transfer of bovine embryos, and other livestock engineering techniques, are being used to upgrade breeding stock, to perpetuate certain favored pedigrees, and to increase beef production and dairy yields. J. DOYLE, *supra* note 7, at 282; Brown, *Biotechnology Gains Acceptance in Poultry Industry*, *FEEDSTUFFS*, Nov. 14, 1988, at 14.

13. S. MCAULIFFE & K. MCAULIFFE, *LIFE FOR SALE* 26 (1981).

14. Russel, *The Marketing of Genetic Science*, 5 *AMICUS J.* 14 (1983).

15. J. KLOPPENBURG, JR., *FIRST THE SEED: THE POLITICAL ECONOMY OF PLANT BIOTECHNOLOGY (1492-2000)*, at 199 (1988).

16. See generally J. RIFKIN, *ALGENY* (1983).

17. See generally C. HASSEBROOK & G. HEGYES, *CHOICES FOR THE HEARTLAND; ALTERNATIVE DIRECTIONS IN BIOTECHNOLOGY AND IMPLICATIONS FOR FAMILY FARMING, RURAL COMMUNITIES, AND THE ENVIRONMENT* (Dec. 1988) (Report for the Center for Rural Affairs); Tangle, *Biotechnology on the Farm: Will New Technology Further Disrupt Our Troubled Agricultural Communities?*, 36 *BIOSCIENCE* 590 (1986).

B. *The Risks of Biotechnology*

Although modern biotechnology holds great promise, it also brings new risks. What if potentially dangerous microorganisms¹⁸ or toxic plants and animals¹⁹ are created? Leaks in fermentation manufacturing or other similar processes could result in workplace contamination.²⁰ Widespread release of genetically altered microorganisms into the environment, perhaps for use as pesticides or to enhance oil recovery, could result in environmental contamination.²¹ Finally, the ingestion of genetically modified plants, animals, or their byproducts that are toxic or impure could cause human illness.²²

The risks of workplace contamination and unsafe foods are generally regarded as similar in magnitude to the risks posed by the use of natural organisms in manufacturing and the use of conventional breeding techniques in food production.²³ No similar consensus exists concerning the magnitude of the risks posed by the general release of microorganisms.²⁴ While most experts agree that products like pathogens and plant pests are dangerous, they disagree on whether other products may be dangerous. Moreover, even where experts agree that a product may be dangerous, they disagree about the magnitude of the danger. These disagreements have arisen because of uncertainties in how to assess risks.

1. *How Risks Are Assessed*

The process of assessing risks involves two different activities. The first step is hazard assessment, identifying how an organism might be harmful.²⁵ An organism can be harmful if it is a pest or pathogen, or if it will enhance existing, or create new, pests or pathogens.²⁶ For example,

18. McGarity & Bayer, *supra* note 8, at 469.

19. Comment, *An Overview of FDA*, *supra* note 7, at 519.

20. *See infra* text accompanying notes 53-56 (discussion of degree of risk posed by closed systems).

21. In these circumstances, it may be difficult, or even impossible, to locate the millions of organisms that have been released. Harlow, *The EPA and Biotechnology Regulation: Coping with Scientific Uncertainty*, 95 *YALE L.J.* 553, 559 (1986). If such organisms threatened natural organisms or the environment, they could cause substantial damage. *See infra* text accompanying notes 61-81 (discussing the risks of environmental release).

22. Comment, *An Overview of FDA*, *supra* note 7, at 517.

23. According to the Occupational Safety and Health Administration (OSHA), no additional regulation of workplaces using biotechnology is needed because no hazards from biotechnology per se have been identified. OSHA, Agency Guidelines on Biotechnology, 50 Fed. Reg. 14,468 (1985).

24. *See infra* text accompanying notes 61-81.

25. Gillett, *Risk Assessment Methodologies for Biotechnology Impact Assessment*, 10 *ENVTL. MGMT.* 515-16 (1986). This analysis must identify the source of the risk, its potential adverse consequences, and the probability of these consequences. *See* OTA, FIELD TESTING, *supra* note 1, at 110.

26. NATIONAL ACADEMY OF SCIENCES, INTRODUCTION OF RECOMBINANT DNA-ENGINEERED ORGANISMS INTO THE ENVIRONMENT: KEY ISSUES 14-15 (1987) [hereinafter NAS, 1987 REPORT]; OTA, FIELD TESTING, *supra* note 1, at 112-13 (discussing the risks of

viruses could infect beneficial insects as well as the targeted host.²⁷ Genetically engineered food might inadvertently increase the level of an existing toxic substance or add a new one.²⁸ Organisms could also transmit novel genetic material to a nontarget host.²⁹ For example, genetic engineering involving benign wild plants could change them into disruptive weeds.³⁰

An organism can also be harmful if it displaces natural species or disrupts ecosystems.³¹ If oil-eating microorganisms persist and feed on naturally occurring hydrocarbons, they could deprive a water ecosystem of oxygen and other nutrients on which naturally occurring species depend.³² Similarly, if microorganisms designed to modify soil pH or add nutrients to the soil found a niche in soils not used for crops, or if they modified the pH or increased the nutrient content of lakes and waterways, they could harm plants or fish.³³

The second step in assessing risk is exposure assessment—estimating the amount of the organism to which the environment, people, or other organisms might be exposed.³⁴ The degree of exposure depends on two factors. The first factor is whether the organism will survive and reproduce.³⁵ If it will not survive, there is little likelihood that the organism poses any ecological or human risk. The other factor is the extent to which the organism will be disseminated beyond the site of its release. If widely disseminated by the wind, water, or insects, it is more likely to cause serious damage.³⁶ Some experts are concerned that the risks of

pests or pathogens); Ecological Society of America, *The Release of Genetically Engineered Organisms: A Perspective from the Ecological Society of America*, 70 *ECOLOGY* 297, 301 (1989) [hereinafter *ESA Report*]. Pests are organisms, such as insects, bacteria, fungi, parasitic plants, and viruses, that can injure or cause disease in plants. See 7 U.S.C. § 150aa(c) (1988) (definition of "plant pest"). Pathogens are organisms, including pests, that can cause disease in plants or animals. OTA, *FIELD TESTING*, *supra* note 1, at 141.

27. *ESA Report*, *supra* note 26, at 301.

28. Gibbs & Kahan, *Federal Regulation of Food and Food Additive Biotechnology*, 38 *ADMIN. L. REV.* 1, 17 (1986).

29. OTA, *FIELD TESTING*, *supra* note 1, at 80. Gene transfer between species occurs by only a limited number of mechanisms, including hybridization and transformation. *Id.* at 11-12; see generally Alexander, *Spread of Organisms with Novel Genotypes*, in *BIOTECHNOLOGY AND THE ENVIRONMENT: RISK & REGULATION* 115, 116-18 (A. Teich, M. Levin & J. Pace eds. 1985) (Proceedings of a Seminar Series conducted for the Environmental Protection Agency by the American Association for the Advancement of Science).

30. See *ESA Report*, *supra* note 26, at 304.

31. NAS, 1987 *REPORT*, *supra* note 26, at 16-17; OTA, *FIELD TESTING*, *supra* note 1, at 88-101; *ESA Report*, *supra* note 26, at 301.

32. McChesney & Adler, *Biotechnology Released From the Lab: The Environmental Regulatory Framework*, 13 *ENVTL. L. REP.* 10,366, 10,368 (1983) (Envtl. L. Inst.).

33. McGarity, *supra* note 6, at 1094.

34. Gillett, *supra* note 25, at 516; see OTA, *FIELD TESTING*, *supra* note 1, at 110 (analysis must consider extent of exposure, analyze the relationship between exposure and extent of risk, and estimate the overall risk).

35. OTA, *FIELD TESTING*, *supra* note 1, at 111; see *ESA Report*, *supra* note 26, at 302.

36. OTA, *FIELD TESTING*, *supra* note 1, at 111; see *ESA Report*, *supra* note 26, at 302-

engineered microorganisms may be greater than those of genetically altered plants or animals because microbes are invisible, easier to disseminate, and able to reproduce more readily under favorable conditions.³⁷

2. Risk Assessment Data

To make these assessments, analysts need data. They may consider the fate of organisms in laboratory experiments, in traditional methods of breeding, or when a species is introduced into a new habitat. They can also consider the data produced from testing organisms in simulated environments, like greenhouses, or in field tests.

It must be noted that scientists disagree about the usefulness of data generated by laboratory experiences. On one side, most biologists believe that laboratory observations over nearly twenty years indicate that there are no "unique hazards" in the transfer of genes between unrelated species.³⁸ They also believe that risks associated with the environmental release of these organisms are the "same in kind" as those posed by unmodified organisms or organisms modified by traditional genetic techniques.³⁹ On the other side, ecologists tend to believe that because laboratory data alone cannot "accurately predict the fate" of genetically modified organisms released into the environment,⁴⁰ the "usefulness of data from laboratory studies for predicting the environmental fate of released organisms will vary widely."⁴¹

The significance of data assembled from observations of the long-term consequences of traditional breeding techniques and from the introduction of natural species into a new habitat or location is also debated.⁴² Biologists generally believe that modern techniques, which permit highly specific and precise changes in an organism, are less likely to cause unpredictable or dangerous alterations than traditional, less precise methods of breeding.⁴³ Ecologists generally believe that modern techniques

03; Alexander, *supra* note 29, at 121.

37. Brill, *Safety Issues in Perspective*, in BIOTECHNOLOGY IN AGRICULTURAL CHEMISTRY 297, 299 (H. LeBaron, R. Mumma, R. Honeycutt & J. Duesing eds. 1987). See OTA, FIELD TESTING, *supra* note 1, at 7; ESA Report, *supra* note 26, at 301.

38. See NAS, 1987 REPORT, *supra* note 26, at 22.

39. *Id.*

40. ESA Report, *supra* note 26, at 306.

41. *Id.*

42. *Id.* See Regal, *Models of Genetically Engineered Organisms and Their Ecological Impact*, 10 NIH, RECOMBINANT DNA TECH. BULL. 67 (1987).

43. See, e.g., NAS, 1987 REPORT, *supra* note 26, at 10-11; Young & Miller, "Old" Biotechnology to "New" Biotechnology: Continuum or Disjunction?, in SAFETY ASSURANCE FOR ENVIRONMENTAL INTRODUCTIONS OF GENETICALLY-ENGINEERED ORGANISMS 13, 16-22 (J. Fiksel & V. Covello eds. 1987) (proceedings of a NATO Advanced Research Workshop held in Rome, Italy, June 6-10, 1987) [hereinafter SAFETY ASSURANCE]; REGULATORY CONSIDERATIONS: GENETICALLY-ENGINEERED PLANTS 16 (1987) (summary of a workshop sponsored by the Boyce Thompson Institute for Plant Research) (plant products created by biotechnology pose "no significantly different risks than have been accepted for decades from

“increase[] confidence that unintended changes have not occurred.” These advanced techniques do not, however, “ensure that all ecologically important aspects” of an organism’s interaction with its environment can be predicted for all environments into which an organism may be released.⁴⁴

In assessing risk, analysts may also consult data derived from testing the organism under controlled circumstances.⁴⁵ While experimental data can improve the predictive accuracy of risk assessment, its usefulness is limited in two ways. First, since testing has been limited so far, little data exists concerning many ecological questions.⁴⁶ Second, testing methods can be unreliable. For example, the dynamic environment a plant experiences in the field cannot be replicated by greenhouse experiments.⁴⁷ Moreover, small-scale field tests may not accurately predict the risks of large commercial applications that occur under different conditions.⁴⁸ Finally, gene tracking does not always indicate when genes are transferred from one organism to another because the specially marked gene may not move with the gene under study.⁴⁹

3. *Estimates of Risks*

Estimates of the risks of biotechnology vary according to whether or not genetically engineered products will be deliberately released into the environment. Scientists concur that microorganisms used in sealed manufacturing systems present a relatively limited risk.⁵⁰ Likewise, they agree that genetically engineered foods pose limited risks.⁵¹ No similar consensus exists, however, concerning the risks posed by the deliberate release of genetically engineered microorganisms into the environment.⁵²

conventional plant breeding”). Biologists generally believe that genetically modified organisms cannot be compared to nonnative species that have caused damage when introduced into new surroundings. NAS, 1987 REPORT, *supra* note 26, at 14.

44. ESA Report, *supra* note 26, at 302; see Regal, *supra* note 42, at 71.

45. Model ecosystems, such as greenhouses, that simulate environmental processes can be used to estimate the survivability of organisms and to evaluate potential adverse effects. Travis & Hattermer-Frey, *Risk Assessment Strategies for Biotechnology*, in SAFETY ASSURANCE, *supra* note 43, at 73, 77. Small-scale field tests can be used to project the effects of large-scale commercial uses of organisms. OTA, FIELD TESTING, *supra* note 1, at 4; see Brill, *supra* note 37, at 297. Scientists can also monitor the likelihood of gene transfer by tracking whether specially marked genes move between organisms. See OTA, FIELD TESTING, *supra* note 1, at 13-15.

46. See Regal, *supra* note 42, at 81 (few empirical studies exist concerning the safety of recombinant populations); Alexander, *supra* note 29, at 119 (scientists have scarcely explored the extent to which microorganisms introduced into the environment will survive).

47. Brill, *supra* note 37, at 297; see OTA, FIELD TESTING, *supra* note 1, at 4.

48. Harlow, *The EPA and Biotechnology Regulation: Coping with Scientific Uncertainty*, 95 YALE L.J. 553, 560 (1986); see Gillett, *supra* note 25, at 522-24.

49. OTA, FIELD TESTING, *supra* note 1, at 15.

50. See *infra* text accompanying notes 53-56.

51. See *infra* text accompanying notes 57-60.

52. See *infra* text accompanying notes 61-81.

The risks associated with the contained use of well-characterized genetically altered organisms, or organisms modified in ways that will produce predictable results, are generally considered to be no greater than the relatively limited risks posed by natural organisms used in the same environment.⁵³ Organisms that are produced within a laboratory, industrial fermenter, or other confined facility pose limited risks because it is relatively easy to prevent harm to workers' health or accidental release into the environment through routine biological and physical containment procedures.⁵⁴ Nonetheless, contamination can occur from the failure to kill microorganisms at the completion of the manufacturing or laboratory processes, the exhaustion of gases contaminated with organisms, and leaks, spills, or breaches of containment vessels.⁵⁵ These dangers can be minimized, however, if workers wear protective gear, if exhaust gases and any leaks are sterilized, and if highly infective microorganisms are not used.⁵⁶

The manufacture of genetically altered foods also poses relatively limited risks. Manufacturers are not likely to use known toxic organisms in the engineering of new foods.⁵⁷ Genetically altered organisms used as foods, or to make foods, are not likely to retain the ability to transform themselves in a way that would produce toxic elements.⁵⁸ Furthermore, the possibility that a food will be dangerous can be substantially decreased by toxicity screening and by monitoring actual use.⁵⁹ Nevertheless, genetically engineered foods may pose greater risks than the foods developed through conventional plant and animal breeding techniques.⁶⁰

In contrast to the consensus about the limited risks of contained systems and food products, the risks of environmental release are the subject of considerable dispute. The controversy, as noted earlier, centers around the disagreement between biologists and ecologists about the value of existing data. Molecular and microbial biologists tend to see modern genetic engineering as an extension of traditional techniques, which have been practiced safely in laboratories and in the field for many

53. See McGarity & Bayer, *supra* note 8, at 470-71; see also OSHA, Agency Guidelines on Biotechnology, 50 Fed. Reg. 14,468 (1985).

54. McGarity & Bayer, *supra* note 8, at 469-70.

55. *Id.*

56. *Id.*

57. See M. MANTEGAZZINI, THE ENVIRONMENTAL RISKS FROM BIOTECHNOLOGY 56 (1986).

58. The relative likelihood that an organism will retain an ability to transform itself, or that transference of DNA will occur, is considered "remote," but should not be ignored. Pape, *Regulation of New Technologies: Is Biotechnology Unique?*, 44 FOOD DRUG COSM. L.J. 173, 178 (1989).

59. M. MANTEGAZZINI, *supra* note 57, at 54-56.

60. Biotechnology may present unique risks because it permits a quicker and greater degree of genetic innovation than conventional breeding techniques. See Pape, *supra* note 58, at 177-78.

years.⁶¹ They are reassured by their safety record in the laboratory and by the high degree of control they have in creating precise genetic combinations with predictable traits.⁶² Ecologists and evolutionary biologists tend to focus on the inherent complexity of biological communities and the difficulty of extrapolating laboratory results to actual environmental experience.⁶³ They believe that “[n]o clear basis presently exists for assessing the potential impacts of the application of biotechnology products in the environment.”⁶⁴

These differences of opinion are reflected in two prominent reports, each authored by a different group of scientists. A 1987 National Academy of Sciences (NAS) report gives the biologists’ perspective, concluding that risks of releasing rDNA organisms are “the same in kind” as the risks of releasing unmodified organisms or those modified by traditional genetic techniques.⁶⁵ By comparison, a 1989 Ecological Society of America (ESA) report concludes that genetically engineered organisms should be introduced into the environment “cautiously” because they can cause a variety of undesirable outcomes.⁶⁶

Two other reports take an intermediate stance. A report by the Office of Technology Assessment (OTA) in 1988, which has been characterized as a “flashing yellow light,”⁶⁷ concludes that “there are reasons to continue to be cautious, but there is no cause for alarm.”⁶⁸ A 1989 NAS report concludes that an “extensive body of information documents safe introductions of some microorganisms” into the environment.⁶⁹ However, for microorganisms without “an established record of safety,” the report cautions that it is “prudent” to control the conditions under which the microorganisms are tested according to whether there is “low, moderate, or high uncertainty” concerning their safety.⁷⁰

As their conclusions suggest, the reports have contradictory hazard and exposure assessments. The 1987 NAS report and the ESA and OTA

61. See, e.g., Brill, *supra* note 37, at 297.

62. See, e.g., Colwell, *Ecology and Biotechnology: Expectations and Outliers*, in SAFETY ASSURANCE, *supra* note 43, at 176.

63. See, e.g., ESA Report, *supra* note 26, at 306. Ecologists also argue that most of the early rDNA work by biologists was with organisms designed to perish outside special conditions provided in the laboratory. They argue that this experience has only limited relevance to understanding the risks presented by organisms designed to survive and reproduce outside of the laboratory. See Colwell, *supra* note 62, at 169-70.

64. Gillett, *supra* note 25, at 515.

65. NAS, 1987 REPORT, *supra* note 26, at 22.

66. ESA Report, *supra* note 26, at 307 (quoting Goodman, Hauptli, Crossway & Knauf, *Gene Transfer in Crop Improvement*, 236 SCI. 48-54 (1987)).

67. Gladwell, *Report Boosts Biotechnology Experiments*, Wash. Post, May 5, 1988, at E1 (quoting Val Giddings, director of the OTA staff that produced the study).

68. OTA, FIELD TESTING, *supra* note 1, at 4.

69. NATIONAL ACADEMY OF SCIENCES, FIELD TESTING GENETICALLY MODIFIED ORGANISMS: FRAMEWORK FOR DECISIONS 124 (1989) [hereinafter NAS, 1989 REPORT].

70. *Id.* at 125.

reports agree that pathogens and pests must be carefully handled,⁷¹ but the 1989 NAS report downplays the risks posed by the transfer of genes from a pathogen to a nonpathogen.⁷² The reports disagree about the risks posed by combining genes from two different species (intergenetic combinations). The 1987 NAS report finds that intergenetic modifications present “no unique hazards.”⁷³ ESA predicts that “[o]rganisms with novel combinations of traits are more likely to play novel ecological roles.”⁷⁴ OTA concludes that the matter is an unresolved question.⁷⁵ In addition, the 1987 NAS report finds that “most” engineered organisms will be less likely to survive and reproduce than their parents.⁷⁶ While ESA agrees, it warns that “some important exceptions might arise.”⁷⁷ Finally, the 1989 NAS report distinguishes between those intergenetic combinations that are familiar and have a safe history of usage in the environment and those that are unfamiliar and have some potential for adverse environmental effects.⁷⁸ It claims, however, that any potential environmental harms from field testing organisms in the second category can be avoided by “the use of appropriate strategies for biological confinement of the introduced microorganism and its genetic material.”⁷⁹

The 1987 NAS report and the ESA report vary widely in their estimates of the risks posed by the deliberate release of genetically engineered organisms. The gulf between the two reports is tied to differences in the scientific perspectives of biologists and ecologists. The OTA report, which evaluates the claims of both groups of scientists, accepts as valid some of the concerns of the ecologists.⁸⁰ Likewise, the 1989 NAS report admits the potential for adverse ecological effects, but it expresses confidence that with appropriate testing microorganisms can be safely used in the environment.⁸¹

71. NAS, 1987 REPORT, *supra* note 26, at 15; ESA Report, *supra* note 26, at 308; OTA, FIELD TESTING, *supra* note 1, at 112. ESA and OTA also agree that deleting a gene from an organism is the least risky type of molecular alteration. ESA Report, *supra* note 26, at 308; OTA, FIELD TESTING, *supra* note 1, at 114. The NAS report does not discuss gene deletions.

72. NAS, 1989 REPORT, *supra* note 69, at 97. The report notes that because the pathogenicity of a microorganism results from a complex interaction of a number of genes and gene products, it is “highly unlikely” that moving one or a few genes from a pathogen to an unrelated nonpathogen will confer on the recipient the ability to cause disease. *Id.*

73. NAS, 1987 REPORT, *supra* note 26, at 14.

74. ESA Report, *supra* note 26, at 300.

75. OTA, FIELD TESTING, *supra* note 1, at 113-14.

76. NAS, 1987 REPORT, *supra* note 26, at 11, 14.

77. ESA Report, *supra* note 26, at 303.

78. NAS, 1989 REPORT, *supra* note 69, at 100, 111. The report considers safe those microorganisms produced by biotechnology that are identical to organisms previously produced by classical breeding techniques. *Id.* at 84-85.

79. *Id.* at 111.

80. See OTA, FIELD TESTING, *supra* note 1, at 85-102.

81. See NAS, 1989 REPORT, *supra* note 69, at 4.

C. Regulatory Reaction

The federal government's response to the potential risks of the new biotechnology can be separated into three phases. During the first phase, the National Institutes of Health (NIH) established guidelines for federally funded biotechnology research. Then, the White House Office of Science and Technology Policy (OSTP) coordinated the development of a joint policy statement by other agencies indicating how those agencies intended to regulate the new technologies. In the third and current phase, those agencies are putting into effect, sometimes in modified form, the policies they announced earlier.

The initial NIH research guidelines were promulgated in June 1976,⁸² in response to the scientific community's concern that some form of regulation was necessary.⁸³ From 1978 to 1986, as confidence grew concerning the safety of laboratory research, NIH made three changes in its guidelines. It eliminated the previous prohibition on five classes of experiments, such as the deliberate release into the environment of any organism containing a recombinant DNA molecule, that were originally thought to be too dangerous to undertake.⁸⁴ NIH also lowered the stringency of precautions required to prevent accidental release for other types of experiments.⁸⁵ Finally, NIH delegated the authority to approve types of experiments considered generally safe to local peer-review committees known as Institutional Biosafety Committees.⁸⁶

82. NIH, Guidelines for Research Involving Recombinant DNA Molecules, 41 Fed. Reg. 27,902 (1976). The guidelines established rules for the conduct of some experiments, prohibited others, and established the NIH Recombinant DNA Advisory Committee, which had responsibility for reviewing certain categories of research proposals and recommending to the Director of NIH whether to approve them. *Id.*

83. After questions concerning the potential hazards of rDNA research were raised at the 1973 Gordon Research Conference on Nucleic Acids, the scientific community accepted a temporary moratorium on some types of experiments, which was proposed by a committee of the National Academy of Sciences. P. WHEALE & R. MCNALLY, *supra* note 1, at 46. After the Asilomar Conference discussed appropriate guidelines for rDNA research, NIH drafted its own guidelines. *Id.*; von Oehsen, *Regulating Genetic Engineering in an Era of Increased Judicial Deference: A Proper Balance of the Federal Powers*, 40 ADMIN. L. REV. 303, 309 (1988). For a history of the developments of the NIH guidelines, see J. GIBBS, I. COOPER & B. MACKLER, *BIOTECHNOLOGY & THE ENVIRONMENT: INTERNATIONAL REGULATION* 104-05 (1987); Fogelman, *Regulating Science: An Evaluation of the Regulation of Biotechnology Research*, 17 ENVTL. L. REV. 183, 205-11 (1987); Jaffe, *Inadequacies in the Federal Regulation of Biotechnology*, 11 HARV. ENVTL. L. REV. 491, 496-500 (1987); McGarity & Bayer, *supra* note 8, at 501-03.

84. NIH, Recombinant DNA Research; Proposed Actions Under Guidelines, 46 Fed. Reg. 59,735 (1981) (the five classes of experiments were no longer prohibited, but three of them still required Recombinant DNA Advisory Committee review and NIH approval before initiation).

85. *See id.*

86. *Id.* at 59,736; NIH, Recombinant DNA Research; Actions Under Guidelines, 47 Fed. Reg. 17,168 (1982). *See generally* NIH, Guidelines for Research Involving Recombinant DNA Molecules, 51 Fed. Reg. 16,958 (1986); 48 Fed. Reg. 24,556 (1983); 47 Fed. Reg. 17,180 (1982).

The second phase began in 1984 when OSTP proposed a "coordinated framework" for biotechnology regulation.⁸⁷ This would consist of policy statements by the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the Department of Agriculture (USDA) indicating how these agencies intended to regulate genetically altered organisms.⁸⁸ In 1985, OSTP announced the creation of a White House-level advisory committee called the Biotechnology Science Coordinating Committee (BSCC).⁸⁹ In 1986, OSTP proposed another version of the "coordinated framework," which assigned the review of specific products to USDA, EPA, or FDA based on the use of the products.⁹⁰ OSTP also published revised policy statements by the same agencies and new statements by NIH and the Occupational Safety and Health Administration (OSHA).⁹¹

The third phase began in 1986, when agencies started the process of deciding how to implement their policy statements: USDA is drafting new safety guidelines for research it sponsors concerning agricultural products created by biotechnology, and it has established regulations for organisms that may be plant pests.⁹² EPA is drafting regulations for microorganisms used as pesticides or for other commercial purposes. FDA is contemplating how to regulate genetically altered plants or animals.

The sections that follow analyze the adequacy of the government's regulation of biotechnology. The discussion is organized according to four elements in the design of the current regulatory system: the structure of statutory authorities, interagency coordination, methods of risk assessment and management, and agency procedures.

87. OSTP, Proposal for a Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. 50,856 (1984).

88. *Id.* at 50,856-57. At that time, considerable confusion existed concerning how the government would regulate biotechnology research and development that fell outside the NIH guidelines. *See, e.g.,* von Oehsen, *supra* note 83, at 332 (describing how Baylor College of Medicine researchers inoculated 1,400 pigs with an rDNA vaccine with knowledge of one agency of the USDA, but without applying for the license required by another USDA agency); U.S. GEN. ACCOUNTING OFFICE, REPORT ON THE U.S. DEPARTMENT OF AGRICULTURE'S BIOTECHNOLOGY RESEARCH EFFORTS 2, 16, 47-64, app. VIII (1985) (USDA had failed to assess environmental risks for 84 of the 87 biotechnology research projects funded).

89. OSTP, Coordinated Framework for Regulation of Biotechnology; Establishment of the Biotechnology Science Coordinating Committee, 50 Fed. Reg. 47,174, 47,176 (1985).

90. OSTP, Coordinated Framework for Regulation of Biotechnology; Announcement of Policy and Notice for Public Comment, 51 Fed. Reg. 23,302, 23,302-06 (1986).

91. *Id.* at 23,309-50.

92. 7 C.F.R. pts. 330, 340 (1989).

II

REGULATORY STRUCTURE: MAKING THE MOST OF
EXISTING STATUTES

The Reagan Administration made a fundamental policy choice concerning the regulatory structure for biotechnology. It determined that biotechnology could be safely regulated under existing legislative authority and that no new legislation was necessary to protect the public or the environment. For this reason, genetically engineered organisms are now regulated under a variety of statutes that address the dangers of experiments and products that may threaten the environment or individuals. This structure poses three challenges to effective regulation. First, different agencies may have concurrent jurisdiction over the same experiment or product. While this problem is not unique to biotechnology, it deserves attention here because research and development in the still-infant biotechnology industry may be discouraged by the costs of duplicative regulation. Second, reliance on existing statutes has left gaps in the regulatory coverage of biotechnology: some products or types of research are not regulated by any agency. Finally, EPA has been forced to regulate biotechnology under authority given to it by Congress to regulate chemical substances. For this reason, EPA may lack sufficient regulatory authority to regulate some aspects of biotechnology.

The following discussion examines the statutory authority under which biotechnology is regulated to assess its effectiveness as a regulatory structure. Although numerous flaws are noted, the section concludes that the most efficient method of reform is to amend existing laws, rather than to create a new law solely for biotechnology.

A. The 1986 Coordinated Framework

The Office of Science and Technology Policy's 1986 "Coordinated Framework" policy statement⁹³ was an attempt by the White House to clarify regulatory responsibilities in cases of concurrent jurisdiction and to start agencies on the road to establishing biotechnology regulations. In its Coordinated Framework, OSTP clarified the jurisdiction of each regulatory agency and designated a "lead agency" where two or more agencies had concurrent jurisdiction.⁹⁴ OSTP did not define "lead agency," but it apparently intended that this agency would assume the responsibility for coordinating its regulation with the other agencies having concurrent jurisdiction.⁹⁵

93. OSTP, Coordinated Framework for Regulation of Biotechnology; Announcement of Policy and Notice for Public Comment, 51 Fed. Reg. 23,302 (1986).

94. *Id.* at 23,305.

95. *See id.*

The Coordinated Framework recognizes several instances where two or more agencies have concurrent regulatory authority. For example, EPA regulates microorganisms if they are pesticides or are used for other commercial purposes. Microorganisms that are pesticides come under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).⁹⁶ EPA has brought other commercial uses of microorganisms under the authority of the Toxic Substances Control Act (TSCA) by defining "chemical substances" to include "organisms."⁹⁷

If the microorganism is also a plant pest, USDA's Animal and Plant Health Inspection Service (APHIS) has regulatory authority as well. APHIS's jurisdiction over microorganisms is granted by the Federal Plant Pest Act (PPA),⁹⁸ which defines a "pest" to include organisms that can injure or damage other plants or plant products.⁹⁹

Genetically altered foods or food additives may also be subject to regulation by more than one agency. Foods and food additives are normally regulated by FDA under the Federal Food, Drug, and Cosmetic Act.¹⁰⁰ A food, such as an agricultural field crop, may also be regulated

96. 7 U.S.C. §§ 136-136y (1988). A "pesticide" is "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant" except for animal drugs, which are regulated by FDA. *Id.* § 136(u). A "pest" is defined as "(1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other microorganisms . . . which [EPA] declares to be a pest" excluding viruses, bacteria, or microorganisms found on or in any other living animals. *Id.* § 136(t).

97. Under TSCA, the Administrator of EPA has the authority to regulate hazardous chemical substances. 15 U.S.C. § 2602(1) (1988) ("Administrator" defined as Administrator of EPA); 15 U.S.C. § 2605 (regulation by the Administrator of hazardous chemical substances and mixtures). TSCA defines a chemical substance as "any organic or inorganic substance of a particular molecular identity, including (i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature." *Id.* 2602(2)(A). EPA includes microorganisms within the definition of chemical substance because "a living organism is a 'combination of such substances occurring [sic] in whole or in part as a result of a chemical reaction or . . . occurring in nature' Also, any DNA molecule, other nucleic acid, or other constituent of a cell, however created, is 'an organic substance of a particular molecular identity.'" EPA, Proposed Policy Regarding Certain Microbial Products, 49 Fed. Reg. 50,880, 50,886 (1984). EPA's jurisdictional claim has been challenged by legal commentators, although no suits have been filed as yet. See *infra* note 129 and accompanying text.

98. APHIS is specifically responsible for PPA. USDA, Animal and Plant Health Inspection Service: Organizations, Functions, and Delegations of Authority, 54 Fed. Reg. 23,193, 23,195 (1989).

99. Federal Plant Pest Act (PPA), 7 U.S.C. §§ 150aa-150jj (1988). A "plant pest" is any living stage of any form of invertebrate animal, parasitic plant, or virus that can "directly or indirectly injure or cause disease or damage" in any plant or any plant product. *Id.* § 150aa(c). APHIS also claims jurisdiction over microorganisms under the Plant Quarantine Act, 7 U.S.C. §§ 151-167 (1988), which authorizes USDA to institute a quarantine against plants of "any character whatsoever" that are capable of carrying any dangerous plant disease or insect infestation. *Id.* § 161.

100. 21 U.S.C. §§ 301-393 (1988). "Food" is defined as "articles used for food or drink for man or other animals" or "articles used for components of any such article." *Id.* § 321(f). A "food additive" is "any substance" added by someone "the intended use of which results or

by APHIS if it is a plant pest.¹⁰¹ In addition, USDA's Food Safety Inspection Service (FSIS) may be involved because of its responsibility to inspect meat and poultry products.¹⁰²

Drugs and biologics are also regulated by more than one agency.¹⁰³ FDA regulates the safety and efficacy of drugs and human biologics, but OSHA regulates the risks to workers in the manufacture of those products.¹⁰⁴ APHIS regulates animal biologics, but OSHA would oversee the use of a vaccine if farmworker exposure is an issue, and FDA would enter the picture if residues of the vaccine can be detected in food products.¹⁰⁵

Jurisdictional overlap also exists in the regulation of noncommercial biotechnology research. Health research funded by NIH and agricultural research funded by the Science and Education division of USDA must comply with the research guidelines established by those agencies.¹⁰⁶ The researcher will also be regulated by APHIS if the research

may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food." *Id.* § 321(s).

101. 7 U.S.C. §§ 150aa-150jj (1988). "Plant pest" is defined *supra* note 99. The delegation of authority to APHIS for plant pests is at 7 C.F.R. § 371.2(c)(2)(iv) (1989).

102. Federal Meat Inspection Act, 21 U.S.C. §§ 601-695 (1988); Poultry Products Inspection Act, 21 U.S.C. §§ 451-470 (1988). USDA has the power to oversee the Federal Meat Inspection Act, 9 C.F.R. §§ 302.1-.3 (1989), and the power to oversee the Poultry Products Inspection Act, 9 C.F.R. §§ 381.3-.7 (1989).

103. "Drugs" are "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals," or "articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1)(B)-(C) (1988). A "veterinary biologic" is any natural or synthetic virus, serum, toxin, or microorganism intended for use in the "diagnosis, treatment, or prevention of diseases of animals." 9 C.F.R. § 101.2(w) (1989).

104. See Huber, *Biotechnology and the Regulation Hydra*, TECH. REV., Nov.-Dec. 1987, 57, 58-60. Under the Food, Drug, and Cosmetic Act, FDA has jurisdiction to regulate new human and animal drugs, including human biologics, made by genetic engineering. 21 U.S.C. §§ 351-360b (1988).

105. See Huber, *supra* note 104, at 58-60. APHIS has jurisdiction to regulate animal biologics under the Virus, Serum, Toxin Act, 21 U.S.C.A. §§ 151-159 (West 1972 & Supp. 1989).

106. NIH requires recipients of its grants for medical and related scientific research to comply with its guidelines for biotechnology research. See NIH, Guidelines for Research Involving Recombinant DNA Molecules, 51 Fed. Reg. 16,958 (1986); see *supra* text accompanying notes 82-86. USDA requires recipients of its agricultural research grants to comply with NIH Guidelines for biotechnology research. See USDA, Final Policy Statement for Research and Regulation of Biotechnology Processes and Products, 51 Fed. Reg. 23,336, 23,346 (1986); USDA, Statement of Policy for Regulations, Biotechnology Processes and Products, 49 Fed. Reg. 50,897, 50,898 (1984). In June 1986, USDA proposed new guidelines. USDA, Advanced Notice of Proposed USDA Guidelines for Biotechnology Research, 51 Fed. Reg. 23,367 (1986). The guidelines proposed in 1986 have been substantially modified, but the new version has not yet been formally proposed. See OFFICE OF AGRICULTURAL BIOTECHNOLOGY, DRAFT USDA GUIDELINES FOR RESEARCH WITH GENETICALLY MODIFIED ORGANISMS OUTSIDE OF CONTAINED FACILITIES (May 1, 1989) [hereinafter USDA DRAFT GUIDELINES].

involves a plant pest or animal biologic,¹⁰⁷ by EPA if it involves a pesticide,¹⁰⁸ and by FDA if it involves a drug or human biologic.¹⁰⁹

Concurrent jurisdiction may also exist in the regulation of commercial research. EPA and APHIS share jurisdiction when a pesticide may be a plant pest.¹¹⁰ There is no overlap, however, in the regulation of commercial research for most other products.¹¹¹ Moreover, EPA and APHIS have divided responsibility for microorganisms according to whether or not they involve an agricultural use.¹¹²

The 1986 Coordinated Framework indicated for the first time how the government would approach the regulation of biotechnology. Although it clarified the division of responsibilities, OSTP's framework left many issues unresolved. Sufficient time has now passed for this structure to be evaluated.

B. Adequacy of the Coordinated Framework

Before the Coordinated Framework, the biotechnology industry and its critics were uncertain about which agencies regulated which areas of biotechnology.¹¹³ Most observers today give the Coordinated Framework generally good marks for the road map it provides to agency responsibility for regulating biotechnology.¹¹⁴ Critics argue, however, that while the framework may have clarified the roles of the various agencies, it did nothing to address the three obstacles created by the Reagan administration's decision to regulate biotechnology under existing statutory

107. See *supra* notes 99, 105.

108. See *supra* note 96.

109. See *supra* note 104.

110. See 7 U.S.C. §§ 136-136y (1988) (EPA); 7 U.S.C. §§ 150aa-150jj, 151-167 (1988) (APHIS).

111. Plants are regulated by APHIS, see *supra* note 99, drugs and biologics by FDA, see *supra* note 104, and animal biologics by APHIS, see *supra* note 105.

112. OSTP, Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,304-05 (1986); see also EPA, Statement of Policy: Microbial Products Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic Substances Control Act, 51 Fed. Reg. 23,313, 23,316 (1986) (pathogenic microorganisms used solely for nonpesticidal agricultural uses are subject to USDA review only).

113. See, e.g., J. GIBBS, I. COOPER & B. MACKLER, *supra* note 83, at 125. The framework "was developed in response to the confusion that arose about [1984] when the first products of biotechnology emerged and companies were unclear about which federal agencies would review their work and what requirements would be imposed." Henderson, *Biotech Policies Win Praise*, Wash. Post, June 21, 1986, at G2 (industry representatives "praised" framework when it was announced).

114. According to the House Commission on Science & Technology, the framework is "noteworthy in that it addresses, in a comprehensive manner, the regulation of commercial and research products of biotechnology at an earlier stage than has been the case with the regulation of other developing technologies." SUBCOMM. ON INVESTIGATIONS & OVERSIGHT, HOUSE COMM. ON SCIENCE & TECHNOLOGY, 99TH CONG., 2D SESS., REPORT ON ISSUES IN THE FEDERAL REGULATION OF BIOTECHNOLOGY: FROM RESEARCH TO RELEASE 89 (Comm. Print 1986) [hereinafter REGULATION OF BIOTECHNOLOGY].

authority. They assert that regulation is inefficient because agencies have concurrent jurisdiction, that some areas of biotechnology are not regulated by any agency, and that the agencies' existing regulatory authority does not adequately protect the public because it does not adequately address risk assessment.¹¹⁵

1. *Inefficient Regulation*

The first criticism of the Coordinated Framework is that it fails to address the considerable redundancy that may make biotechnology regulation unworkable. Because of this overlap, one observer has predicted that "there is little hope that the profusion of regulatory regimes applicable to industry and university researchers will result in [a] streamlined, efficient, and effective review process."¹¹⁶

Agencies have sought to address the problem of regulatory inefficiency by setting up procedures to coordinate their interaction. These include day-to-day contacts between regulators,¹¹⁷ standing interagency committees,¹¹⁸ and joint sponsorship of conferences and studies.¹¹⁹ At least for the present time, these efforts appear to be succeeding. For example, both USDA and EPA are meeting statutory deadlines, generally ranging from 90 to 120 days, for processing applications they receive.¹²⁰ However, other key parts of the effort to coordinate agency interaction are not yet in place. As Section III discusses, an interagency committee set up by the White House to assist the agencies in their coordination efforts has dissolved amid controversy and must be reformed.¹²¹ Also, USDA is only in the initial phases of its ambitious National Biological Impact Assessment Program, which will provide researchers with computerized information about relevant guidelines and future regulations.¹²²

115. See Henderson, *supra* note 113, at G2 (relating the opinions of critics of the framework).

116. M. MELLON, *supra* note 3, at 49.

117. Interview with Terry Medley, Director Biotechnology and Environmental Coordination Staff, APHIS, USDA, in Hyattsville, Md. (May 30, 1989) [hereinafter Medley Interview]; interview with Henry Miller, Special Assistant to the Commissioner, FDA, in Rockville, Md. (May 30, 1989) [hereinafter Miller Interview].

118. For example, FDA and USDA have a standing committee to determine whether a new animal product is a drug or biologic. Miller & Young, *FDA and Biotechnology: Update 1989*, 6 *BIO/TECHNOLOGY* 1385, 1391 (1988).

119. See, e.g., Fox, *The Federal Scene: Waiting Out the Eclipse*, 6 *BIO/TECHNOLOGY* 1379, 1380 (1988) (1987 conference on questions of food safety in biotechnology jointly sponsored by FDA, USDA, and EPA).

120. Medley Interview, *supra* note 117; interview with Amy Rispin, Office of Pesticide Programs, EPA, in Arlington, Va. (May 30, 1989) [hereinafter Rispin Interview]; interview with Ron Evans, Office of Toxic Substances, EPA, in Washington, D.C. (May 31, 1989) [hereinafter Evans Interview].

121. See *infra* text accompanying note 160.

122. Interview with David McKenzie, Director of NBIAP, Cooperative State Research

Since the coordination process is still evolving, it is difficult to determine whether the Coordinated Framework will prove unwieldy. Experience does not yet suggest that new legislation is required for effective interagency coordination of biotechnology regulation. However, the capacity of the government to regulate efficiently within the existing statutory structure will be tested more substantially in the next few years when agencies are called on to regulate a larger volume of products and research projects. Because of the importance of biotechnology to the nation's economic and social well-being, the President and the Congress should monitor the fate of the coordination process closely and seek corrective legislation if needed to resolve future problems.

2. *Products No Agency Regulates*

The second criticism of the Coordinated Framework is that some genetically novel organisms may not be regulated by any agency. The National Wildlife Federation, for example, argues that genetically novel animals, "ranging from rats and fish and oysters to insects," are excluded from regulation.¹²³ In addition, EPA's authority to regulate microorganisms under TSCA may be problematic.¹²⁴

Regulatory gaps over genetically engineered animals do exist, but they are not as broad as the Federation suggests. The release of an engineered animal comes under regulation if the research is funded by the government or if the animal is a plant pest, an agent for animal or human diseases, administered as a drug or biologic, or sold for food.¹²⁵ Still, unregulated genetically engineered animals could endanger the environment in some contexts.¹²⁶

Because further information is necessary to determine whether problems might arise from limitations in coverage, the President and the Congress—through OSTP and the Office of Technology Assessment, Congress' research arm—should conduct surveys of biotechnology activ-

Service, USDA, in Washington, D.C. (June 14, 1989) [hereinafter McKenzie Interview].

123. M. MELLON, *supra* note 3, at 48-49; *see also* Gibbs & Kahan, *supra* note 28, at 31.

124. Legal commentators question EPA's jurisdictional claim. *See infra* notes 127-29 and accompanying text.

125. USDA's Science and Education division research guidelines cover USDA-funded animal research outside of contained facilities. USDA DRAFT GUIDELINES, *supra* note 106, at 3-17. APHIS regulates invertebrate animals, such as insects, which are plant pests, *see supra* note 99, FDA regulates the use of animals as food, *see supra* note 100, and FDA and APHIS regulate the administration of animal drugs and biologics, *see supra* notes 104, 105. Finally, the Public Health Service of the Department of Health and Human Services regulates the interstate movement of etiologic agents that carry human diseases. 42 U.S.C. § 264 (1982 & Supp. V 1987).

126. The National Wildlife Federation suggests that there are notorious examples of agricultural organisms, such as sorghum and goats, that have escaped from agricultural settings to survive and do great damage in the wild. M. MELLON, *supra* note 3, at 34. A genetically altered goat released from noncommercial research would not necessarily be regulated under the existing regulatory structure. *See infra* text accompanying notes 130-32.

ities not presently regulated. Those areas should then be evaluated to determine whether or not additional federal regulation is necessary.

Amendments may also become necessary to clarify EPA's jurisdiction over microorganisms under TSCA. Under the Coordinated Framework, TSCA is the backstop in the sense that any organism not regulated under some other statute would be regulated under TSCA. For example, microorganisms released into the environment that are not pesticides or plant pests are now regulated under TSCA.¹²⁷ For purposes of TSCA regulation, EPA includes "organisms" in its definition of "chemical."¹²⁸ But this definition has been challenged as "strained."¹²⁹ If the courts rule that TSCA does not apply to microorganisms, the Coordinated Framework would cease to be an effective regulatory approach.

Noncommercial research, such as university-based research, is another area where congressional amendment may be needed to provide regulatory coverage. Under TSCA, EPA has authority to regulate commercial research only.¹³⁰ Noncommercial research involving environmental releases would be unregulated unless it is funded by the government or involves a plant pest.¹³¹ EPA is attempting to narrow this gap by applying TSCA to research conducted at universities for commercial purposes, but it is not clear what quantity of university-based research would remain unregulated if EPA's efforts succeed.¹³²

Even if EPA's implementation of TSCA substantially closes existing gaps, Congress should amend TSCA to give EPA authority to require prerelease notification of any deliberate release of genetically engineered organisms. The resistance to EPA's attempts to extend TSCA to university-based research indicates that Congressional amendment of TSCA for prerelease notification purposes may also be opposed. Academic scientists, however, are not immune from the types of pressures that cause errors of judgment that endanger people or the environment. Congress should not yield to pressure in this case.¹³³

127. See *supra* notes 96-99 and accompanying text.

128. See *supra* note 97.

129. REGULATION OF BIOTECHNOLOGY, *supra* note 114, at 58 (statement of Monica Riley, representing the American Society for Microbiology) ("the definition of genetically altered microorganisms as 'new chemicals' is strained"); E. KORWECK, THE 1989-90 BIOTECHNOLOGY REGULATIONS HANDBOOK 136-37 (1989); McGarity & Bayer, *supra* note 8, at 506 (although the DNA within microorganisms "can reasonably be characterized as a chemical substance, the EPA may be going too far in calling the entire microorganism a chemical substance").

130. See 15 U.S.C. §§ 2602(3)-(4), 2603(a), 2604(a), 2605(a) (1988).

131. See *supra* text accompanying notes 106-07.

132. See EPA, DRAFT PROPOSED RULE, MICROBIAL PRODUCTS OF BIOTECHNOLOGY; PROPOSED AMENDMENT TO REQUIRE USER FEES; PREMANUFACTURE NOTIFICATION REQUIREMENTS; DESIGNATION OF SIGNIFICANT NEW USES 34-37 (Dec. 1, 1988) [hereinafter EPA DRAFT RULE]; Fogelman, *supra* note 83, at 257-58.

133. See Burns, Foster & Cheaper, *Laboratory Safety and the Law*, CHEMTECH, May 1988, at 267; see generally McGarity, *Contending Approaches to Laboratory Safety*, 28 U. KAN.

A related problem is that TSCA exempts from regulation small quantities of new chemical substances used for scientific research.¹³⁴ EPA's draft regulations have proposed a rule that would deny this exemption in cases where there is an environmental release of a genetically engineered organism.¹³⁵ EPA takes the position that, because microorganisms can multiply in the environment, there is no such thing as research involving "small quantities" of microorganisms.¹³⁶ Since EPA is attempting to define small quantities as no quantity whatsoever, a court might find that the Agency has violated Congress' intent to exempt research and development activities from regulation.

Congress could wait until the issue of EPA's authority is decided by the courts and then make appropriate changes in the agency's regulatory powers. The problem with this approach is that EPA would lack regulatory authority to protect the environment during the period between a dispositive court decision and legislation that would restore the agency's authority to regulate. In the meantime, unregulated products could harm the environment. To prevent such a result, Congress should clarify EPA's regulatory jurisdiction to regulate bioengineered organisms under TSCA.

3. *Inadequate Regulatory Authority*

The final criticism of the Coordinated Framework is that the environmental release of organisms that are not pesticides is underregulated. First, because of concurrent jurisdiction, the existing framework leads to inconsistent regulation, which could result in litigation. Second, USDA's review of microorganisms looks only at whether a genetically engineered organism is a plant pest and ignores potential environmental impacts. Third, EPA lacks sufficient authority under TSCA to regulate microorganisms because of its burden of proving the organisms are dangerous.

The first charge is that the Coordinated Framework will result in inconsistent regulations, inviting litigation. One critic asserts that the "patchwork of law that defines the Coordinated Framework" will produce a "never ending tangle of new definitions, amended definitions, ad hoc rule-makings, BSCC subcommittee meetings, scientific advisory committee meetings, exemptions, listings and de-listings, appeals, ad nauseam," which is the "perfect prescription for litigation."¹³⁷ This pre-

L. REV. 183 (1980).

134. 15 U.S.C. § 2604(h)(3) (1988).

135. EPA DRAFT RULE, *supra* note 132, at 44-47.

136. *Id.* at 45.

137. Letter from Jack Doyle, Director, Agriculture and Biotechnology Project, Environmental Policy Institute, to Ron Evans, Office of Toxic Substances, EPA, at 9 (May 16, 1989). Another critic made the same point differently: "'Bad rules, like bad art, look better in a frame.'" Lavelle, *Biotech: The Unknown Frontier for Lawyers*, Nat'l J., Feb. 6, 1989, at 1, 28

diction is probably correct. When five different agencies attempt to apply as many as ten different laws to an emerging technology, anything less would be a complete surprise. More vigorous efforts to coordinate current regulations could eliminate at least some of the problems arising from the multiagency approach.¹³⁸

Moreover, a new law written specifically to apply to biotechnology could be subject to similar failings. Major environmental legislation tends to generate considerable litigation to clarify matters left ambiguous by the statute.¹³⁹ While a new law could increase the efficiency of biotechnology regulation by housing more aspects in one agency, this advantage, while important, does not necessarily justify a new law.

A second charge is that USDA's lack of a specific mandate to protect the environment means the agency is less likely to protect the environment than EPA.¹⁴⁰ Critics acknowledge that USDA is required to comply with the National Environmental Policy Act (NEPA),¹⁴¹ but they allege that the agency's past actions indicate a lack of commitment to a comprehensive assessment of environmental dangers.¹⁴² This distrust can be traced to USDA's enthusiastic support for biotechnology in agriculture and its legacy of poorly regulating pesticides when it had that responsibility.¹⁴³

These allegations are difficult to assess objectively because counter evidence exists. USDA's track record in protecting plants and animals from well-known plant pests, noxious weeds, and infectious diseases is impressive.¹⁴⁴ Moreover, USDA has promulgated new regulations that apply the Federal Plant Pest Act to genetically modified organisms that are plant pests.¹⁴⁵ USDA has also engaged in a reorganization intended to increase its regulatory effectiveness and is in the process of hiring additional scientists and other professionals to staff its new effort.¹⁴⁶

(quoting William Anderson).

138. OSTP's efforts to coordinate have so far been very weak. See *infra* section III for further discussion.

139. See, e.g., MELNICK, REGULATION AND THE COURTS: THE CASE OF THE CLEAN AIR ACT 1-23 (1983).

140. See, e.g., M. MELLON, *supra* note 3, at 47, 49; see also von Oehsen, *supra* note 83, at 326-27.

141. 42 U.S.C. §§ 4371-4374 (1982).

142. See, e.g., M. MELLON, *supra* note 3, at 48.

143. One critic charges that "USDA is in the classic conflict-of-interest situation when it tries to evaluate the release of genetically engineered organisms for their potential environmental effects." Doyle Letter, *supra* note 137, at 9. See also Jaffe, *supra* note 83, at 529; McGarity, *supra* note 6, at 1145.

144. U.S. GEN. ACCOUNTING OFFICE, BIOTECHNOLOGY: AGRICULTURE'S REGULATORY SYSTEM NEEDS CLARIFICATION 31 (1986).

145. USDA, Plant Pests; Introduction of Genetically Engineered Organisms or Products: Final Rule, 52 Fed. Reg. 22,892 (1987).

146. Medley Interview, *supra* note 117.

Moving USDA's responsibilities to EPA would not necessarily result in improved regulation. Although EPA is not burdened by USDA's institutional conflict of interest, its effectiveness in regulating chemicals is far from exemplary.¹⁴⁷ Moreover, whereas USDA has institutional experience in evaluating plant pests, EPA would have to develop that expertise. As a result, the transition from USDA to EPA would probably create its own set of management and regulatory problems. These might overwhelm the benefits that ultimately would be garnered from the switch.¹⁴⁸

Another option would be to give EPA power of review. Professor McGarity has suggested that "[p]erhaps an adequate check on any perceived tendencies on USDA's part to slight risks and accentuate benefits is to provide for dual review of all genetically engineered organisms that might be plant pests."¹⁴⁹ At the current time, EPA does review intergeneric microorganisms containing genetic material from a pathogenic source organism.¹⁵⁰ Providing for EPA review of all of USDA's environmental assessments could be a way to reveal if USDA had a pattern of ignoring important environmental considerations. In cases where USDA has slighted environmental considerations, EPA would be in a position to call any oversight to USDA's attention. This step would also alert environmentalists who might wish to challenge USDA's decision.

The last argument concerning weak regulation is that EPA lacks sufficient regulatory authority under TSCA. Under TSCA, EPA may require a manufacturer to submit health and safety information before a product is sold.¹⁵¹ However, the Agency must prove that the chemical presents "an unreasonable risk of injury to health or the environment" in order to establish limitations on its use.¹⁵² Because the burden of proof rests with EPA, commentators and environmental groups have expressed doubt that EPA's authority under TSCA is adequate.¹⁵³ In other stat-

147. McGarity, *supra* note 6, at 1145.

148. Moreover, in order to eliminate entirely any conflict of interest, Congress would have to give EPA the authority to supervise agricultural research involving biotechnology now regulated by USDA's Science and Education division. See *supra* note 106 and accompanying text. This switch would compound the transition difficulties.

149. McGarity, *supra* note 6, at 1148. Professor McGarity also notes that such dual review may be inefficient. *Id.*

150. EPA, Statement of Policy; Microbial Products Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic Substances Control Act, 51 Fed. Reg. 23,318 (1986).

151. 15 U.S.C. § 2604(a)-(b) (1988). EPA can also require manufacturers to maintain records or submit reports. *Id.* § 2607(a).

152. *Id.* § 2605. EPA can also order the manufacturer to test the chemical if the chemical "presents or may present an unreasonable risk of injury to health or the environment" and if, because of insufficient information, testing is necessary to develop data to determine the degree of risk. *Id.* § 2603(a).

153. See, e.g., M. MELLON, *supra* note 3, at 46; Fielding, *Agricultural Biotechnology and the Environment*, 14 INT'L BUS. LAW. 285, 292 (1986); Harlow, *The EPA and Biotechnology*

utes used to regulate biotechnology, the manufacturer has the burden of proving that the product is safe and must have a permit or license before a product can be sold.¹⁵⁴

The logic of regulating some genetically engineered organisms under permitting statutes, but regulating other organisms under TSCA's nonpermit regime, is not immediately apparent. EPA officials express confidence that they can regulate microorganisms safely under TSCA.¹⁵⁵ Certainly, EPA's long-planned TSCA regulations take as cautious an approach to regulating genetically engineered organisms as is possible under TSCA.¹⁵⁶ But the fact remains that TSCA places the burden on EPA to first prove that an organism is dangerous before the Agency can control someone who is determined to release genetically engineered organisms over EPA's objections.

Congress apparently chose not to make TSCA a permitting statute because of concerns about the potential burden a licensing system would place on the chemical industry.¹⁵⁷ The biotechnology industry has told Congress that it should not establish new regulatory burdens over biotechnology for the same reason.¹⁵⁸

Deciding whether EPA has adequate regulatory authority under TSCA is complicated by two circumstances. First, as discussed earlier, the scientific community is split concerning the degree of risk posed by the release of genetically engineered organisms.¹⁵⁹ Differences in perception about the risks of biotechnology partly explain the differences in perception about the adequacy of TSCA. Second, how large a role TSCA will play in the regulation of biotechnology is not yet clear. If most organisms come within the regulatory jurisdiction of permitting statutes because they are plant pests, pesticides, new drugs, and so on, the fact that TSCA is not a permitting regime will be less important than if EPA ends up regulating a large number of organisms under TSCA.

Regulation: Coping with Scientific Uncertainty, 95 YALE L.J. 553, 564 (1987).

154. See, e.g., Virus, Serum, Toxin Act, 21 U.S.C.A. § 151 (West 1972 & Supp. 1989); Poultry Products Inspection Act, 21 U.S.C. §§ 451-470 (1988); Federal Meat Inspection Act, 21 U.S.C. §§ 601-695 (1988).

155. Interview with Alan Carpián, General Counsel's Office, EPA, in Washington, D.C. (June 1, 1989) [hereinafter Carpián Interview].

156. See *infra* text accompanying notes 252-74.

157. See Outen, *Toxic Chemicals*, in 2 LAW OF ENVIRONMENTAL PROTECTION § 15.01, at 15-5 (S. Novick, D. Stever & M. Mellon eds. 1988).

158. See *The Biotechnology Science Coordination Act of 1986: Hearings Before the Subcomm. on Natural Resources, Agricultural Research, and the Environment, and the Subcomm. on Science, Research, and Technology, of the House Comm. on Science and Technology*, 99th Cong., 2d Sess. 273 (1986) (statement of Jeffrey Gibbs, Associate General Counsel, Association of Biotechnology Companies) (industry opposes legislation that would establish new regulations for biotechnology).

159. See *supra* text accompanying notes 18-24.

These circumstances suggest that Congress ought to monitor EPA's progress under TSCA carefully to determine whether legislation is necessary. If it appears that EPA will rely significantly on TSCA to regulate potentially dangerous organisms, Congress should enact an amendment to establish a permit regime for biotechnology that would shift the burden of proof to the industry.

III

REGULATORY COORDINATION: AVOIDING INTERAGENCY CONFLICT

If several agencies are to share the responsibility for regulating biotechnology, they must coordinate their actions in order to regulate effectively and efficiently. In the 1986 Coordinated Framework, OSTP established a Biological Science Coordinating Committee (BSCC) for the purpose of helping agencies coordinate their biotechnology regulatory policies. However, BSCC's efforts have been dogged by controversy and conflict. At the time of this writing, BSCC no longer functions because EPA refuses to attend its meetings.¹⁶⁰ Its demise has left a void which must be filled if there is to be future coordination. This section describes the history of BSCC's efforts to assist agency coordination, analyzes why BSCC failed in those efforts, and recommends ways to reformulate BSCC to avoid the problems that led to its demise.

A. BSCC Hindered By Conflict

BSCC is composed of seven governmental officials from five agencies. The Director of NIH and the Assistant Director for Biological, Behavioral, and Social Services of the National Science Foundation (NSF) chair BSCC on a rotating basis. The other members are the USDA's Assistant Secretaries for Marketing and Inspection Services and Science and Education, FDA's Commissioner, and EPA's Assistant Administrators for Pesticides and Toxic Substances and for Research and Development.¹⁶¹ BSCC's charter aims to identify gaps in scientific knowledge, to facilitate cooperation among agencies in reviewing bioengineered products, and to serve as "a coordinating forum for addressing scientific problems, sharing information, and developing consensus."¹⁶²

From its inception, BSCC has been troubled by disagreements among its members on complicated policy questions concerning the scope of regulation of biotechnology. These disagreements include

160. Evans Interview, *supra* note 120.

161. OSTP, Coordinated Framework for Regulation of Biotechnology; Establishment of the Biotechnology Science Coordinating Committee, 50 Fed. Reg. 47,174, 47,176 (1985).

162. *Id.*

whether some areas of biotechnology can be exempted from regulation, whether EPA's draft TSCA rule is appropriate, and how domestic and international regulation of biotechnology can best be coordinated.

1. *The Regulatory Exemption Controversy*

One of the most controversial issues has been whether some bioengineered organisms can be exempt from regulation and, if so, under what definition. In the 1986 Coordinated Framework policy statement, BSCC proposed that agencies should not consider an organism to be "intergeneric" or a "pathogen" (and hence subject to regulation) if it resulted from the addition of intergeneric material that is "well-characterized and contains only non-coding regulatory regions."¹⁶³ BSCC's effort to exclude certain organisms met with a mixed reaction. Researchers and industry representatives protested that BSCC should have proposed more exemptions from regulation.¹⁶⁴ Environmentalists argued that there was no scientific justification for the exclusions that BSCC did create.¹⁶⁵ By taking their case to court, they forced BSCC in late 1986 to state that the definitions were not binding on any of the regulatory agencies that had participated in writing them.¹⁶⁶

163. OSTP, Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,307 (1986). An organism is "intergeneric" if it consists of a deliberate combination of genetic material from sources in different genera. *Id.* at 23,306. A pathogen is a "virus or microorganism" that has the "ability to cause disease in other living organisms." *Id.* at 23,307.

The basis of the exclusion was that well-characterized noncoding regulatory regions have "no coding capacity for the production of any gene product" and therefore do not "promote the production of any new material." *Id.* at 23,307 n.2. In other words, noncoding regulatory sequences were understood to be like a police officer who controls the "amount" of traffic allowed to move in any given direction over time, but generally cannot reverse the traffic's flow, direction, or its composition of cars, cycles, and trucks. *See* EPA, Statement of Policy; Microbial Products Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic Substances Control Act, 51 Fed. Reg. 23,313, 23,326-27 (1986). For this reason, the BSCC had decided that "the probability of any incremental hazard compared to the unmodified organism host is low." OSTP, Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,307 (1986).

164. *See, e.g., Regulatory Tangle Snarls Agricultural Research in Biotechnology Arena*, 234 Sci. 275-76 (1986). Researchers and industry also charged that BSCC failed to reach agreement on other key regulatory terms such as "environmental release." *Id.*

165. *Id.* EPA's scientific staff also opposed the exclusion from regulation of noncoding regulatory regions. *What Did EPA Know and When Did They Know It*, Genetic Engineering Letter, Nov. 24, 1986, at 3. "[T]op EPA officials overruled the fears of agency scientists in approving an exemption for a broad class of genetically engineered microbes from the proposed federal regulations." *Id.*

166. The suit against OSTP was filed by the Foundation on Economic Trends, Jeremy Rifkin's organization. It alleged that the government had authorized the environmental release of "certain types of genetically engineered organisms without significant review by federal agencies of their environmental or public health impacts." *Foundation on Economic Trends v. Johnson*, Civ. No. 86-1956 (D.D.C. filed July 15, 1986), *cited in* J. GIBBS, I. COOPER & B. MACKLER, *supra* note 83, at 133. After BSCC responded that the definitions were not binding, OSTP, Biotechnology Science Coordinating Committee; Meeting, 51 Fed. Reg. at 44,397, the

BSCC's proposal for regulatory exclusions was dealt another blow in October 1987 when a House committee charged that the chairman of BSCC, David Kingsbury, was a director of a biotechnology company at the time he helped write the BSCC definitions.¹⁶⁷ Although Kingsbury protested that he had merely "served as a consultant" to the predecessor of a biotechnology company prior to joining NSF,¹⁶⁸ he resigned as chairman in October 1988.¹⁶⁹ The allegations against Kingsbury and his subsequent resignation suggested that BSCC's decision to recommend regulatory exclusions may have been the product of a conflict of interest by its chairman.

2. *The TSCA Rule*

In 1988, BSCC definitions became a source of contention between EPA and other members of BSCC. In May 1988, EPA informed BSCC that its draft TSCA rule would require regulation of "non-coding regulatory sequences" whenever the modification involved a pathogen.¹⁷⁰ Upon learning EPA's intent, the BSCC chairman immediately wrote to the President's Office of Management and Budget (OMB) to request that OMB withhold clearance of EPA's proposed rule until the "other committee members could review the proposed rule from a scientific perspective."¹⁷¹

After reviewing the proposal, the other BSCC members were generally critical.¹⁷² FDA, for example, concluded that "[n]either scientific principles nor experience argue for the need for [EPA's proposed] regulation."¹⁷³ Some members went further. FDA's representative and BSCC

district court dismissed the Foundation's lawsuit. *Foundation on Economic Trends v. Johnson*, Civ. No. 86-1956, slip op. at 5 (D.D.C. 1986), cited in J. GIBBS, I. COOPER & B. MACKLER, *supra* note 83, at 134.

167. Gladwell, *Panel Probes White House Biotech Aide*, Wash. Post, Oct. 16, 1987, at F1; *Around the Agencies*, Nat'l J., Oct. 22, 1988, at 2685; see Fox, *The U.S. Regulatory Patchwork*, 5 BIO/TECHNOLOGY 1273, 1274 (1987).

168. McGraw-Hill's *Biotechnology Newswatch*, Nov. 2, 1987, at 5. The National Science Foundation carried out its own investigation and "determined that no immediate administrative action would be appropriate." *Id.*

169. *Around the Agencies*, Nat'l J., Oct. 22, 1988, at 2685.

170. Memorandum from John A. Moore, Assistant Administrator for Pesticides and Toxic Substances, EPA, to Members, BSCC, at 3 (May 24, 1988).

171. Letter from James B. Wyngaarden, Chairman, BSCC, to James B. MacRae, Acting Administrator for Information and Regulatory Affairs, OMB (May 23, 1988). The first time that the BSCC considered the EPA draft rule was at its May 1988 meeting. See Letter from John A. Moore, Assistant Administrator for Pesticides and Toxic Substances, EPA, to James B. Wyngaarden, Chairman, BSCC (Apr. 12, 1988).

172. See, e.g., Letter from Frank E. Young, Commissioner, FDA, to John A. Moore, Assistant Administrator for Pesticides and Toxic Substances, EPA (July 5, 1988) [hereinafter Young Letter]; Letter from William J. Garland, Director, NIH, to John A. Moore, Assistant Administrator for Pesticides and Toxic Substances, EPA (June 6, 1988).

173. Young Letter, *supra* note 172. FDA complained that EPA had ignored the "well established principle that the degree of government regulation should be commensurate with

legal counsel recommended that the general counsels of the other BSCC members should attempt to redraft EPA's rule into a more acceptable form.¹⁷⁴

Over the summer of 1988, EPA's staff met with the staff of other BSCC member agencies in an attempt to win them over.¹⁷⁵ EPA had little success, however, perhaps because it stoutly defended its draft rule.¹⁷⁶ For example, it rejected FDA's contention that regulation of "non-coding regulatory sequences" was "unscientific" on the grounds that "credible scientific societies" opposed FDA's position that regulatory sequences should be exempted from regulation.¹⁷⁷

In August 1988, Dr. Wyngaarden, the BSCC Chairman, conveyed to OMB that the other BSCC members opposed EPA's draft rule.¹⁷⁸ He

the degree of risk posed by the product in question." *Id.* at 1. It alleged that EPA's draft "has moved toward a still broader scope of what is regulated" despite a "growing consensus that the newest techniques of genetic manipulation are extensions, or refinements, of the earlier ones (often providing more precise and better characterized genetic changes, with better predictability of behavior of the regulatory organisms)." *Id.* at 1-2. FDA also contended that EPA's "proposed approach covering virtually all research field trials seems to us likely to inhibit R&D activities, and in the long term could have significant negative effects on U.S. innovation in this field." *Id.* at 2.

174. At a July 11, 1988 meeting of OSTP's International Biotechnology Subcommittee, whose membership includes representatives of all of the BSCC member agencies, the BSCC counsel and FDA's representative recommended that "the General Counsels (GC) of all the concerned agencies should work on correcting the proposed rule." Memorandum from Elizabeth Milewski, Special Assistant on Biotechnology, EPA, to the Record, at 4 (undated) (report on the discussion of the International Biotechnology Subcommittee of the Life Sciences Committee). FDA's representative said that he would "ask FDA's GC to look at the proposed rule." *Id.* at 7. USDA's representative warned that the proposal was "dangerous" because having "GCs from other agencies perform the task entrusted to EPA by Congress would erode EPA's authority." *Id.* at 4.

175. See Letter from Terry Medley, Director, Biotechnology and Environmental Coordination Staff, APHIS, USDA, to Janet Dorigan, Senior Policy Analyst, Executive Office of the President (June 21, 1988) (concerning meeting with EPA staff); Memorandum from John A. Moore, Assistant Administrator for Pesticides and Toxic Substances, EPA, to James Wyngaarden, Chairman, BSCC (June 21, 1988) (concerning discussions and EPA staff meetings with staff from three BSCC member agencies).

176. See Memorandum from John A. Moore, Assistant Administrator for Pesticides and Toxic Substances, EPA, to James Wyngaarden, Chairman, BSCC (June 21, 1988) (discussing EPA's responses to the criticisms of the other agencies).

177. EPA complained that "[a] myth appears to have developed around this concept in the sense that any suggestion to review the exemption proposed in the 1986 policy statement is seen as unscientific." Letter from John A. Moore, Assistant Administrator for Pesticides and Toxic Substances, EPA, to Frank E. Young, Commissioner, FDA, at 4 (July 14, 1989). Moore explained that "it is well documented that credible scientific societies, including the American Society for Microbiology, Ecological Society of America, and our own Biotechnology Science Advisory Committee, feel the exclusion is without scientific foundation. Indeed, EPA was roundly criticized for including this exclusion as part of the 1986 policy statement." *Id.*

178. OMB was informed that despite "extensive discussions" between BSCC members, "scientific concerns regarding the proposed rules remained" and that "[f]urther attempts at resolution of these scientific issues appear unlikely to produce consensus." Letter from James B. Wyngaarden, Chairman, BSCC, to Jay Plager, Administrator, Office of Information and Regulatory Affairs, OMB, at 1 (Aug. 19, 1988). The BSCC objected that the proposed rules

pointed to EPA's decision to include intergeneric organisms formed by noncoding regulatory regions as an example of EPA's intent to regulate "organisms scientifically considered to be of low risk."¹⁷⁹ EPA countered that Dr. Wyngaarden's letter "does not convey either the nature or the substance of the issues discussed in the BSCC."¹⁸⁰ According to EPA, "Dr. Wyngaarden states as fact that microorganisms formed by the addition of noncoding regulatory sequences from organisms in other genera are low risk. This is not a fact, but an opinion held by some."¹⁸¹

Despite making changes to its draft rule,¹⁸² EPA was unable to obtain OMB's permission to issue a Notice of Proposed Rulemaking.¹⁸³ EPA reacted by indicating that its draft rule was publicly available and

were "inconsistent with the conceptual basis of the Coordinated Framework" because they did not "use scientifically determined likelihood of risk bases for categories of regulated microorganisms." *Id.* at 1-2.

At the same time that EPA and BSCC were trying to influence OMB, other agencies and parties were also lobbying OMB. The Small Business Administration weighed in against EPA. Letter from Frank S. Swain, Chief Counsel for Advocacy, Small Business Administration, to Jay Plager, Administrator, Office of Information and Regulatory Affairs, OMB at 4 (Sept. 7, 1988) ("EPA's draft rule regulating microorganisms is burdensome and ill-conceived"). The Association of Biotechnology Companies (ABC) also voiced its complaints. Letter from Bruce F. Mackler, General Counsel, ABC, to C. Boyden Gray, Counsellor to the President (July 11, 1988).

179. Letter from James B. Wyngaarden, Chairman, BSCC, to Jay Plager, Administrator, Office of Information and Regulatory Affairs, OMB, at 1 (Aug. 19, 1988).

180. EPA argued that "[t]he example used by Dr. Wyngaarden to illustrate EPA's alleged failure to base its proposed rule on risk demonstrates how such uncertainties affected BSCC review and led to the failure of the BSCC process to come to grips with the issues involved in writing a functional rule." Letter from John A. Moore, Assistant Administrator for Pesticides and Toxic Substances, EPA, to Jay Plager, Administrator, Office of Information and Regulatory Affairs, OMB, at 1-2 (Aug. 30, 1988).

181. *Id.* at 2. EPA noted that "many eminent and respected scientists have suggested that this type of manipulation may present a level of potential risk which places such microorganisms among those warranting a cautious approach." *Id.*

182. Letter from John A. Moore, Assistant Administrator for Pesticides and Toxic Substances, EPA, to Jay Plager, Administrator, Office of Information and Regulatory Affairs, OMB (Sept. 23, 1988).

183. At OMB's request, BSCC solicited and received comments on the revised EPA rules and they were still largely critical. *See, e.g.*, Letter from James B. Wyngaarden, Chairman, BSCC, to Janet Dorigan, Senior Policy Analyst, Executive Office of the President (Dec. 9, 1988); Letter from Kenneth A. Gilles, Assistant Secretary for Marketing and Inspection Services, USDA, to Janet Dorigan, Senior Policy Analyst, Executive Office of the President (Dec. 5, 1988); Letter from Frank E. Young, Commissioner, FDA, to Janet Dorigan, Senior Policy Analyst, Executive Office of the President (Dec. 2, 1988).

by soliciting comments on the proposal.¹⁸⁴ As of this writing, EPA has also refused to attend any further BSCC meetings.¹⁸⁵

3. *International Spillover*

Disagreements between BSCC members have also had an international spillover. The State Department has consulted BSCC as an advisory committee concerning State's participation in the Organization for Economic Cooperation and Development (OECD) for issues relating to biotechnology.¹⁸⁶

BSCC, however, was unable to function in this capacity due to internal discord, which resulted when the State Department referred to BSCC an OECD document that outlines a set of principles known as Good Development Practices (GDP).¹⁸⁷ GDP's would exempt small-scale field testing from case-by-case approval by regulatory authorities as long as researchers met predesignated safety requirements.¹⁸⁸ BSCC took up the matter at the same time its members were disputing the TSCA draft rule. The issue polarized the committee: officials from EPA and USDA disputed the scientific validity of the GDP principles, and officials from FDA defended them.¹⁸⁹

Officials who participated in BSCC meetings believe that the United States has been embarrassed by its inability to agree on a timely response to the OECD draft, and each side of the debate blames the other for this result.¹⁹⁰ Worse, by not commenting on the OECD draft, the United States may have lost an opportunity to influence a recent initiative by the European Community to standardize the regulation of biotechnology research in Europe by 1992.¹⁹¹ If the European Community adopts the GDP approach, and USDA and EPA reject it for this country, domestic

184. EPA, Microbial Pesticides and Biotechnology Products; Request for Comments on Regulatory Approach, 54 Fed. Reg. 7027 (1989). OMB protested this procedure. Letter from Jay Plager, Administrator, Office of Information and Regulatory Affairs, OMB, to John A. Moore, Assistant Administrator for Pesticides and Toxic Substances, EPA, at 2 (Nov. 29, 1988). EPA responded, "[I]f any sequence of activities are in conflict in your point of view, it is the fault of the review process at OMB." Letter from Lee M. Thomas, EPA, to Jay Plager, Administrator for Information and Regulatory Affairs, OMB (Dec. 5, 1988).

185. Evans Interview, *supra* note 120.

186. Fox, *supra* note 119, at 1380. The OECD issues recommendations to its members concerning how biotechnology should be regulated. See, e.g., OECD, RECOMBINANT DNA SAFETY CONSIDERATIONS: SAFETY CONSIDERATIONS FOR INDUSTRIAL, AGRICULTURAL AND ENVIRONMENTAL APPLICATIONS OF ORGANISMS DERIVED BY RECOMBINANT DNA TECHNIQUES (1986).

187. Fox, *supra* note 119, at 1380.

188. See *infra* text accompanying notes 262-66.

189. Letter from Frank E. Young, Commissioner, FDA, to John A. Moore, Assistant Administrator for Pesticides and Toxic Substances, EPA (July 5, 1988).

190. Interview with Carl Mazza, Office of Toxic Substances, EPA, in Washington, D.C. (June 1, 1989) [hereinafter Mazza Interview]; Miller Interview, *supra* note 117.

191. Mazza Interview, *supra* note 190; Miller Interview, *supra* note 117.

regulation of research will be stricter than European regulation. This could discourage biotechnology companies from doing research in the United States and shift that research to Europe.

B. Reformulating BSCC

The demise of BSCC has left the White House without a method to assist agencies in coordinating their biotechnology activities. Since only the White House is in a position to bring the agencies together for that purpose, it must consider how to reactivate BSCC. This section analyzes why the BSCC failed and proposes ways to avoid similar failure in the future.

1. Where BSCC Went Wrong

BSCC was chartered to be "a forum for discussing scientific questions raised in regulatory and research applications and, thus, make available a wider understanding of emerging scientific questions and promote consistency in agency approaches."¹⁹² David Kingsbury, the first BSCC chairman, vowed that BSCC had no intention of imposing on its members policy decisions reached by the committee. He told a Congressional committee that BSCC could confine itself to "scientific" questions and that it "would have no formal or informal contacts with OMB regarding agencies' proposed rules."¹⁹³ These assurances were given after an early OSTP proposal for regulatory coordination was criticized for being duplicative of agency review.¹⁹⁴

BSCC failed to keep Kingsbury's promises for two reasons. First, the original charter had assumed that BSCC would be able to distinguish scientific from policy issues. However, most regulatory questions are mixed questions of science and policy not easily separated into their scientific and policy components;¹⁹⁵ thus, it was improbable that BSCC could limit itself to "scientific" issues.¹⁹⁶ Whatever chance the commit-

192. OSTP, Coordinated Framework for Regulation of Biotechnology; Establishment of the Biotechnology Science Coordinating Committee, 50 Fed. Reg. 47,174, 47,175 (1985).

193. REGULATION OF BIOTECHNOLOGY, *supra* note 114, at 52 (summarizing the testimony of Dr. Kingsbury) (citation omitted).

194. In 1984, OSTP had proposed a committee structure that required each regulatory agency to use scientific advisory committees and established a White House-level committee, called the Biotechnology Science Board (BSB), to review committee decisions. OSTP, Proposal for a Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. 50,897, 50,904-05 (1984). OSTP received numerous comments that the ill-defined role of the BSB would result in duplicative and time-consuming review of applications before the regulatory agencies. See, e.g., *Regulatory Muddle Somewhat Clearer, But AHI Says Much Confusion Remains*, AGRICULTURAL BIOTECHNOLOGY NEWS, Sept. 1985, at 4; *Tuning the Advisory Mechanism*, 3 BIO/TECHNOLOGY 279 (1985). The BSCC plan was OSTP's response to these complaints. J. GIBBS, I. COOPER & B. MACKLER, *supra* note 83, at 126-27.

195. See Cheaper & McGarity, *Reorienting OSHA: Regulatory Alternatives and Legislative Reform*, 6 YALE J. ON REG. 1, 35-36 (1989).

196. The BSCC's attempt to exclude from regulation microorganisms engineered with

tee had to function as a “scientific” committee was lost when OSTP appointed as its members high-level “political” appointees from the regulatory agencies.¹⁹⁷ Second, BSCC became embroiled in policy matters because it was lobbied to do so by industry and FDA. Those who opposed EPA’s draft TSCA rule seized upon BSCC as a vehicle to stop EPA from adopting the rule.¹⁹⁸

The lesson to be drawn from BSCC’s demise is that there are two types of interagency coordination that do not mix well. One type of coordination involves the identification of issues, exchange of information, and preparation of reports concerning issues common to several agencies. This was BSCC’s original function. The other type of coordination involves the imposition of certain policies on agencies intended to move the Executive Branch in a unified and consistent direction. This was the function that BSCC tried to perform. The second function—requiring common policies—is inimical to the first function—exchanging information and data—because no agency will be anxious to cooperate with a process that threatens its independence.

2. *A Reorganized BSCC*

BSCC’s attempt to dictate policy has caused two significant dislocations. First, the White House’s coordination strategy has been delegitimized because OSTP and BSCC decisionmaking occurred behind closed doors, without public accountability.¹⁹⁹ Access to BSCC was uneven: some industry members were able to lobby BSCC members,²⁰⁰ but other interested parties were excluded from participation.²⁰¹ Second, in addi-

noncoding regulatory sequences illustrates this problem. Although reputable ecologists believe that such organisms may pose significant environmental risks, *see supra* note 177, the BSCC chairman told OMB that such organisms are “scientifically considered to be of low risk.” *See supra* text accompanying note 179.

197. *See supra* text accompanying note 161.

198. Miller Interview, *supra* note 117; interview with Bruce Mackler, General Counsel, Association of Biotechnology Companies, in Washington, D.C. (May 31, 1989) [hereinafter Mackler Interview].

199. *Biotechnology Science Coordination Act of 1986: Hearings Before the Subcomm. on Natural Resources, Agricultural Research, and Environment, and the Subcomm. on Science, Research, and Technology of the House Comm. on Science & Technology*, 99th Cong., 2d Sess. 35 (1986) (statement of David Kingsbury, Chairman, BSCC) (most of the BSCC activities are closed); interview with Margaret Mellon, Director, Biotechnology Project, Wilderness Society, in Washington, D.C. (May 9, 1989) (U.S. policy concerning international regulation of biotechnology is made by BSCC behind closed doors) [hereinafter Mellon Interview].

200. Mackler Interview, *supra* note 198.

201. *See, e.g., Coordinated Framework for Regulation of Biotechnology: Hearing Before the Subcomm. on Investigations and Oversight, the Subcomm. on Natural Resources, Agricultural Research, and Environment, and the Subcomm. on Science, Research, and Technology of the House Comm. on Science & Technology*, 99th Cong., 2d Sess. 74-75 (1986) (statements of Elliot Norse, Ecological Society of America) (BSCC sought scientific input only from genetic engineers and not ecologists in devising 1986 definitions).

tion, EPA's refusal to participate renders BSCC dysfunctional as a coordinating agent.

To overcome the BSCC legacy and to institute effective coordination between agencies concerning biotechnology, the White House must do three things. First, it should return BSCC to its original function of being a clearinghouse where agencies can meet, exchange information, and, if possible, reach a consensus about pending issues. The responsibility for establishing uniform government policies should be returned to OMB and other White House committees established for that purpose. Second, the White House should enlarge BSCC's mandate and membership to permit it to consider the broad sweep of policy issues created by biotechnology. Finally, the White House should require that BSCC meetings be open to the public on the same basis as meetings held under the Federal Advisory Committee Act.

As a clearinghouse, a reorganized BSCC could assist agencies in the coordination of their activities in several ways: by identifying scientific and policy issues relating to the government's regulation of biotechnology, by preparing reports concerning those issues, and by serving as a forum for the exchange of scientific data. In addition, BSCC could utilize committee reports as a vehicle for reaching interagency consensus. But to avoid the type of rancor that permeated the original BSCC and ended its usefulness, BSCC should avoid taking a position on the specific initiatives of its members. If a consensus on a committee report cannot be reached, BSCC should mitigate infighting by focusing its efforts on evaluating and developing a variety of options available to decisionmakers.

If the White House returned BSCC to a clearinghouse function, the responsibility for ensuring consistency among agencies would be moved back to OMB or other White House agencies, such as the Domestic Policy Council. OMB might object that it lacks the expertise to carry out these functions unless BSCC can advise it. BSCC should be free to advise OMB, but where its members are not in agreement the nature of its advice should be limited to identifying the options available to decisionmakers. While this procedure may not be as valuable to OMB as having BSCC take a position on the regulatory initiatives of its members, it seems less likely to cause the type of antagonisms that currently cripple BSCC.

Moreover, this division of labor has two advantages. First, because it has more legal and political authority, OMB is in a better position to require agencies to follow common policies. Second, OMB would not be able to avoid public scrutiny of its decisions by having OSTP do its work.²⁰²

202. See BRUFF, REPORT TO THE ADMINISTRATIVE CONFERENCE, PRESIDENTIAL MAN-

Besides returning BSCC to a clearinghouse function, the White House should enlarge its mandate to include three types of additional issues important to the development and regulation of biotechnology. First, BSCC should address the major economic issues that affect biotechnology, such as patent protection, technology transfer, and international trade rules. Government decisions concerning these issues may affect the biotechnology industry to the same, or a greater extent, than the resolution of regulatory issues.²⁰³ Second, BSCC should consider the social impact of biotechnology, including the implications of agricultural biotechnology for family farming and rural development.²⁰⁴ BSCC could serve a useful function in this area by helping agencies anticipate and understand the consequences of their actions for society. Finally, BSCC should also assist agencies in the coordination of biosafety research and funding. As the next section explains, the coordination of biosafety research and funding is an important element in developing a more efficient regulatory system.

If the mandate of BSCC is enlarged, its membership must also be enlarged.²⁰⁵ At the present time, several departments or agencies that make decisions relevant to biotechnology, such as the Agency for International Development, the Commerce Department, the Department of Defense, and the Department of Health and Human Services, are not represented on BSCC.²⁰⁶ Surprisingly, not even all of the agencies that directly regulate biotechnology are represented on BSCC.²⁰⁷ For in-

AGEMENT OF AGENCY RULEMAKING, at VII 9-10 (Nov. 21, 1988).

203. Interview with David Bayer, Vice President, Genetech, in Washington, D.C. (June 14, 1989) [hereinafter Bayer Interview].

204. See C. HASSEBROOK & G. HEGYES, *supra* note 17, at 4-7.

205. OSTP could reorganize BSCC under the Federal Coordinating Council for Science, Engineering, and Technology (FCCSET), 42 U.S.C. § 6651 (1982), as it did the original BSCC. FCCSET is chaired by the Director of OSTP and is composed of representatives of agencies and departments with science, engineering, and technology programs. Its function is to plan, identify research needs, eliminate duplication, and further international cooperation for those programs. *Id.* §§ 6651(b), (e). FCCSET membership may be augmented as necessary. *Id.* § 6651(d). OSTP is authorized to appoint subcommittees "[f]or the purpose of conducting studies and making reports." *Id.* § 6651(h).

206. The Agency for International Development is responsible for international protection of biological diversity (the raw materials of biotechnology) and international development. Adler, *Biotechnology: The U.S. Needs an Integrated Policy*, 24 FORUM 3 (June 1986). Commerce has responsibility for the Patent and Trademark Office, which controls patent protection for biotechnology products, and the Export Administration, which addresses international trade issues. *Id.* DOD funds biological warfare research. See *Department of Defense Safety Programs for Chemical and Biological Warfare Research: Hearings Before the Subcomm. on Oversight and Government Management of the Comm. on Government Affairs*, 100th Cong., 2d Sess. (1988). The Department of Health and Human Services is responsible for setting reimbursement policies for government-funded medical care, which affects the research incentives of genetically engineered drugs. Bayer Interview, *supra* note 203 (pricing decisions affect incentives of pharmaceutical companies to do biotechnology research and development).

207. See 5 U.S.C. § 552(b) (1988) (exclusion of agencies).

stance, OSHA, which regulates the exposure of workers to microorganisms, has been excluded.²⁰⁸

Finally, BSCC meetings should be open to the public on the same basis as meetings held under the Federal Advisory Committee Act.²⁰⁹ Thus, meetings would be open unless they involved the exchange of confidential information such as draft agency rules that have not yet been published.²¹⁰ Draft copies of BSCC reports should be available to the public before they are discussed. An open process would enable BSCC both to legitimize its reports and to obtain public input.²¹¹

A revitalized BSCC can serve as the government's coordinating agent for biotechnology development, regulation, and biosafety research and funding. The new BSCC should be able to avoid the type of inter-agency infighting that led to EPA's withdrawal so long as its role is limited to factfinding, reporting, and serving as a clearinghouse for information relating to biotechnology. It should also be able to assist all government agencies concerned with biotechnology to coordinate their efforts if its mission and memberships are enlarged to permit it to function for that purpose.

208. See OSHA, Agency Guidelines on Biotechnology, 51 Fed. Reg. 23,347 (1986).

209. Federal Advisory Committee Act, 5 U.S.C. app. § 10(a)(1) (1988); see also H.R. 4452, 99th Cong., 2d Sess. § 104(b) (1986) (would mandate open meetings of BSCC); REGULATION OF BIOTECHNOLOGY, *supra* note 114, at 89 (recommending open meetings of BSCC at the earliest opportunity).

210. Advisory committee meetings must be open unless the information to be discussed would not have to be released under the Freedom of Information Act (FOIA). Federal Advisory Committee Act, 5 U.S.C. app. § 10(d) (1988). FOIA creates nine exceptions to the public disclosure of governmental information, 5 U.S.C. § 552(b)(1)-(9) (1988), including an exemption for "inter-agency or intra-agency memoranda or letters which would not be available by law to a party other than an agency in litigation with the agency. *Id.* § 552(b)(5). This exemption creates a "deliberative process privilege," ADMINISTRATIVE CONFERENCE OF THE UNITED STATES, FEDERAL ADMINISTRATIVE PROCEDURE SOURCEBOOK 603 (1985), which should protect the exchange of draft rules and other documents used by agencies to make decisions.

211. Some persons might prefer that BSCC also have public members in order to obtain public input or technical expertise. *Cf.* McGarity, *Regulating Biotechnology*, 1 ISSUES IN SCI. & TECH. 40, 54 (1985) (committees that have a direct role in setting biotechnology policy should have public members). However, public members may not be necessary. Having open meetings and circulating drafts of its reports would give a reformed BSCC a means to obtain a wide variety of public views. Moreover, public members are not necessary to obtain expertise. BSCC can appoint scientific and policy experts from its member agencies to subcommittees. BSCC would be free, however, to add public members to its subcommittees to increase the scope of its input. If BSCC added public members, it would have to comply with the requirements of the Federal Advisory Committee Act (FACA), 5 U.S.C. app. § 10(a)(1) (1988). BSCC should comply with FACA on a voluntary basis in any case.

IV

IMPROVING REGULATORY METHODS: THE RISK
ASSESSMENT AND RISK MANAGEMENT DEBATE

The third aspect in the design of a regulatory system for biotechnology involves the relationship between risk assessment and risk management. As discussed earlier, risk assessment is the use of scientific data to estimate the effects of exposure to hazardous materials or conditions.²¹² Risk management involves selecting the most appropriate strategy to reduce hazards to the level required by an agency's mandate.²¹³ The two functions are connected because judgments about risk management are based on risk assessments. Those who perceive the risks to be significant tend to favor more stringent regulatory methods; those who perceive the risks to be less significant take the opposite position.

This section analyzes how the regulatory system for biotechnology can be designed to resolve the contending approaches to regulation. One approach is better identification and coordination of research that supports risk assessment. Another is the use of advisory committees, regulatory negotiation, and other consensus-building procedures to identify areas where agencies can adopt generic regulations or policy statements. Generic regulations would specify how an agency would resolve an issue each time it came up. Policy statements would specify what information or criteria an agency would use in resolving an issue.

A. Risk Assessment

Participants in the debate over the risks of released organisms have not been kind to each other. Critics of the 1987 NAS report, which downplayed the risks of released organisms,²¹⁴ dismiss it as an "unbolstered 'pamphlet'" that "buries cautionary environmental statements."²¹⁵ Critics of the OTA report, which calls for a cautious regulatory approach amounting to a case-by-case review,²¹⁶ describe it as a "ruinous corrupting lie" marked by "regulatory doublespeak."²¹⁷ If the regulation of biotechnology is to proceed effectively and efficiently, this contentiousness must be overcome. The BSCC episode surrounding EPA's TSCA rule indicates how decisions about risk management can easily become stalled by strong disagreements over risk assessment.

212. See *supra* text accompanying notes 25-37.

213. Gillett, *supra* note 25, at 515, 516. Risk management depends on the findings of risk assessment, but it also considers technical, social, economic, and political concerns. *Id.* at 516.

214. See NAS, 1987 REPORT, *supra* note 26.

215. Fox, *supra* note 167, at 1276 (citing anonymous sources on Capitol Hill).

216. See OTA, FIELD TESTING, *supra* note 1.

217. Shuger, *How to Revolutionize Washington with 140 People*, THE WASH. MONTHLY, June, 1989, at 42 (citing anonymous academicians).

Both sides in the debate concede that they must have additional research before they can form a consensus. The 1987 NAS report recognizes "an urgent need for the scientific community to provide guidance . . . in evaluating planned introductions of modified organisms from an ecological perspective."²¹⁸ The ESA report recognizes a "pressing need" for interdisciplinary research.²¹⁹ A workshop convened by the American Association for the Advancement of Science and EPA also concluded that regulators require predictive risk assessment models for products of biotechnology, analogous to the models employed for predicting chemically induced effects.²²⁰

Unfortunately, some of the necessary research may not be forthcoming. USDA and EPA have been slow to fund research on the ecological effects of releasing microorganisms into the environment in the past. Federal budget constraints and the difficulty of reallocating existing funds currently stymie efforts to increase research support.²²¹ Given these problems, a reorganized BSCC could play an important role in developing the techniques and data necessary for assessing the risks of released organisms.²²²

First, the reformed BSCC could assist agencies in identifying ecological research needs and resource limitations. This effort would include helping agencies identify research projects that would permit biologists and ecologists to clarify and perhaps resolve their disagreements. Second, to avoid duplication and to ensure that research data is disseminated, BSCC could serve as a clearinghouse for the exchange of information by the agencies that fund this type of research. BSCC could also obtain information about the ecological research projects undertaken by foreign countries.

B. Risk Management

Most biotechnology products are now regulated on a case-by-case basis, while biotechnology research is regulated by a mixture of case-by-

218. NAS, 1987 REPORT, *supra* note 26, at 7.

219. ESA Report, *supra* note 26, at 312.

220. BIOTECHNOLOGY AND THE ENVIRONMENT: RISK & REGULATION 6-7 (A. Teich, M. Levin & J. Pace eds. 1985) (Proceedings of a Seminar Series conducted for EPA by the American Association for the Advancement Of Science). EPA's Science Advisory Board has reached the same conclusion. SCIENCE ADVISORY BOARD, EPA, ASSESSING EPA'S BIOTECHNOLOGY RESEARCH AND INFORMATION NEEDS: REPORT OF THE STUDY GROUP ON BIOTECHNOLOGY 4 (1986).

221. McKenzie Interview, *supra* note 122; interview with Leslie Russell, Professional Staff, House Energy and Commerce Committee, in Washington, D.C. (May 8, 1989); interview with Kathleen Merrigan, Professional Staff, Senate Agriculture Committee, in Washington, D.C. (Apr. 26, 1989).

222. Mazza Interview, *supra* note 190; interview with Greg Simon, Professional Staff, House Science and Technology Committee, in Washington, D.C. (May 8, 1989) [hereinafter Simon Interview].

case and generic approaches. In a case-by-case approach, safety issues are resolved product-by-product. In a generic approach, the agency adopts rules to specify how it will resolve safety issues as they come up. The case-by-case approach provides more protection because the agency considers the safety of each product individually, but it can discourage innovation and product development because it is slower than the alternative generic approach.

1. Current Methods

a. EPA

EPA, USDA, and FDA all rely primarily on a case-by-case approach to the regulation of biotechnology. Each, however, could adopt generic rules applicable to certain situations.

EPA's regulation of pesticides is primarily case-by-case. Under FIFRA, each pesticide is reviewed individually.²²³ Although EPA may waive some data requirements (or add new ones), it does so only on an individual basis.²²⁴ EPA is authorized to exempt pesticides from registration if they do not pose a risk to the environment,²²⁵ but it is unlikely to exempt any microbial pesticides any time in the near future.²²⁶ Finally, although FIFRA authorizes EPA to exempt small-scale field trials from experimental use permit requirements,²²⁷ the Agency has refused to apply this exemption to microbial pesticides. Instead, it permits researchers to submit less data for small-scale field trials than is required for an environmental use permit.²²⁸

EPA has drafted TSCA regulations that initially would also adopt a predominantly case-by-case approach.²²⁹ As Table 5-1 indicates, EPA would exempt manufacturers from reporting some types of contained microorganisms,²³⁰ but no exemption would exist for the environmental re-

223. See generally Comment, *EPA's Pesticides-in-Groundwater Strategy: Agency Action in the Face of Congressional Inaction*, 17 *ECOLOGY L.Q.* 143 (1990) (discussion of EPA registration and review of pesticides under FIFRA).

224. 40 C.F.R. §§ 158.45(a)(2), 158.65(b)(1) (1988).

225. FIFRA, 7 U.S.C. § 136w(b) (1988).

226. J. GIBBS, I. COOPER & B. MACKLER, *supra* note 83, at 10.

227. 40 C.F.R. § 172.3(a) (1988). EPA exempts field tests of conventional chemicals involving 10 acres or less of land surface or one surface-acre or less of water. *Id.* § 172.3(a)(1)-(2).

228. EPA has two levels of reporting requirements for small-scale field trials. Level I, which applies to less risky microbial pesticides, requires the applicant to submit less information than Level II, which applies to more risky products. EPA, Statement of Policy; Microbial Products Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic Substances Control Act, 51 Fed. Reg. 23,313, 23,321-22 (1986). After receiving this information, EPA decides whether to require the applicant to apply for an experimental use permit. *Id.* at 23,321, 23,323.

229. Although EPA has not yet proposed a rule, it has made public a draft rule now under consideration. See EPA DRAFT RULE, *supra* note 132.

230. Intrageneric microorganisms would be exempted from reporting, if they were con-

lease of any microorganism until EPA listed it as exempt at a future time.²³¹ Moreover, unlike its approach to conventional chemicals, which

TABLE 5-1
EPA'S DRAFT TSCA RULE REPORTING REQUIREMENTS
FOR BIOENGINEERED COMMERCIAL PRODUCTS

	Microorganisms Produced in Contained System	Microorganisms Released in the Environment
Intergeneric (new)	reporting required	reporting required
Intergeneric (previously registered with EPA)	none	reporting required until EPA lists as exempt
Intragenetic	none	reporting required until EPA lists as exempt

Source: EPA, DRAFT PROPOSED RULE, MICROBIAL PRODUCTS OF BIOTECHNOLOGY; PROPOSED AMENDMENT TO REQUIRE USER FEES; PREMANUFACTURER NOTIFICATION REQUIREMENTS; DESIGNATION OF SIGNIFICANT NEW USES, (Dec. 1, 1988), at 15.

exempts manufacturers from reporting "small quantities" of substances used for "scientific research,"²³²

EPA's proposal for biotechnology research does not have an automatic small-quantity exemption for the release of intergeneric organisms.²³³ Instead, as Table 5-2 indicates, commercial researchers would be required to submit a TSCA Experimental Release Application

tained. A system is "contained" if it is one for which the NIH has established a containment guideline or one for which certain conditions are met that would prevent the escape of microorganisms, including a requirement that the microorganism is used in "a closed vessel system that physically separates the fermentation process from the environment and from which the microorganism is not deliberately released to the environment." EPA DRAFT RULE, *supra* note 132, at 162-63.

Intergeneric microorganisms that are "inventoried" would also be exempt. *Id.* at 11. Under TSCA, a "new" chemical substance is defined as one that EPA has not placed on an "inventory" of chemical substances. 15 U.S.C. § 2602(9) (1988). EPA is to place a chemical substance on the inventory once it receives a premanufacturing notice concerning that substance. *Id.* § 2607(b).

231. EPA DRAFT RULE, *supra* note 132, at 167.

232. 40 C.F.R. § 720.36 (1988); *see* 15 U.S.C. § 2604(h)(3) (1988). EPA has defined "small quantities" as those quantities that are "not greater than reasonably necessary for [research and development] purposes." 40 C.F.R. § 720.3(cc) (1988).

233. EPA DRAFT RULE, *supra* note 132, at 44-46. The legality of EPA's position is open to challenge. *See supra* text accompanying notes 134-36.

(TERA) requiring less data than a manufacturer must submit for a new chemical substance. The TSCA Experimental Release Application would be submitted to EPA or to a local Environmental Biosafety Committee (EBC) unless EPA had exempted the research based on previous experience with similar field trials.²³⁴

TABLE 5-2
EPA'S DRAFT TSCA RULE REPORTING REQUIREMENTS FOR
SMALL-SCALE COMMERCIAL BIOTECHNOLOGY
RESEARCH

	Microorganisms Produced in Contained System	Microorganisms Released in the Environment
Intergeneric (new)	none	TERA, or EBC only, until EPA lists as exempt
Intergeneric (inventoried)	none	TERA, or EBC only, until EPA lists as exempt
Other	none	none

Source: EPA, DRAFT PROPOSED RULE, MICROBIAL PRODUCTS OF BIOTECHNOLOGY; PROPOSED AMENDMENT TO REQUIRE USER FEES; PREMANUFACTURE NOTIFICATION REQUIREMENTS; DESIGNATION OF SIGNIFICANT NEW USES (Dec. 1, 1988), at 15.

b. USDA

USDA regulates biotechnology research by a generic approach and biotechnology products by a case-by-case approach. Recipients of USDA funding are required to comply with the NIH guidelines for biotechnology research,²³⁵ which prescribe different levels of safety precautions for the physical containment of organisms.²³⁶ USDA is drafting a

234. EPA DRAFT RULE, *supra* note 132, at 47-72. *Compare id.* at 171-76 (proposed data requirements for products), *with id.* at 187-90 (proposed data requirements for a TSCA Experimental Release Application). The Environmental Biosafety Committees (EBC) would be modeled on NIH's Institutional Biosafety Committee (IBC) program. *See supra* note 86 and accompanying text. The EBC's would have both technical and public members and would provide local review of proposed experiments. In some cases, EBC's would serve as advisory committees for EPA, and in others, they would decide whether an experiment could proceed. EPA DRAFT RULE, *supra* note 132, at 51-62, 185-224.

235. *See supra* note 106 and accompanying text.

236. These precautions, known as biosafety levels, require appropriate standard microbiological practices, special practices, containment equipment, and laboratory facilities appropriate for each of four different degrees of containment. *See* NIH, Guidelines for Research Involving Recombinant DNA Molecules, 51 Fed. Reg. 16,960 (1986). NIH determines whether a researcher is in compliance with the relevant biosafety level for some experiments,

second set of guidelines for research outside of contained facilities.²³⁷ The guidelines classify organisms into safety categories and require compliance with applicable safety precautions. They also mandate either notification to, or approval by, USDA or an Institutional Biosafety Committee before any environmental release.²³⁸

By comparison, USDA product regulation by the Animal and Plant Health Inspection Service and the Food Safety Inspection Service is largely case-by-case. APHIS makes individual determinations of whether an organism can damage plants,²³⁹ although it has promulgated varying levels of data requirements to indicate the safety of contained and released plant pests.²⁴⁰ It has also issued a rule that prescribes packaging and labeling procedures for shipping plant pests.²⁴¹ APHIS's regulation of animal vaccines is likewise case-by-case,²⁴² although the Service varies the intensity of its screening process depending on the risk classification of a given vaccine.²⁴³ Finally, the Food Safety Inspection Service (FSIS) inspects meat and poultry products altered by biotechnology on a product-by-product basis.²⁴⁴

c. FDA

FDA also reviews the "intended use of each [biotechnology] product on a case-by-case basis."²⁴⁵ To address recurring drug and biological

but others are approved by an Institutional Biosafety Committee. *Id.*

237. See Draft USDA Guidelines for Research with Genetically Modified Organisms Outside of Contained Facilities (May 1, 1989).

238. *Id.* at 6-19.

239. See 7 C.F.R. § 340.1 (1988) for a definition of "regulated article." Although APHIS has published a list of organisms that are or contain plant pests, *id.* § 340.2, it will still determine on a case-by-case basis whether an organism that contains any part of a plant on this list is itself a plant pest. APHIS also regulates any unclassified organism, organism of unknown classification, or any other genetically engineered organism if it "has a reason to believe it is a plant pest." *Id.*

240. For release into the environment, an applicant must submit detailed scientific information concerning the nature of the regulated article, the system used to produce it, the purpose of introduction, the quantity, release procedures and safeguards, destination, uses, and distribution. *Id.* § 340.3(a)(1)-(14). Only some of this information is required for a permit to move a pest in interstate commerce. *Id.* § 340.3(c).

241. *Id.* §§ 340.5-6 (defining proper labeling and packaging of plant pests).

242. Medley, *Issues in Assessing the Environmental Impact of Veterinary Biologics Produced Through Biotechnology*, 43 FOOD DRUG COSM. L.J. 821, 825 (1988).

243. APHIS utilizes three risk classifications for screening animal vaccines. See USDA, Final Policy Statement for Research and Regulation of Biotechnology Processes and Products, 51 Fed. Reg. 23,336, 23,339 (1986) [hereinafter USDA Policy Statement].

244. The Food Safety Inspection Service (FSIS) regulation consists of two elements. First, FSIS regulations prohibit animals used in research concerning experimental animal drugs, biologics, or chemicals from being slaughtered for food until the owner demonstrates their safety. 9 C.F.R. §§ 309.17, 381.75 (1988). Second, FSIS plans to subject animals that are bred using new biotechnology techniques to the same inspection procedures it uses for traditionally inspected animals. USDA Policy Statement, *supra* note 243, at 23,343.

245. FDA, Statement of Policy for Regulating Biotechnology Products, 51 Fed. Reg. 23,309, 23,310 (1986).

issues, FDA issues policy statements called "Points to Consider" documents.²⁴⁶ FDA does have a method for exempting some biotechnology food products from case-by-case review,²⁴⁷ but it has not yet decided the extent to which it will allow exemptions.²⁴⁸ Although EPA, APHIS, and FDA can adopt generic regulations, and have done so to a limited extent, their approach to regulation is overwhelmingly case-by-case. Their failure to utilize a more generic approach is explained by the fact that the agencies find themselves in the middle of a political battle over competing theories of risk management.

2. *Competing Theories of Risk Management*

Biotechnology firms and environmental groups react differently to the current pattern of regulation. While acknowledging the need for regulation, the firms warn that overly burdensome and unpredictable regulation will mean the loss of American leadership in biotechnology.²⁴⁹ Firms generally favor the rapid adoption of generic rules that would create exemptions for some organisms and some types of research.²⁵⁰ Environmentalists counter that because so little is known about the effects of releasing organisms into the environment, all products and research should be screened individually until experience indicates which are safe.²⁵¹

The controversy over EPA's draft TSCA rule illustrates these opposing approaches to risk management. EPA's existing approach exempts nonpathogenic organisms and organisms engineered from well-characterized noncoding regulatory regions.²⁵² By comparison, EPA's

246. See J. GIBBS, I. COOPER & B. MACKLER, *supra* note 83, at 116; see, e.g., Food Drug Cosm. L. Rep. (CCH) 1-2 (July 5, 1989) (NIH request for comments on "Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant DNA into Human Subjects").

247. A substance is regulated as a "food additive" unless it is GRAS [generally recognized as safe] or "generally recognized, among experts . . . as having been . . . shown . . . to be safe under the conditions of its intended use." 21 U.S.C. § 321(s) (1988); 21 C.F.R. §§ 170.3(e), 170.30 (1989). Genetic manipulation of plants or animals may be GRAS if the altered plant or animal is sufficiently similar or identical to a traditionally produced product that additional safety testing is unnecessary. See Mahinka & Sanzo, *Biotechnology Litigation and Federal Regulation: Status and Implications*, 42 FOOD DRUG COSM. L.J. 500, 503 (1987).

248. Interview with Jim Maryanski, Division of Food Safety and Applied Nutrition, FDA, in Rockville, Md. (June 2, 1989).

249. Mackler Interview, *supra* note 198. Industry points to the drop in stock prices for many biotechnology companies and the bankruptcy of others as evidence that regulation is currently too restrictive. See Pollack, *Farm Gene Makers' Money Woes*, N.Y. Times, Apr. 24, 1989, at D1, col. 3. These problems, however, can also be attributed to the unanticipated difficulties that industry has had in developing products with commercial potential. See J. KLOPPENBURG, JR., *supra* note 15, at 202.

250. See *infra* text accompanying notes 257-58.

251. See *infra* text accompanying notes 254-56.

252. EPA proposed eliminating the first exemption because its BSAC advised the Agency that "it would be difficult to write a clear, precise, simple-to-understand definition of pathogen

proposed draft rule (see Table 1) would not allow exemptions from TSCA's reporting requirements for noncontained organisms, although it states an intention to compile a list of exempt organisms and their uses, should experience indicate that reporting is no longer required.²⁵³ As EPA now rewrites its draft rule, it must decide whether it will retain case-by-case review or create exemptions for certain organisms or research projects. EPA must also determine whether it will form institutional review committees. Because other regulatory agencies will be confronted by the same issues, the fight over EPA's TSCA rule illustrates the nature of the disagreement over how biotechnology should be regulated.

The OTA and ESA risk assessment studies discussed earlier support EPA's cautious approach.²⁵⁴ These studies recommend that regulatory agencies develop a system of categories or guidelines for releases requiring a minimum degree of screening and review. These categories would then be progressively developed and refined based on experience from field testing and other ecological research.²⁵⁵ For this reason, the Environmental Defense Fund endorsed EPA's plan as "scientifically sound."²⁵⁶

Industry and other government agencies, however, are critical of EPA's effort to abandon its current exemptions. As discussed earlier, BSCC voted to oppose EPA's proposed draft rule. BSCC contended that nonpathogens and noncoding regulatory regions should be exempt because scientists agree they present low risks.²⁵⁷ One biotechnology company complained that "EPA exemptions from review are cosmetic" and that the draft rule is "even more complex and stifling than previous regulations proposed by EPA."²⁵⁸

EPA also decided to require case-by-case review for commercial research.²⁵⁹ It attempted to lessen the regulatory burden on researchers by proposing to reduce reporting requirements and paperwork and to

which would function well for regulatory purposes." Memorandum from John Moore, Assistant Administrator for Pesticides and Toxic Substances, EPA, to BSCC Members, at 2 (May 24, 1988); *see also* EPA DRAFT RULE, *supra* note 132, at 7, 107. It proposed eliminating the second exemption because a "sufficient degree of uncertainty was associated with modifications of regulatory regions in general to indicate that review is appropriate at some stage." *Id.*

253. EPA DRAFT RULE, *supra* note 132, at 7, 10; *see also supra* text accompanying notes 229-33.

254. *See supra* text accompanying notes 65-81.

255. OTA, FIELD TESTING, *supra* note 1, at 23-24; ESA Report, *supra* note 26, at 310.

256. Letter from Rebecca Goldberg, Staff Scientist, EDF, to Elizabeth Milewski, Special Assistant on Biotechnology, EPA, at 1 (Dec. 16, 1988) [hereinafter EDF Letter].

257. *See supra* note 179 and accompanying text.

258. Letter from Winston J. Brill, Vice President, Research and Development, Agracetus, to Charlene Dunn, Office of Toxic Substances, EPA, at 1 (Dec. 15, 1988) [hereinafter Agracetus Letter].

259. *See supra* note 233 and accompanying text.

shorten its review period.²⁶⁰ EPA describes this approach as falling between the option of exempting field research and requiring full compliance with the notification requirements of TSCA.²⁶¹ It poses less of a burden on researchers but still permits EPA to monitor field research.

FDA argues that EPA should instead adopt a system of safety rules similar to the Good Developmental Practices being proposed by the Organization of Economic Cooperation and Development in which the United States participates.²⁶² The GDP would exempt from review releases that meet certain low-risk criteria.²⁶³ The State Department is also pressuring EPA, claiming that EPA's failure to adopt the GDP approach runs "counter to the position on biotechnology regulation that the United States Government has been advocating in various international fora and would likely impact our international competitive position adversely."²⁶⁴

EPA answers that it does not have sufficient information on the environmental effects and potential uses of microorganisms to develop practical containment standards for releases.²⁶⁵ It rejects the concept that exemptions can be based on the quantity or scale of a release because even a low number of microorganisms can adversely affect the environment.²⁶⁶

EPA proposes to reduce the regulatory burden on researchers by allowing local Environmental Biosafety Committees (EBC's) based in the institutions conducting such research to approve certain types of activities.²⁶⁷ For other research, the local EBC would advise EPA, but the Agency would retain decisionmaking authority. EPA hopes that forming EBC's will also enlist the help of the scientific community, ensure public participation in the regulatory process, and encourage development of local biotechnology data bases.²⁶⁸ In addition, EPA views the EBC as a "neutral party" that could more effectively represent local public interests without interference from Washington-based scientists and bureaucrats.²⁶⁹

260. See *supra* note 234 and accompanying text.

261. Mazza Interview, *supra* note 190.

262. Letter from Frank E. Young, Commissioner, FDA, to John A. Moore, Assistant Administrator for Pesticides and Toxic Substances, EPA, at 2 (July 5, 1988).

263. These would be based on the nature of the hazard, its use, and the extent of exposure. Mazza Interview, *supra* note 190.

264. U.S. DEPARTMENT OF STATE, BUREAU OF OCEANS AND INTERNATIONAL ENVIRONMENTAL AND SCIENTIFIC AFFAIRS, INFORMAL COMMENTS OF THE DEPARTMENT OF STATE ON EPA PROPOSAL TO REGULATE MICROORGANISMS UNDER AUTHORITY OF TSCA 3 (July 7, 1988) (the proposed regulations would establish a complex new bureaucracy and would require a detailed case-by-case determination).

265. EPA DRAFT RULE, *supra* note 132, at 41.

266. *Id.* at 42.

267. See *supra* note 234 and accompanying text.

268. EPA DRAFT RULE, *supra* note 132, at 51-52.

269. Letter from John A. Moore, Assistant Administrator for Pesticides and Toxic Sub-

EPA's enthusiasm for the EBC concept is not widely shared. Its biotechnology advisory committee gave the proposal only a qualified endorsement.²⁷⁰ Everyone else has criticized it. The Environmental Defense Fund predicted that EBC's would become dominated by individuals with a vested interest in the research being reviewed²⁷¹ while industry predicted they would become dominated by opponents of biotechnology.²⁷² Industry also contends that using EBC's would produce inconsistent decisions, create duplicative review, and cause leaks of confidential business information.²⁷³ Finally, the National Science Foundation is concerned that since most universities already have Institutional Biosafety Committees to comply with NIH's requirement, they would be unnecessarily burdened if they also had to set up EBC's.²⁷⁴

3. *Resolving Contending Approaches*

The reaction to EPA's TSCA rule indicates how little agreement exists concerning the appropriate design for risk management. This lack of agreement reflects the lack of consensus about risk assessment. To use generic methods, an agency must have sufficient data about a product or type of research so that it can frame applicable general rules. When information is lacking, an agency has no choice but to proceed on a case-by-case basis.²⁷⁵

The Administrative Conference, a federal agency that recommends ways to improve the regulatory process, has endorsed the use of generic rules for regulating carcinogens as long as agencies proceed cautiously in view of the "complexity and uncertainty of the issues involved."²⁷⁶ Simi-

stances, EPA, to Jay Plager, Administrator, Office of Information and Regulatory Affairs, OMB, at 7 (Aug. 30, 1988).

270. EPA's Biotechnology Safety Advisory Committee (BSAC) supports the idea of local review, but it warned that the EBC concept as proposed may not be workable. Report from BSAC Considering the TSCA Proposed Rule 6-7 (Jan. 9, 1989). The problems identified by BSAC concerned potential jurisdictional disputes among EBC's, mechanisms for appeal of EBC decisions to EPA, adequacy of the public notice and review process, and protection of confidential business information. *Id.* It suggested that EPA might expend more effort guiding and monitoring EBC's than it would to conduct all TSCA Experimental Release Application reviews. *Id.* It recommended that EPA use other types of local review boards such as regional committees established in conjunction with each EPA Regional Office, or statewide committees established through Governors' offices. *Id.*

271. EDF Letter, *supra* note 256, at 2.

272. See, e.g., Agracetus Letter, *supra* note 258, at 1.

273. Comments of the Industrial Biotechnology Association on EPA's Approach to Regulating Biotechnology Under TSCA 12-13 (May 15, 1989).

274. National Science Foundation, Comments on Draft Version of Proposed Rules for Regulating Certain Microbial Products of Biotechnology Under Toxic Substances Control Act 2 (June 7, 1988) (W.F. Harris).

275. The choice of methods is also related to degree of risk. Since the case-by-case method permits an agency to take all individual circumstances into account, it may be more appropriate for the regulation of significantly dangerous risks.

276. ACUS, Federal Regulation of Cancer-Causing Chemicals, 1 C.F.R. § 305.82-5 (1988)

larly, agencies could rely on generic rules for regulating biotechnology when appropriate. If generic rules can be used to forestall repetitive disputes in case-by-case proceedings, the public will be well served. In light of the disagreement concerning the risks of environmental releases, however, agencies should be careful to rest generic rules only on those scientific principles for which a consensus exists.

Several agencies have relied on negotiated rulemaking for drafting the text of proposed regulations in the past few years. Regulatory negotiation may assist agencies in adopting generic regulations, but agencies must be careful to use it only for appropriate issues.²⁷⁷ Regulatory negotiation is unlikely to succeed where fundamental value conflicts prevent negotiation over the outcome or where a matter involves so few issues that tradeoffs between parties are impossible.²⁷⁸ An example of an inappropriate topic is the issue of whether EPA should exempt well-characterized noncoding regulatory regions from TSCA's reporting requirements. On the other hand, regulatory negotiation may be very useful for less controversial topics such as designing the role, functions, and makeup of EPA's proposed EBC's.²⁷⁹ In fact, EPA has hired the Conservation Foundation to determine whether mediation concerning EBC's is feasible.²⁸⁰

Another Administrative Conference recommendation for regulating carcinogens, which is appropriate for biotechnology, is that agencies develop "systematic statements" of the principles they will apply in risk assessment and management.²⁸¹ FDA's "Points To Consider" documents, which give specific and detailed guidance to drug and biological manufacturers concerning what information the agency needs to resolve in recurring scientific issues, already use this technique for regulating biotechnology.²⁸²

The use of policy statements would also mitigate one of the primary disadvantages of a case-by-case approach. Under a case-by-case approach, regulated entities and other interested parties often have a limited basis for predicting what principles an agency will use to resolve future cases. This is particularly true when the agency does not publish a

[hereinafter Recommendation 82-5].

277. Perritt, *Analysis of Four Negotiated Rulemaking Efforts*, in ACUS, RECOMMENDATIONS AND REPORTS 677-745 (1985). The idea has received a strong endorsement from the Administrative Conference. See ACUS, Procedures for Negotiating Proposed Regulations, 1 C.F.R. §§ 305.85-5, 305.82-4 (1988).

278. See Harter, *Negotiating Regulations: A Case of Malaise*, 71 GEO. L.J. 1, 42-52 (1982); see also Perritt, *supra* note 277, at 671-75.

279. See, e.g., *supra* text accompanying notes 267-74 (EPA proposes to enlist local EBC's to approve certain activities).

280. Interview with Anne Hollander, Associate, The Conservation Foundation, in Washington, D.C. (June 1, 1989).

281. See Recommendation 82-5, *supra* note 276.

282. See *supra* note 246 and accompanying text.

complete explanation of its actions or when its explanation is not widely available.²⁸³ Policy statements would enable industry and others to better anticipate agency action. Moreover, unlike generic rules, policy statements are easily modified to reflect new scientific developments.²⁸⁴

Agencies can, however, fall into three traps in utilizing policy statements. First, unless agencies revise statements to reflect new scientific developments, the documents may be misleading to those who depend on them to indicate the agency's intentions.²⁸⁵ Second, agencies may be tempted to treat policy statements as if they were binding regulations. When this happens, policy statements become *de facto* generic rules adopted without the benefit of a rulemaking process. Third, policy statements can easily lose their legitimacy if they fail "to distinguish between elements that are intended to summarize current scientific consensus and others that represent policy judgments reached in the absence of consensus."²⁸⁶ If agencies avoid these problems, the expanded use of policy statements would improve the regulatory process.

Agencies should also consider consulting their science or policy advisory committees for assistance in the development of policy statements.²⁸⁷ Agencies could also hold one or more "consensus workshops" to which industry and environmental representatives would be invited.²⁸⁸ Even if no overall consensus was developed at these workshops, an agency would have the benefit of knowing where the parties agree and disagree.

As agencies improve their capacity for risk assessment, they should be able to increase the efficiency of the regulatory process by adopting generic rules. With an improved understanding of the risks biotechnology poses to humans and to the environment, agencies can better decide whether to exempt some areas of biotechnology from regulation and whether to resolve recurring issues in a generic manner. In the meantime, agencies can improve the effectiveness of the regulatory process by utilizing policy statements wherever sufficient information exists

283. See generally Malloy, *Balancing Public Confidence and Confidentiality: Adjudication Practices and Procedures of the Federal Bank Regulatory Agencies*, 61 TEMPLE L. REV. 723, 791-93 (1988).

284. See Recommendation 82-5, *supra* note 276 ("Where scientific developments in the near term are likely to require modification, or where individual studies or chemicals are often likely to deviate from the 'norm', [agency statements] should not be framed as binding rules.").

285. See J. GIBBS, I. COOPER & B. MACKLER, *supra* note 83, at 116.

286. Recommendation 82-5, *supra* note 276.

287. See *infra* text accompanying notes 378-417.

288. The usefulness of this approach is suggested by the experience of the Keystone Center, which has been successful in conducting consensus workshops on technical issues relevant to questions of public policy concerning natural resources, including biotechnology. See, e.g., KEYSTONE NATIONAL BIOTECHNOLOGY FORUM, INTERIM SUMMARY REPORT: AN ANALYSIS OF THE FEDERAL FRAMEWORK FOR REGULATING PLANNED INTRODUCTIONS OF ENGINEERED ORGANISMS (1989).

to indicate what principles or types of data will be used in making regulatory determinations.

V

IMPROVING REGULATORY PROCEDURES: USING PUBLIC PARTICIPATION TO INCREASE LEGITIMACY

In the design of a regulatory system for biotechnology, decisionmakers must also choose what procedures an agency will use to make regulatory determinations. Two principle issues are involved. First, an agency must determine the form and extent of public participation. This involves deciding both what type of procedures will be used and who will be able to participate. For example, should agencies make special efforts to notify citizens who live near the sites of proposed field tests of genetically engineered organisms? Agencies must also address a related issue: how should the public's interest in reviewing the scientific data underlying a decision be balanced against industry's interest in protecting confidential information? Second, the agency must determine what role, if any, technical advisory committees should play in the decisionmaking process.

Resolving these issues will involve agencies in the ongoing debate concerning the value of public participation in agency decisionmaking. Critics of public participation believe that because most citizens lack the training to understand complicated scientific issues, their participation delays decisionmaking without creating offsetting benefits.²⁸⁹ Worse, critics fear irrational public reactions,²⁹⁰ such as the efforts of some communities to ban DNA research when it was first introduced.²⁹¹

Supporters of public participation make two responses. First, they contend that the critics ignore the value of public participation in establishing the legitimacy of regulatory decisions. Public participation in agency decisionmaking builds greater public acceptance of new technologies.²⁹² Second, public participation can increase the accuracy of agency decisions. Most Institutional Biosafety Committee (IBC) chairpersons

289. Goggin, *Governing Science and Technology: Reconciling Science and Technology with Democracy*, in *GOVERNING SCIENCE AND TECHNOLOGY IN A DEMOCRACY* 263 (M. Goggin ed. 1986).

290. Jennings, *Representation and Participation in the Democratic Governance of Science and Technology*, in *GOVERNING SCIENCE AND TECHNOLOGY IN A DEMOCRACY* 227-29 (M. Goggin ed. 1986).

291. See S. KRIMSKY, *GENETIC ALCHEMY: THE SOCIAL HISTORY OF THE RECOMBINANT DNA CONTROVERSY* 294-311 (1982).

292. See Jennings, *supra* note 290, at 235. For example, public distrust of nuclear power can be traced in part to the secrecy of government decisionmaking in the industry's early years. See Cole, *Resolving Science Controversies: From Science Court to Science Hearing Panel*, in *GOVERNING SCIENCE AND TECHNOLOGY IN A DEMOCRACY* 247-49 (M. Goggin ed. 1986); see generally D. FORD, *THE CULT OF THE ATOM: THE SECRET PAPERS OF THE ATOMIC ENERGY COMMISSION* (1982).

report that public representatives have "contributed positively" to their review process.²⁹³ While not every member of the public may be as sophisticated as public representatives to IBC's, many informed citizens do have the capacity to contribute.²⁹⁴

Although both sides of this debate have merit, there are good reasons for favoring increased public participation in the regulation of biotechnology. Because biotechnology poses questions of risk assessment and risk management that necessarily involve policy judgments, an agency's recognition of public concerns can help to build confidence in its determinations. This confidence is necessary to avoid an irrational public reaction. Moreover, as the following analysis indicates, agencies have available to them procedures for public participation that do not significantly slow agency decisionmaking. Thus, they can avoid the criticism that the value of public participation is outweighed by the delay it causes.

A. Current Procedures

Most regulatory decisions concerning biotechnology are made without a hearing. However, agencies do generally solicit public input by inviting written public comments. Regulators may also seek additional comments from other agencies, their own advisory committees, or independent scientific organizations.

1. EPA

EPA approves pesticide registrations by informal adjudication, but with notice to the public that an application has been received and that comments are invited. FIFRA requires EPA to publish a notice of the receipt of any application for pesticide registration that involves a new ingredient or new use.²⁹⁵ EPA then allows thirty days for public com-

293. U.S. GEN. ACCOUNTING OFFICE, BIOTECHNOLOGY: ROLE OF INSTITUTIONAL BIOSAFETY COMMITTEES 9 (1987) [hereinafter INSTITUTIONAL BIOSAFETY COMMITTEES].

294. In addition, public sophistication about biotechnology is increasing. Government agencies such as USDA (interview with Al Young, Director, Office of Agricultural Biotechnology, USDA, in Washington, D.C. (June 14, 1988) [hereinafter Young Interview]), nonprofit groups like the Keystone Center (see KEYSTONE NATIONAL BIOTECHNOLOGY FORUM, *supra* note 288), and biotechnology companies (see Naj, *Clouds Gather Over the Biotech Industry*, Wall St. J., Jan. 30, 1989, at B1, col. 3 (Monsanto sponsored public information campaign to gain public approval for environmental release)), are sponsoring or facilitating public education efforts. These efforts have had an effect in moderating public opinion. A recent poll conducted for the Office of Technology Assessment (OTA) indicates that the public generally favors the development of biotechnology with appropriate regulatory controls. See OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONG., NEW DEVELOPMENTS IN BIOTECHNOLOGY—BACKGROUND PAPER: PUBLIC PERCEPTIONS OF BIOTECHNOLOGY (1987). OTA found that a majority (55%) of the public agree that the risks of biotechnology have been greatly exaggerated, but also that more than three-fourths of the public agree that "strict regulation" is necessary. *Id.* at 81.

295. FIFRA, 7 U.S.C. § 136a(c)(4) (1988).

ment on the application.²⁹⁶ EPA must also publish a notice of the receipt of any Environmental Use Permit (EUP) application that is of "regional or national significance."²⁹⁷ Since FIFRA requires pesticide manufacturers to obtain an EUP before performing field tests,²⁹⁸ this serves to inform the public whenever an experimental release is planned. If public comments indicate "sufficient interest" in the application, or if it would otherwise be in the "public interest," EPA "may" hold a hearing concerning an EUP.²⁹⁹

EPA uses similar procedures under TSCA. TSCA also requires EPA to publish a notice of the receipt of any premanufacture notification (PMN).³⁰⁰ However, PMN's are subject to no other procedural requirements unless EPA attempts to limit the sale of a substance³⁰¹ or to order that it be tested.³⁰² In such cases, EPA must use hybrid rulemaking involving both a notice and comment procedure and a hearing.

In addition to obtaining public input, EPA's Office of Pesticide Programs and its Office of Toxic Substances have two additional ways to obtain advice when a regulatory decision presents significant issues. First, the issues may be given intra-agency review by other EPA programs and offices, interagency review by other BSCC members, or advisory committee review.³⁰³ Second, agency staff may informally consult with scientific experts, members of industry or environmental interest groups, or other parties.³⁰⁴

296. 7 C.F.R. § 152.102 (1988). EPA will also publish a notice of the issuance of a registration. *Id.* If EPA disapproves the application, the registrant is entitled to a hearing. FIFRA, 7 U.S.C. §§ 136c(6), 136d (1988) (denial of registration and option for public hearings).

297. 40 C.F.R. § 172.11(a) (1988). EPA must also publish a notice of the issuance of any Environmental Use Permit. *Id.* § 172.11(c).

298. 7 U.S.C. § 136c (1988).

299. 40 C.F.R. § 172.11(b); *see also* FIFRA, 7 U.S.C. § 136s(b) (1988) (Administrator may solicit views concerning pesticide registration).

300. TSCA, 15 U.S.C. § 2604(d)(2) (1988). A manufacturer of chemical substances is required to file a PMN before it manufactures a new chemical substance, or manufactures or processes a chemical substance for a use determined to be "a significant new use." *Id.* § 2604(a)(1). The notice includes the specific identity of the chemical substance, the categories of its use, a list of data submitted by the manufacturer, and the submitter's identity. 40 C.F.R. § 720.70(a)-(b) (1988). This information, however, will not be disclosed if it is confidential business information. 40 C.F.R. §§ 720.70(b), 720.87; *see infra* text accompanying notes 351-53.

301. *See* 15 U.S.C. § 2605(c) (1988).

302. *Id.* § 2603(b)(5).

303. Rispin Interview, *supra* note 120. For the last purpose, EPA has established the Biological Science Advisory Committee (BSAC), which is composed of nine scientists and two persons representing the general public. EPA, Establishment of the Biotechnology Science Advisory Committee, 51 Fed. Reg. 24,221 (1986).

304. Carpien Interview, *supra* note 155 (Office of Toxic Substances consultations); 40 C.F.R. § 155.30 (1988) (meetings and communications concerning FIFRA registration standards).

2. USDA

USDA's Animal and Plant Health Inspection Service uses informal adjudication to review applications to move plants that are pests or to release them into the environment.³⁰⁵ When it receives such an application, APHIS also gives notice and invites public comments.³⁰⁶ APHIS—unlike EPA—is not required by statute to invite public comment because the Federal Plant Pest Act (PPA) has no provision for public participation.³⁰⁷ In addition, APHIS forwards a copy of each application to the agriculture department in the state where the release will occur,³⁰⁸ as well as a copy of its initial review.³⁰⁹

Although PPA does not specify decisionmaking procedures for approving the release of plant pests, APHIS is subject to the National Environment Policy Act, which does so specify. NEPA requires APHIS either to make and publish a finding of “no significant impact on the environment” or to write an Environmental Impact Statement.³¹⁰

Finally, APHIS, like EPA, may obtain intra-agency review by USDA's Science and Education division and the Office of Agricultural Biotechnology, or interagency review by other BSCC members.³¹¹ APHIS may also seek advisory committee review by consulting the department's Agricultural Biotechnology Research Advisory Committee (ABRAC) or chartering an ad hoc advisory committee.³¹²

305. Medley Interview, *supra* note 117.

306. See APHIS, Receipt of a Permit Application for Release into the Environment of Genetically Engineered Organisms, 53 Fed. Reg. 40,482 (1988). APHIS may also inspect the site where a release is to occur or where pests are to be contained after their movement. 7 C.F.R. § 340.3(d) (1988).

APHIS holds a hearing only for an applicant whose permit was denied. If a permit is denied or withdrawn, a person may appeal in writing to the Deputy Administrator within 10 days. *Id.* § 340.3(g). Any material disputes as to facts shall be resolved by a “hearing” with rules of practice as adopted by the administrator. *Id.*

307. See 7 U.S.C. §§ 147a-149 (1988). Like the Federal Plant Pest Act, the other statutes under which USDA regulates biotechnology products do not establish a mechanism for public comment concerning agency adjudications. See Virus, Serum, Toxin Act, 21 U.S.C.A. §§ 151-159 (West 1972 & Supp. 1989); Poultry Products Inspection Act, 21 U.S.C. §§ 451-470 (1988); Federal Meat Inspection Act, 21 U.S.C. §§ 601-695 (1988). A hearing is available only to the regulated entity if USDA takes an action adverse to it. See 21 U.S.C. §§ 156 (Virus, Serum, Toxin Act); 21 U.S.C. § 467(b) (Poultry Products Inspection Act); 21 U.S.C. § 671 (Federal Meat Inspection Act).

308. 7 C.F.R. § 340.3(b) (1988).

309. See, e.g., Letter from Arnold Foudin, Acting Deputy Director, Biotechnology Permit Unit, Biotechnology, Biologics, and Environmental Protection, APHIS, USDA, to Howard M. Singletary, Plant Pest Administrator, North Carolina Department of Agriculture (Dec. 30, 1988) (concerning APHIS Preliminary Review of Rohm and Haas Application to Field Test Genetically Engineered Insect Resistant Tobacco Plants).

310. See 40 C.F.R. § 1508.9 (1988); see, e.g., USDA, Availability of Environmental Assessment and Finding of No Significant Impact Relative to Issuance of a Permit to Field Test Genetically Engineered Insect Resistant Tobacco Plants, 54 Fed. Reg. 14,123-24 (1989).

311. Medley Interview, *supra* note 117.

312. *Id.* See *infra* text notes 382-83 and accompanying text.

USDA also informally adjudicates decisions concerning its research guidelines, but with the participation of advisory committees. In some cases, ABRAC advises the Assistant Secretary for Science and Education on whether a proposed research project will comply with the guidelines.³¹³ In other cases, the Institutional Biosafety Committee for the institution that received the research grant is delegated the authority to determine compliance.³¹⁴

3. FDA

FDA also approves new drugs by informal adjudication. The procedure usually includes consultation with advisory committees,³¹⁵ but does not provide for public participation.³¹⁶ The advisory committees are composed of persons with medical or other scientific expertise.³¹⁷ Veterinary drugs present the only exception to this decisionmaking pattern. Because administration of these drugs may involve the environmental release of organisms, FDA may be required to comply with NEPA for applications to test a veterinary drug.³¹⁸

Unlike approval of drugs, FDA's approval of food additives involves public participation. Any person may petition FDA to establish a regulation to approve the use of a food additive.³¹⁹ If FDA concurs that a regulation should be promulgated, it must publish a notice of its decision

313. Despite its name, ABRAC also serves as an advisory committee for regulatory functions. See USDA, Agricultural Biotechnology Research Advisory Committee, Members and Alternates (Aug. 18, 1988). ABRAC is composed of eleven scientists and two lawyers. The scientists include persons with backgrounds in animal science and veterinary medicine, ecology and environmental science, entomology, immunology, industrial microbiology, microbiology and plant pathology, and plant science. *Id.*

314. Young Interview, *supra* note 294.

315. FDA consults standing advisory committees for most applications. Cheaper, *Scientific Issues and the Function of Hearing Procedures: Evaluating the FDA's Public Board of Inquiry*, 1986 DUKE L.J. 288, 302 & n.100 [hereinafter *Public Board of Inquiry*].

316. For new drugs, the Food, Drug, and Cosmetic Act mandates a decisionmaking process consisting of several steps, each requiring the drug manufacturer to submit different types of testing data. The Act, however, has no provisions for public input. Manufacturers must present a three-phase test of a drug on human beings and at least two well-controlled clinical studies. 21 U.S.C. § 355(a) (1988); 21 C.F.R. § 314.5 (1989). See also Cheaper, *Divorcing Profit Motivation from New Drug Research: A Consideration of Proposals to Provide Reliable Test Data*, 1978 DUKE L.J. 155, 157. Before human trials can commence, however, the manufacturer must submit a Notice of Claimed Investigation Exemption for a New Drug containing the results of *in vitro* and animal studies on the pharmacologic and toxic effects of the drug. 21 C.F.R. § 312.20; Cheaper, *supra*, at 157-58. If FDA refuses to approve an application, a drug manufacturer is entitled to a formal adjudicatory hearing or several informal methods of resolving its dispute. 21 U.S.C. § 355(c)(2); 21 C.F.R. § 314.200. An applicant can have a hearing before a Public Board of Inquiry (a three-person scientific panel), before an advisory committee, or before the Commissioner of FDA. *Public Board of Inquiry*, *supra* note 315, at 290.

317. See *infra* note 386 and accompanying text.

318. von Oehsen, *supra* note 10, at 853-61.

319. 21 U.S.C. § 348(b)(1) (1988).

in the *Federal Register*.³²⁰ Within thirty days of this notice, any person adversely affected by the proposed decision may request a hearing.³²¹

B. *Designing Improved Procedures for Public Participation*

The current pattern of public participation presents three issues. First, is notice and comment adjudication adequate to ensure accurate and legitimate agency decisions? Second, should there be additional procedures to enable persons located near the site of proposed field tests of bioengineered organisms to participate in the decisionmaking process? Third, can FDA justify a process for approval of bioengineered drugs that has no public participation?

1. *Notice and Comment Adjudication*

Public participation in decisions about biotechnology occurs almost exclusively by written comments.³²² Limiting public participation to written comments is associated with informal rulemaking. This regulatory procedure is usually considered suitable for health and environmental disputes because such disputes are dominated by questions that typically do not involve adjudicatory facts, which require objective determinations, but rather involve "legislative facts" or value judgments.³²³ Questions of biotechnology risk assessment and risk management similarly do not have objective answers,³²⁴ and therefore also involve "legislative facts" or policy judgments. This suggests that the use of a notice and comment procedure should generally be adequate to promote the accuracy and legitimacy of regulatory decisionmaking for biotechnology.³²⁵

Both EPA and USDA invite public comments during their regulatory decisionmaking for biotechnology, although only EPA is under stat-

320. *Id.* § 348(e).

321. *Id.* § 348(f)(1).

322. Note that while the approval of food additives may require a hearing, FDA does not provide for public participation in the approval of new drugs. See *supra* note 316 and accompanying text.

323. *Public Board of Inquiry*, *supra* note 315, at 297. The framers of EPA chose informal rulemaking for the production of regulations because they assumed that disputes concerning "legislative facts" did not require a highly developed advocacy process. *Id.* at 296. Legislative facts, in Professor Davis' characterization, are "general facts which help the tribunal decide questions of law, policy, and discretion." Davis, *The Requirement of a Trial-Type Hearing*, 70 HARV. L. REV. 193, 199 (1956). Hearings were reserved for disputes concerning "adjudicatory facts" or facts that are capable (at least theoretically) of an objective determination. *Public Board of Inquiry*, *supra* note 315, at 296. "Adjudicatory facts" are facts that answer "the questions of who did what, where, when, how, why, with what motives and intent." Davis, *supra*, at 199.

324. See *supra* text accompanying notes 50-81, 223-88.

325. See McGarity, *Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA*, 67 GEO. L.J. 729, 732 (1979); Yellin, *High Technology and the Courts: Nuclear Power and the Need for Institutional Reform*, 94 HARV. L. REV. 489, 549 (1981).

utory requirement to do so.³²⁶ The fact that USDA is not formally required to invite public participation may discourage public comment by creating the appearance that such comments are not considered. Moreover, without a formal requirement, APHIS could withdraw its procedure for public participation on a whim. For these reasons, APHIS should adopt regulations that specify how the public can participate in its decisionmaking process.

A notice and comment procedure may ordinarily be adequate for public input, but certain situations arguably call for agencies to consider holding informal hearings. Hearings can increase the legitimacy of the decisionmaking process in cases involving significant public interest.³²⁷ Similarly, hearings can increase the accuracy of decisions in scientifically complex cases by clarifying what inferences the agency and the parties have drawn from the scientific data in their assessments.³²⁸ EPA's regulations under FIFRA specify that it "may" hold a hearing concerning an Environmental Use Permit if public comments indicate "sufficient interest" in the application or it would otherwise be in the "public interest."³²⁹ Other agencies would do well to follow this example.

2. *Local Participation*

Current procedures have one major deficiency that is undermining public confidence in the regulation of biotechnology: they do not enable citizens who live near the release site of engineered organisms to comment on pending agency decisions except in the unlikely case that they read the *Federal Register*. Agencies have recognized the need for local input in such cases; however, none of their responses ensures that local public notice will always occur.

Current efforts to encourage local participation take three forms. First, agencies sometimes notify local officials of pending environmental releases.³³⁰ Second, some decisions involve local institution based review

326. See *supra* text accompanying notes 295-302, 305-309.

327. See Jennings, *supra* note 290, at 240-41.

328. *Public Board of Inquiry*, *supra* note 315, at 298.

329. See *supra* note 299 and accompanying text.

330. For example, USDA sends a copy of each Federal Plant Pest Act application for an environmental release to the applicable state agricultural officials. See *supra* notes 308-09 and accompanying text.

committees with public representation.³³¹ Third, for some decisions, local review committees must seek public input.³³²

In some cases, these steps will still leave the public without notice of pending agency decisions. Notification of state officials will not necessarily result in local notice, nor do institution-based review committees—whether Institutional Biosafety Committees or Environmental Biosafety Committees—ensure local notice.³³³ First, local review committees are not always consulted. EPA's decisions concerning pesticides might not involve EBC's, for example.³³⁴ Likewise, APHIS's decisions concerning plant pests would not involve IBC's.³³⁵ Second, public representation on these committees does not guarantee local notice. A General Accounting Office study of research sponsored by the National Institutes of Health found that a majority of IBC chairpersons did not feel that public members provided a sufficient mechanism for notifying the community about recombinant DNA research activities.³³⁶ Third, only EPA is proposing that institution-based review committees be required to seek local participation. USDA proposes that IBC's decide for themselves whether to notify the public and seek comments.³³⁷

The hit-and-miss nature of provisions for local public notification may reflect agency fears that notification will delay agency decisionmaking or invite irrational public reactions. These concerns, however, are unfounded. The idea of local notice is to provide citizens who do not read the *Federal Register* an opportunity to file written comments; this step need not unduly delay an agency.³³⁸ Moreover, as noted earlier, the

331. For example, both USDA's draft proposed guidelines for research and EPA's draft proposed TSCA regulations require review committees (IBC's or EBC's) to have at least two public members. USDA DRAFT GUIDELINES, *supra* note 106, § XIIB-1-b. An IBC must have at least six members with technical expertise and at least two members not affiliated with the institution who represent the interests of the community. *Id.* § XIIB-1. EBC's would be required to have at least three technical members and at least two public members. EPA DRAFT RULE, *supra* note 132, at 196.

332. EPA's proposed TSCA rules, for example, would require EBC's to "take measures to ensure that the public has an opportunity to participate in the review process," including "active solicitation of public comments" and "opening EBC meetings to public attendance." EPA DRAFT RULE, *supra* note 132, at 209. Meetings could be closed to discuss confidential business information. *Id.*

333. See *supra* text accompanying notes 267-74.

334. See *supra* text accompanying note 234.

335. See *supra* text accompanying notes 239-43.

336. INSTITUTIONAL BIOSAFETY COMMITTEES, *supra* note 293, at 11.

337. IBC's would not be required to hold open meetings, although USDA would "encourage" them to do so whenever possible. An IBC would be obligated to notify the public and solicit comments only if it decided to make its meeting public. USDA DRAFT GUIDELINES, *supra* note 106, § XIIB-2a.

338. The agency is free to limit the time period for comment to 30 days or some other short time period. Moreover, if the agency has already invited comments from those persons who receive notice in the *Federal Register*, the agency can use the same time period to receive comments from those responding to local notice. See *supra* text accompanying notes 319-21.

availability of public participation could legitimize the agency's decision-making and therefore reduce irrational reactions.³³⁹ It can also assist the agency. Local review committee chairpersons consider public representatives to have "contributed positively" to their review process,³⁴⁰ suggesting that informed local citizens have the capacity to increase the quality of agency decisionmaking.

Thus a local notice and comment procedure could be useful, at least in cases that present more than *de minimis* risks. Agencies should develop criteria that would require local notice any time the release of organisms impacts citizens living near the release site in a different manner than other citizens. For instance, the regulated entity could be required to place notices in a newspaper in the locality of the site of the release.³⁴¹ Similarly, the local institution based review committee could be required to give local notice whenever it had responsibility for making decisions.

3. *Adjudication Without Public Participation*

FDA is the only agency that resolves the safety of engineered organisms without inviting public comment. The process for approving new drugs is closed due to three reasons. First, FDA treats all health and safety information submitted to it as confidential.³⁴² The unavailability of this information limits the value of public input.³⁴³ Second, the agency apparently believes that new drug regulation involves such scientifically complex issues that public input would be of uncertain use, even if testing data were available.³⁴⁴ Third, FDA depends heavily on technical advisory committees for input and peer review,³⁴⁵ which it may consider a form of public participation.

The exclusion of the public from FDA's regulatory decisionmaking concerning new biotechnology products is indefensible. As noted earlier in this section, public input adds democratic legitimacy to agency decisionmaking, and it may provide an agency with useful advice. Moreover, FDA's confidentiality policies need not bar public participation. FDA currently releases summaries of testing data for public consideration at

339. See *supra* text accompanying notes 322-29.

340. See INSTITUTIONAL BIOSAFETY COMMITTEES, *supra* note 293, at 9.

341. See H.R. 4452, 99th Cong., 2d Sess. (1986). The purpose of the notice would be to describe the nature and extent of the proposed release. *Id.* It might also be useful to require the regulated entity to notify local government officials. *Id.*

342. See *infra* text accompanying notes 365-69.

343. McGarity & Cheaper, *The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies*, 93 HARV. L. REV. 837, 843 (1980). Where health and safety information is confidential, public input is not based on informed and independent scientific judgment. *Id.*

344. This conclusion is inferred from the fact that FDA does not have nonscientific members on its new drug advisory committees. See *infra* note 386 and accompanying text.

345. See *infra* text accompanying notes 384-86.

open meetings of advisory committees and other forums.³⁴⁶ FDA could routinely make such summaries available for purposes of public comment without compromising the need to protect confidential business information.

C. Confidential Business Information

Whatever procedures are used, the extent and value of public participation is a function of how much information is available to the public. Environmental groups assert that overzealous protection of scientific data limits public involvement in agency decisionmaking. Biotechnology companies contend that there is too little protection for proprietary data. Creating acceptable agency disclosure policies is central to establishing a legitimate and accurate regulatory system for biotechnology.

1. Current Practices

Current disclosure practices result from the interaction of three laws. First, government employees are subject to criminal penalties under the Trade Secrets Act for the disclosure of "confidential information," unless such disclosure is "authorized by law."³⁴⁷ Second, "exemption four" of the Freedom of Information Act permits agencies to withhold "trade secrets and commercial and financial information obtained from a person as privileged or confidential."³⁴⁸ While the tests for trade secrets³⁴⁹ and confidential commercial information³⁵⁰ differ, both seek to protect information that would be of commercial value to a firm's competitors. Third, Congress has ordered EPA and FDA to release

346. See *infra* notes 366-67 and accompanying text. Greater disclosure of health and safety data may also be warranted. See *infra* text accompanying notes 371-77.

347. 18 U.S.C. § 1905 (1988).

348. 5 U.S.C. § 552(b)(4) (1988); see *Chrysler Corp. v. Brown*, 441 U.S. 281, 291 (1979). The Supreme Court considers the scope of FOIA and the Trade Secrets Act to be effectively the same. *Chrysler Corp.*, 441 U.S. at 319 n.49.

349. The *Restatement of Torts* defines "trade secret" as "any formula, pattern, device, or compilation of information which is used in one's business and which gives him an opportunity to obtain an advantage over competitors who do not know or use it." *RESTATEMENT OF TORTS* § 757, comment b at 5 (1939); see also 12 *MILGRIM ON TRADE SECRETS* § 2.01 (1988). Most courts follow this definition. *McGarity & Cheaper*, *supra* note 343, at 862. However, *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280 (D.C. Cir. 1983), narrowed the definition by defining "trade secret" as "a secret, commercially valuable plan, formula, process or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Id.* at 1288 (definition to be used solely for the purpose of the FOIA exemption).

350. Exemption four of FOIA has three requirements: Information must be commercial or financial, obtained from a person, and confidential or privileged. 5 U.S.C. § 552(b)(4) (1988). Information is "confidential" if its disclosure would "impair the Government's ability to obtain necessary information in the future" or "cause substantial harm to the competitive position of the person from whom the information was obtained." *National Parks & Conservation Ass'n v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974).

some types of scientific data in certain circumstances. In these cases, the Trade Secrets Act does not apply since disclosure is "authorized by law."

a. EPA

FIFRA requires EPA to protect confidential business information except under two circumstances. Health and safety testing data is disclosed for "registered" pesticides, and data concerning the "production, distribution, sale, or inventories of a pesticide" may be disclosed "in connection with a public proceeding" if disclosure is "necessary in the public interest."³⁵¹ Similarly, TSCA requires EPA to protect confidential business information, except that health and safety testing data is disclosed when a substance "has been offered for commercial distribution."³⁵² Thus, while TSCA and FIFRA permit the eventual disclosure of testing data, neither one permits disclosure of data that qualifies as confidential business information during EPA's decisionmaking process. For example, when EPA publishes a notice that it has received a premanufacture notice, it deletes the submitter's identity and publishes only "generic" descriptions of the chemical and its uses if this information is confidential business information.³⁵³

Another problem constrains public participation at EPA. EPA often fails to determine whether or not data is confidential in time to release nonconfidential portions to persons seeking to comment on a pending decision.³⁵⁴ For example, EPA regulations seem to require that EPA must decide whether to require testing of the chemical substance or restrict its sale within ninety days of the receipt of a PMN.³⁵⁵ Even if EPA receives a Freedom of Information Act request immediately after publishing a notice that it has received a PMN, it may be unable to determine the validity of a manufacturer's confidential business information claim before a decision on the PMN is due.³⁵⁶

EPA has taken two steps to mitigate this problem. First, under its "up-front" documentation policy, it requires manufacturers to justify their confidentiality claims at the time they submit data instead of waiting until someone files a Freedom of Information Act request.³⁵⁷ Second, as part of an announced policy of maximum possible disclosure,

351. FIFRA, 7 U.S.C. §§ 136h(b), h(d) (1988); see 40 C.F.R. § 152.119 (1988). EPA is prohibited from "knowingly" disclosing data to "foreign and multinational pesticide producers." 7 U.S.C. § 136h(g). There are restrictions on the subsequent use of the data submitted by domestic manufacturers to register their own products. *Id.* § 136a.

352. TSCA, 15 U.S.C. § 2613(b)(1)(A)(i) (1988); see 40 C.F.R. § 720.90 (1988).

353. 40 C.F.R. § 720.70 (1988); see *id.* §§ 720.80, 720.85.

354. Mellon Interview, *supra* note 199; see also Evans Interview, *supra* note 120.

355. See TSCA, 15 U.S.C. § 2604(a) (1988).

356. Mellon Interview, *supra* note 199; see also Evans Interview, *supra* note 120.

357. Interview with Bob Nicholas, McDermott, Will & Emery, in Washington, D.C. (May 9, 1989); Evans Interview, *supra* note 120.

EPA encourages the biotechnology industry to refrain from making broad confidentiality claims.³⁵⁸ Companies have agreed to comply with this policy in order to build public confidence in the safety of their products and the legitimacy of the regulatory process.³⁵⁹

b. USDA

During its decisionmaking process, APHIS is bound by the Trade Secrets Act not to disclose confidential business information.³⁶⁰ When APHIS receives an application for a permit to release a plant pest into the environment, it sends a copy of the application to the appropriate officials,³⁶¹ but withholds any information designated by the applicant as confidential business information.³⁶² Moreover, unlike the situation at EPA, Congress has not required that APHIS disclose the data at a later time. APHIS also has a problem of responding to Freedom of Information Act requests before its deadline for making a decision.³⁶³ To minimize this problem, APHIS also lobbies biotechnology manufacturers to limit their confidential business information claims.³⁶⁴

c. FDA

FDA has the most restrictive confidential business information policies. Unlike EPA and USDA, FDA does not publish a notice of the receipt of an application to market a new drug.³⁶⁵ Furthermore, no data is disclosed during the approval process, although FDA does release summaries of the safety and effectiveness data after a drug is approved.³⁶⁶ FDA may at its discretion publicly release summaries of "selected" portions of safety and effectiveness data while an application is pending.³⁶⁷ Finally, although Congress requires that actual health and safety testing data for a new drug be released once another manufacturer is eligible to sell the drug, it permits that data to be withheld if "extraordinary circumstances are shown."³⁶⁸ Because FDA defines "extraordinary cir-

358. See EPA, Statement of Policy; Microbial Products Subject to Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic Substances Control Act, 51 Fed. Reg. 23,313, 23,319 (1986).

359. See M. MELLON, *supra* note 3, at 52.

360. See APHIS, Policy Statement on the Protection of Privileged or Confidential Business Information, 50 Fed. Reg. 38,561 (1985).

361. See *supra* text accompanying notes 308-09.

362. 7 C.F.R. § 340.3(a)-(b) (1988).

363. APHIS regulations require that it make a decision concerning the environmental release of a pesticide within 120 days. *Id.* § 340.3(b).

364. Medley Interview, *supra* note 117.

365. Applications for FDA Approval to Market a New Drug or an Antibiotic Drug, 21 C.F.R. § 314.430(b) (1989). FDA will release the information if it "has been previously publicly disclosed or acknowledged." *Id.*

366. *Id.* § 314.430(e)(2).

367. *Id.* § 314.430(d).

368. Drug Price Competition and Patent Term Restoration Act of 1984 § 104, 21 U.S.C.

cumstances” to include any claim that the data is confidential business information—perhaps even a claim that the data could be used by competitors in foreign countries—little data is actually released.³⁶⁹

2. *Adequacy of Disclosure*

Under the current legal framework, a biotechnology company can seek protection for its scientific data by arguing that its competitors would be benefitted by disclosure of the data. If an agency accepts this claim, it protects the data unless the data comes within the disclosure requirements established by Congress for health and safety testing data. None of these provisions requires disclosure during an agency’s decision-making process. Nevertheless, health and environmental data are often available before EPA or USDA makes a decision because, with agency encouragement, biotechnology companies are restricting their confidential business information claims.³⁷⁰

This availability of data suggests that the existing approach is adequate. Environmentalists concede that they currently have adequate information to participate in most cases at EPA and USDA.³⁷¹ However, industry cooperation may be a weak base on which to build disclosure policies. First, not all companies are willing to disclose the information upon which agency decisions are based.³⁷² Second, the data currently being disclosed concern small-scale field testing. Companies are likely to

§ 355(l) (Supp. V 1987); see 21 C.F.R. § 314.430(f)(5) (1989).

369. 130 CONG. REC. S10988-89 (daily ed. Sept. 12, 1984) (letter of Frank Young, Commissioner, FDA, to Sen. Orrin Hatch, defining “extraordinary circumstances” to include testing data if it is shown to have commercial value to competitors). See Shacknai, *Trade Secrets under the Drug Price Competition and Patent Term Restoration Act of 1984*, 40 FOOD DRUG COSM. L.J. 329, 334-36 (1985).

Although it was settled, a recent lawsuit illustrates the effect of FDA’s policy on public participation. In 1986, three public interest groups petitioned FDA to prepare an environmental impact statement concerning applications by several pharmaceutical companies to sell bovine growth hormone, a genetically engineered animal drug that increases the milk yield of dairy cows. von Oehsen, *supra* note 10, at 856-57. FDA refused because the companies had prepared environmental assessments that concluded environmental impacts were not significant. The petitioners filed suit under FOIA seeking disclosure of the assessments and other documents on which FDA relied. *Foundation on Economic Trends v. Health & Human Serv.*, No. 87-1009 (D.D.C. settled Jan. 16, 1988), *cited in* von Oehsen, *supra* note 10, at 857. The pharmaceutical companies intervened to object that those documents contained trade secrets. According to the companies, environmental data analyzing the discharge of production wastes and drug toxicity could be used by rivals to deduce production patterns, research strategies, approximate date of market entry, and other valuable information that could give them a competitive advantage. *Id.* In this way, broad claims of confidentiality can conflict with public participation.

370. See M. MELLON, *supra* note 3, at 52.

371. See, e.g., *id.*

372. Rispin Interview, *supra* note 120; see Withers, *Biotechnology: An Industry Perspective*, 34 U. KAN. L. REV. 665, 676 (1986) (arguing that companies’ data should not be disclosed in order to speed the registration process and to protect the confidentiality of the information).

expand their confidential business information claims as they move closer to the production of commercial products.³⁷³

Existing laws permitting companies to claim confidential business information status for health and environmental data focus on whether disclosure may be harmful to a company. A more appropriate approach would be a balancing process that weighs the public interest in disclosure of health and environmental safety information against the private interest in nondisclosure of data that might incidentally give other firms a competitive advantage.³⁷⁴ Under this approach, once a microorganism or other biotechnology product was patented, a firm that wished to prevent the disclosure of health and environmental data would have the burden of demonstrating why patent protection was insufficient to protect its proprietary interest.³⁷⁵

As long as the current process is retained, agencies should require companies to narrow their confidential business information claims as much as possible. For example, companies should not be allowed to claim protection for an entire page to protect one sentence. As a last resort, agencies could publish summaries of confidential health and environmental data, which would give interested persons some idea of the information that is before the agency.³⁷⁶

373. Interview with Edward Korwek, Hogan & Hartson, in Washington, D.C. (May 31, 1989); Medley Interview, *supra* note 117.

374. See McGarity & Cheaper, *supra* note 343, at 863-64 (discussing both sides of the balancing approach).

375. McGarity & Bayer, *supra* note 8, at 475-76. Canada has taken this approach: disclosure is authorized if it is in the "public interest as it relates to public health, public safety or protection of the environment" and if it "clearly outweighs in importance" the financial loss to the "competitive position" of a company or person. Access to Information Act, 1980-83, c. 111, Sch. I §§ 20(1), 20(6), 1980-83 Can. Stat. §§ 3324, 3337-3338 (1985).

376. Although more data would be released under a balancing test, the data used by an agency to make a decision might still be treated as confidential. For example, a company could probably justify broader confidentiality claims if its product were not patented. Moreover, a balancing approach does not solve the problem of delay in adjudicating FOIA claims. To avoid these problems, Congress could order the immediate release of health and environmental data. This approach would be easiest to adopt under TSCA and FIFRA, which already limit how competitors can use another company's data to obtain regulatory approval for their own products. See Abramson, *Confidential Business Information Versus the Public's Right to Disclosure—Biotechnology Renews the Challenge*, 34 U. KAN. L. REV. 681, 698 (1986) (discussing FIFRA).

Since industry strongly objects to existing FIFRA and TSCA disclosure provisions, it is not likely to look favorably on broader disclosure requirements. For example, a Monsanto lawyer argues that "destruction of trade secrets through required disclosures" is "prevalent" at EPA. Withers, *supra* note 372, at 676. He contrasts the situation at EPA, where "foreign governments and potential competitors can engage in fishing expeditions for trade secrets and other confidential information," to that at FDA, where nondisclosure "serves the national interest not only by providing the public with safe and effective pharmaceutical products," but also by protecting "the United States' lead in the international market." *Id.* at 676-77.

Although legislative solutions to industry's concerns have been proposed, their adoption could be politically difficult. See, e.g., H.R. 4364, 99th Cong., 2d Sess. § 101 (1986) (providing for limited preregistration access to health, safety, and environmental data). This proposal,

Under the existing approach, delays in adjudicating Freedom of Information Act claims invite companies to make extensive confidential business information claims so as to frustrate disclosure during the time a decision is pending. Besides requiring documentation of confidential business information claims, or making quicker Freedom of Information Act decisions, agencies might try two other solutions to deter such abuse. First, some pesticide companies have been willing to release health and environmental data to public interest groups subject to limitations on the data's use and distribution.³⁷⁷ Agencies could encourage the use of similar confidentiality agreements for data on genetically engineered organisms. Second, agencies could also invite the public to petition for reconsideration of decisions after the data is released. This option would not prevent injuries to persons or the environment that might occur before agency action on the petition, but such a policy might help to discourage companies from abusing their right to seek protection for confidential business information.

D. Advisory Committees

The final element in the design of a regulatory process for biotechnology is to determine the role of advisory committees. Technical advisory committees can assist an agency to make accurate regulatory decisions. All three regulatory agencies rely on advisory committees, but they differ concerning committee structure, membership, and function.

1. Current Practices

EPA determines whether to consult its Biotechnology Science Advisory Committee (BSAC) on an ad hoc basis.³⁷⁸ Consultation with BSAC³⁷⁹ takes one of two forms. Either BSAC itself is consulted, or EPA forms a three-person BSAC subcommittee consisting of a BSAC member as chairperson and two other scientists who, although not BSAC

developed by a coalition of industry and environment groups, would have permitted immediate public access to health and environmental data submitted in pesticide registrations under several restrictions including time limits for viewing data, a prohibition on copying and removal, and proof that observers are neither employed by nor acting on behalf of anyone engaged in the production, sale, or distribution of pesticides. Abramson, *supra*, at 699-700. But if voluntary industry disclosure does not continue and if a balancing process does not work, Congress may have to consider forced disclosure as a last resort.

377. Abramson, *supra* note 376, at 699.

378. Evans Interview, *supra* note 120; interview with Elizabeth Milewski, Special Assistant on Biotechnology, EPA, in Washington, D.C. (May 31, 1989) [hereinafter Milewski Interview].

379. See *supra* note 303. EPA could also consult other agency advisory committees such as its Science Advisory Board or the Administrator's Toxic Substance Advisory Committee. See Ashford, *Advisory Committees in OSHA and EPA: Their Use in Regulatory Decisionmaking*, 9 SCI., TECH. & HUM. VALUES 72, 75 (1984).

members, have expertise relating to the issue under consideration.³⁸⁰ The second option is preferred when BSAC members do not have scientific expertise directly relevant to the issue under consideration.³⁸¹

USDA also uses advisory committees on an ad hoc basis.³⁸² Both APHIS and the Food Safety Inspection Service either consult the Agricultural Biotechnology Review Advisory Committee, which meets infrequently, or form an ad hoc advisory committee.³⁸³

At FDA, advisory committees are an integral part of the new drug approval process.³⁸⁴ FDA has nineteen standing new drug committees including a committee on vaccines and related biological products.³⁸⁵ Voting membership of the new drug committees is limited to persons with scientific expertise. However, depending on statutory construction, FDA's other advisory committees may have nonvoting consumer representatives.³⁸⁶

By comparison, FDA eschews the use of advisory committees for questions about food additives.³⁸⁷ Instead, it relies on scientific organizations, such as National Academy of Sciences and the Federation of

380. Evans Interview, *supra* note 120.

381. *Cf. Releasing Genetically Engineered Organisms into the Environment: Hearings Before the Subcomm. on Toxic Substances and Environmental Oversight of the Senate Comm. on Environment and Public Works*, 99th Cong., 2d Sess. 13 (1986) (testimony of John Moore, Assistant Administrator for Pesticides and Toxic Substances, EPA, that different scientific expertise is needed for the varied requests for release of microbial pesticides).

382. Medley Interview, *supra* note 117.

383. *Id.* For example, APHIS formed an ad hoc advisory committee of governmental scientists to obtain advice about a permit application for a controlled field test of a genetically engineered vaccine. See APHIS, Public Meeting; Availability of Environmental Assessment and Preliminary Finding of No Significant Impact for Field Testing a Genetically Engineered Vaccinia Vectored Rabies Vaccine, 54 Fed. Reg. 9241 (1989). About 80 people attended a public meeting of the committee, and a number of them presented their views. BIOTECH. NEWS, May 1989, at 3. Similarly, the Food Safety Inspection Service formed the National Advisory Committee on Microbiological Criteria for Foods for several reasons, including to advise FSIS on how to develop methods to detect and enumerate "microorganisms and toxic agents that are important to the safety and quality of food." See *Public Citizen v. Nat'l Advisory Comm. of Microbiological Criteria for Foods*, 708 F. Supp. 359, 360 (D.D.C. 1988), *aff'd*, 886 F.2d 419 (D.C. Cir. 1989) (citation omitted). Consumer groups have challenged the membership of this committee on the grounds that no consumer representative was included. See *infra* note 413.

384. *Public Board of Inquiry*, *supra* note 315, at 306; Brown & Richard, *Advisory Committees and the Drug Approval Process*, 2 J. CLINICAL RES. & DRUG DEV. 15, 16 (1988).

385. See 21 C.F.R. § 14.100(b)(5) (1989).

386. 21 C.F.R. §§ 14.80(b)(1), 14.80(b)(2)(i), 14.80(e) (1989). Most FDA committees consist of nine members, seven of whom are professionals in the field of the committee's subject matter. One member represents industry and one represents consumers. See Brown & Richard, *supra* note 384, at 25; Friedman, *Representation in Regulatory Decision Making: Scientific, Industrial, and Consumer Inputs to the F.D.A.*, 38 PUB. ADMIN. REV. 205, 206 (1978).

387. Interview with Jim Maryanski, Director, Center for Food Safety and Applied Nutrition, FDA, in Washington, D.C. (June 2, 1988).

American Societies for Experimental Biology (FASEB), or on ad hoc consultants.³⁸⁸

2. *Advantages and Disadvantages of Advisory Committees*

Advisory committees have several advantages. First, they can supply expertise that agencies lack, particularly for issues on the cutting edge of scientific developments.³⁸⁹ Second, committees made up of persons with national reputations can enhance the credibility of agency decisionmaking.³⁹⁰ Third, consultation with outside experts may mitigate any policy biases that the agency's staff or the industry brings to risk analysis.³⁹¹ Fourth, advisory committee meetings can provide open forums for discussion among industry, environmentalists, and other interested persons.³⁹² Finally, when health and environmental data are confidential, advisory panels may be the only way for an agency to obtain peer review of the scientific evidence on which it must base its regulatory decisions.³⁹³

Advisory committees, however, also have several disadvantages. First, scientific advisory committees sometimes depart from the confines

388. Merrill, *Federal Regulation of Cancer-Causing Chemicals*, in 2 ADMINISTRATIVE CONFERENCE OF THE UNITED STATES, RECOMMENDATIONS AND REPORTS 21, 137 (1982) (discussing mechanisms FDA uses in internal review of food additives). For example, FDA recently hired FASEB to identify and categorize the issues that will influence FDA's responsibilities for food safety for the rest of this decade. See *Food Chem. News v. Young*, 709 F. Supp. 5, 6 (D.D.C. 1989). A news organization and a consumer group successfully challenged FDA's contract with FASEB on the basis that it violated the Federal Advisory Committee Act (FACA). *Id.* For discussion of FACA, see *infra* text accompanying notes 414-15. FASEB has also been hired to consult on how FDA will regulate foods containing genetically engineered organisms, although FASEB no longer advises FDA. Interview with Alan Goldhammer, Director of Technical Affairs, Industrial Biotechnology Association, in Washington, D.C. (May 30, 1989) [hereinafter Goldhammer Interview].

389. Merrill, *supra* note 388, at 127; *Use of Advisory Committees by the Food and Drug Administration: Hearings Before a Subcomm. of the House Comm. on Government Operations*, 93rd Cong., 2d Sess. 13-15 (1974) [hereinafter *FDA Hearings*] (testimony of Alexander Schmidt, FDA Commissioner); DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, REVIEW PANEL ON NEW DRUG REGULATION, FINAL REPORT 52 (1977) [hereinafter REVIEW PANEL]. This function includes explaining complex issues and identifying areas of consensus among scientists. Ashford, *The Role of Advisory Committees in Resolving Regulatory Issues Involving Science and Technology: Experience from OSHA and EPA*, in LAW AND SCIENCE IN COLLABORATION: RESOLVING REGULATORY ISSUES OF SCIENCE AND TECHNOLOGY 166 (1983); see also NATIONAL ACADEMY OF SCIENCES/NATIONAL RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS 98 (1983) (discussing OSHA's peer review policy).

390. Merrill, *supra* note 388, at 127; *FDA Hearings*, *supra* note 389; *Public Board of Inquiry*, *supra* note 315, at 306-07.

391. Merrill, *supra* note 388, at 128. Cf. REVIEW PANEL, *supra* note 389, at 52 (FDA advisory committees are an "important source of peer review" for proposed FDA decisions).

392. Milewski Interview, *supra* note 378.

393. For example, at FDA, where health and safety data are confidential business information, see *supra* text accompanying notes 365-69, the agency makes the data available to its advisory committee members. 21 C.F.R. § 20.84 (1989).

of science, where technical expertise is critical, and wander into the realm of policy, where technical expertise has no particular virtue.³⁹⁴ Most policymakers understand this problem, but some may decide to disregard it. As long as the policy component of a science/policy question is not immediately apparent to the public, an administrator can use a committee as a shield from criticism by maintaining that the decision was based on the neutral advice of an independent scientific advisory panel.³⁹⁵

Second, although conflict of interest regulations screen out committee members with a direct financial interest in a matter,³⁹⁶ other problems of bias can emerge. An administrator may politicize the process of selecting committee members by choosing those whose past actions indicate general agreement with the administrator's policy preferences.³⁹⁷ Advisory committees can also exhibit a more subtle form of bias. Most scientists on biotechnology advisory committees work for industry as employees or consultants,³⁹⁸ employment that might subconsciously influence the type of advice they give.³⁹⁹

Finally, those who believe committee members will not give candid advice in open meetings perceive the requirement that advisory committee meetings be public as a disadvantage.⁴⁰⁰ This concern may have influenced FDA's decision to hire a contractor for advice concerning

394. Cheaper & McGarity, *supra* note 195, at 35-36; see *Public Board of Inquiry*, *supra* note 315, at 320-24.

395. For this policy to work, the administrator must ensure that a majority of the committee will supply the "proper" answer. This can be accomplished by "stacking" the committee with scientists whose past actions indicate they will generally resolve policy questions to the decisionmaker's liking. See *infra* note 397 and accompanying text.

396. See, e.g., 21 C.F.R. § 19.5 (1989) (FDA regulations).

397. For example, prior to the Reagan administration, the FDA Commissioner was responsible for all committee appointments. The decision by the Secretary of Health and Human Services (HHS) to reclaim the appointment power has been interpreted as an attempt to reward political loyalists and to increase the number of members with views of regulation compatible with the administration's. Brown & Richard, *supra* note 384, at 26 n.3; see Sun, *FDA Spars with HHS on Advisory Posts*, 224 *SCI.* 698 (1985); Russell, *Some at the FDA Fear Politics Tainting Science*, *Wash. Post*, June 8, 1982, at A1, A8. In addition, "hit lists" were reportedly circulated during the transition in 1981 suggesting that certain members of EPA's scientific advisory committee be purged. Ashford, *supra* note 379, at 72; Address by T. McGarity, *Risk and Trust—The Role of Regulatory Agencies in Dealing with Risk: The Courts, the Agencies and Congress 16* (1985) (presentation delivered at the Fourteenth Annual Conference on the Environment).

398. See, e.g., USDA, *Agricultural Biotechnology Research Advisory Committee, Members and Alternates* (Aug. 18, 1988).

399. T. GREENWOOD, *KNOWLEDGE AND DISCRETION IN GOVERNMENT* 194 (1984).

400. See Lakshmanan, *The FDA's Advisory Committees: Some Suggestions Based on Empirical Data*, 43 *FOOD DRUG COSM. L.J.* 877, 889-90 (1988). The Federal Advisory Committee Act requires that advisory committees be public unless information that can be withheld from the public under FOIA is discussed. Federal Advisory Committee Act, 5 U.S.C. app. §§ 10(a)(1), 10(d) (1988).

engineered foods.⁴⁰¹ Rather than charter its own advisory committee, FDA instructed the Federation of American Societies For Experimental Biology, the contractor, to assemble an expert panel of scientists to prepare a report.⁴⁰² Public Citizen challenged the arrangement on the basis that FASEB was an advisory committee subject to the requirements of the Federal Advisory Committee Act (FACA).⁴⁰³ In *Food Chemical News v. Young*, the court agreed and required FDA to comply with FACA by making its advisory committee meetings open to the public.⁴⁰⁴

3. *An Appropriate Role for Advisory Committees*

The Administrative Conference favors the use of scientific advisory committees as an "important" means of "validating the technical bases of regulatory decisions" concerning carcinogens.⁴⁰⁵ Regulatory agencies could similarly benefit by working with advisory committees in their regulatory decisionmaking concerning biotechnology.

EPA and USDA now use advisory panels on an ad hoc basis, but they may find it useful in the future to establish standing committees, like those at FDA. EPA currently finds it difficult to form a new committee and have it meet within the time deadlines Congress has set for a final decision on a product or research project.⁴⁰⁶ This problem is likely to worsen as the number of products and research projects the agencies must approve increases.

Despite the advantages of advisory committees, public interest groups are lukewarm about them because of the potential for inappropriate advice, politicization, or bias.⁴⁰⁷ One way to address these concerns is to appoint public members to all panels in order to increase the committees' public accountability.

Some scientists and regulators object to the appointment of consumer representatives to FDA's scientific panels on the grounds that nonexperts offer little technical expertise and that their discussion is often not focused on the technical goals of the panel.⁴⁰⁸ Other observers disagree. FDA has placed consumer and industry representatives as nonvoting members on advisory committees for over-the-counter drugs,

401. See *supra* note 388 and accompanying text.

402. *Food Chem. News v. Young*, 709 F. Supp. 5, 6 (D.D.C. 1989). See *supra* note 388 and accompanying text.

403. *Food Chem. News*, 709 F. Supp. at 5, 6. FACA requires advisory committee meetings to be open to the public unless one of the exemptions listed in FACA applies. See *infra* text accompanying note 414.

404. *Food Chem. News*, 709 F. Supp. at 9.

405. Recommendation 82-5, *supra* note 276.

406. Milewski Interview, *supra* note 378.

407. See, e.g., Mellon Interview, *supra* note 199; Friedman, *supra* note 386, at 212.

408. Brown & Richard, *supra* note 384, at 21 (survey of persons who serve on drug advisory panels); Miller Interview, *supra* note 117.

medical devices, and biologics.⁴⁰⁹ While these committees have their share of problems, participants believe they have generally functioned well.⁴¹⁰ Moreover, as previously mentioned, most chairpersons of Institutional Biosafety Committees formed to review NIH-sponsored research conclude that public members have made a valuable contribution to their committees.⁴¹¹

FDA's model of including one or two nonvoting public representatives on scientific and technical advisory committees is one method to establish the committee's credibility.⁴¹² Nonvoting public members could participate in committee deliberations, thus having the opportunity to influence committee decisions by their advocacy, but without an actual vote on the outcome.⁴¹³

If consumer or environmental representatives cannot participate on advisory committees, the public must depend on the documentation required by FACA to determine how a committee reached its decision and whether its recommendations were justified. FACA requires agencies to give prior notice of meetings, to hold open meetings in most cases, to keep detailed minutes of each meeting, and to give the public access to most committee records, transcripts, minutes, and other documents.⁴¹⁴ In some instances, however, the minutes only briefly summarize the dis-

409. See Friedman, *supra* note 386, at 210.

410. *Id.*; see also Field, *GMPAC: A Perspective*, MED. DEVICES & DIAGNOSTIC INDUSTRIES, Dec. 8, 1986, at 8; Brown & Richard, *supra* note 384, at 25 (FDA use of consumer representatives has been "successful").

411. See *supra* note 293 and accompanying text.

412. ACUS has stated that "[m]embers of an expert advisory panel should be selected primarily for their expertise in relevant scientific fields." Recommendation 82-5, *supra* note 276. FDA committees meet this requirement because seven of nine members are selected on that basis. See Friedman, *supra* note 386, at 210.

413. Despite the benefits (and feasibility) of including public members, not all agencies are willing to make such appointments. Unfortunately, the courts support such exclusions. *Public Citizen v. Nat'l Advisory Comm. of Microbiological Criteria for Foods*, 708 F. Supp. 359 (D.D.C. 1988), *aff'd*, 886 F.2d 419 (D.C. Cir. 1989), illustrates this trend. In *Public Citizen*, the plaintiffs argued that USDA had violated the federal Advisory Committee Act's requirement that advisory committees be "fairly balanced in terms of view represented." FACA, 5 U.S.C. app. § 5(b)(2) (1988). USDA's committee was composed of eight government employees and eleven employees, consultants, or contractors of the food industry. 708 F. Supp. at 360. The court applied a test of whether "'the Committee's members represent a fair balance of viewpoints given the function to be performed.'" *Id.* at 362 (*citing* National Anti-Hunger Coalition v. Executive Comm. of the President's Private Sector Survey on Cost Control, 711 F.2d 1071, 1074 (D.C. Cir.), *aff'g* 557 F. Supp. 524 (D.D.C.), *as modified by*, 566 F. Supp. 1515 (D.D.C. 1983)). It concluded that the committee was "balanced" because it was charged with a "highly technical mandate," the members had "extensive professional backgrounds in various aspects of food microbiology," and there was "no indication" that it was "unable to fulfill its functions." 708 F. Supp. at 363. Decisions such as this one are inconsistent with FACA's legislative history, which indicates that one objective of the balance requirement was to secure interested and knowledgeable nonexperts on advisory committees. Ashford, *supra* note 379, at 76. If the courts continue to exclude public members, Congress should clarify its intentions.

414. FACA, 5 U.S.C. app. § 10 (1988).

position of a matter. They fail to identify clearly either the questions that an agency posed to the committee or the specific answers the committee formulated and the basis for those answers.⁴¹⁵

Agencies that rely on advisory panels could increase the legitimacy of their decisions with better documentation of the advisory committee process. Agencies should require a panel to identify the questions it was asked, the possible answers to those questions, which answer was recommended, and why that answer was chosen. In addition, the agency should document the reasons for its response to the committee's recommendations. The Administrative Conference recommends that when an agency rejects an advisory panel's scientific judgment, it "should explain the basis for the rejection."⁴¹⁶ It further recommends that "[w]hen an agency selects a regulatory approach whose basis appears inconsistent with a panel's advice, it should explain the legal, social, and other reasons that dictate or justify that choice."⁴¹⁷

E. General Principles

In summary, the design of a procedural system for biotechnology should reflect two general principles. First, as a minimum, agencies should give notice to the public that an application has been received and invite public comments. This step recognizes that in a democratic system, public input legitimizes agency decisionmaking and can increase its quality. Public input of this type should not unduly delay agency determinations. Second, agencies should consider using additional procedures when they are likely to increase the legitimacy or accuracy of agency decisions. Appropriate cases include giving local notice to alert citizens with a unique interest in a decision, holding an informal hearing concerning matters of unusual public interest or controversy, and making scientific information available to citizens so long as doing so does not seriously damage an applicant's interest in protecting confidential business information.

CONCLUSION

The government has an almost unprecedented opportunity to make the regulation of biotechnology more effective. It can design a workable regulatory system before the commercial use of genetically engineered organisms becomes widespread. If it takes this step, the country might avoid some of the environmental harms that occurred before regulatory systems were established for chemicals.

415. *Public Board of Inquiry*, *supra* note 315, at 331.

416. Recommendation 82-5, *supra* note 276.

417. *Id.*

This Article recommends a number of changes toward that end. First, the regulatory structure should be adjusted to ensure interagency coordination and complete regulatory coverage of the range of biotechnology activities. Second, the White House should redesign BSCC, the committee responsible for regulatory coordination, to avoid the type of interagency conflict that caused the collapse of current governmentwide coordination efforts. Third, agencies should adopt improved methods of risk assessment and risk management to make regulation more efficient without endangering the public. Finally, agencies should adopt regulatory procedures that increase the legitimacy of their decisions by ensuring public participation.

While the outline of how to improve the regulatory systems is clear, the fate of reform is in doubt. The changes suggested require action by individual agencies, Congress, and the White House. Such reform is unlikely to occur, however, without strong leadership.

Congress has shown sporadic interest in biotechnology regulation, but it has tended to address narrow problems rather than the overall design of the regulatory system.⁴¹⁸ The division of oversight responsibility among multiple committees may constrain Congress from taking the lead.⁴¹⁹

The White House is in a better position to assume a leadership role, particularly through the Office of Science and Technology Policy. OSTP could monitor agency and legislative activity and report to the President concerning progress toward the reforms identified in this Article. The President's commitment to leadership in the area of science and technology policy has been questioned, however, because of his slow pace in staffing OSTP. After one year in office, the Bush Administration still has not filled several important positions in OSTP.⁴²⁰

The history of the regulation of chemicals in this country demonstrates the fateful consequences of ineffective regulation. If history is not to repeat itself, the President must make the reform of biotechnology regulation one of OSTP's highest priorities. Although achieving reform will not be easy, effective White House leadership could make it a reality.

418. See, e.g., H.R. 4452, 99th Cong., 2d Sess. § 104(b) (1986) (would mandate open meetings of BSCC).

419. See J. WILSON, BUREAUCRACY, WHAT GOVERNMENT AGENCIES DO AND WHY THEY DO IT 256 (1989).

420. See *White House Science Office On Slow Road to Revival*, SCI. & GOV'T REP., Nov. 15, 1989, at 1-2 ("For White House watchers, the message of all this dawdling was simply that science advice and the office that's supposed to provide it do not rank high with the President or his inner circle."); *Bush Science Aide Sworn in and Goes on Vacation*, SCI. & GOV'T REP., Aug. 15, 1989, at 4 ("The resuscitation of Presidential science advice continues at an unhurried pace that mocks the campaign pledges of George Bush and the importance attached to the role by chiefs of the science establishment.").