State Biotechnology Oversight: The Juncture of Technology, Law, and Public Policy

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STATE BIOTECHNOLOGY OVERSIGHT: THE JUNCTURE OF TECHNOLOGY, LAW, AND PUBLIC POLICY

> The Cassandras talk darkly of Andromeda strains, of developments that could change the ecology of the earth in a relatively short period of time. The Babbitts scoff at that gloom, dismissing past mistakes as minor laboratory accidents, explaining about the implications of thwarting innovation and suffocating th[e] fledgling industry [of biotechnology] in an irrational overreaction to extremely remote events. Rational analysis of the science is *somewhere between* the two extremes.[1]

I. INTRODUCTION

A. The Technology Comes of Age

In 1953, the physical structure and chemical composition of DNA was discovered. DNA is the sub-cellular component which is specifically organized into macromolecular units of heredity called genes. Every higher lifeform known to humankind today utilizes DNA and a gene-based transmission of inheritable traits.

In 1973, only twenty years later, scientists successfully created a hybrid form of DNA, consisting of genes from both a bacteria and a virus, using newly discovered biochemical techniques which allowed removing discrete segments of DNA from one lifeform and joining them with those from another. Not only was the creation of this hybrid form of DNA a prior impossibility, but the further discovery that this hybrid form of DNA could act as a template for the replication of thousands of copies indicated that artificially created DNA hybrids may be indistinguishable from those that had been evolving naturally for millions of years.

In 1978, scientists discovered techniques allowing them to sequence DNA and decipher the precise molecular code embodied in a particular gene. Moreover, in this same year, scientists reported having successfully fashioned the first functional synthetic gene, a DNA-based unit of heredity created using solely chemical, non-cellular means. Scientists now had available the basic tools with which to biochemically circumvent interspecies barriers and construct lifeforms endowed with any number of novel genetic traits.

The impact of discoveries such as those described above did not remain confined to the scientific community. In a 1980 landmark decision, the Supreme Court of the United States ruled that geneti-

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1. James J. Florio, *Regulation in Biotechnology*, BIOTECHNOLOGY: IMPLICATIONS FOR PUBLIC POLICY 41 (S. Panem, ed. 1985) (emphasis added).

cally engineered lifeforms such as bacteria were patentable.[2] The significance of this decision to the emerging biotechnology industry—an industry predicated on intellectual property rights—was incalculable. The characteristically research-intensive, capital-intensive biotechnology industry now had the economic incentive to push the technology of genetic engineering to previously unimagined extremes.

The genetic engineering and recombinant DNA applications pursued by the biotechnology industry over the past ten years have engendered a spectrum of perplexing inquiries[3] concerning ethical and

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2. Diamond v. Chakrabarty, 447 U.S. 303 (1980). Although the Court ruled that lifeforms fell within the scope of the existing patent statutes, the Court clearly confronted the attendant policy issues in this matter and rejected any attempt to place them within the jurisdiction of the judiciary. The policy position of the majority of the Court, with which the dissenting Justices appear to agree, may be found within the following excerpt:

> [T]he petitioner . . . points to grave risks that may be generated by research endeavors such as respondent's. The brief[] present[s] a gruesome parade of horribles. Scientists, among them Nobel laureates, are quoted suggesting that genetic research may pose a serious threat to the human race, or, at the very least, that the dangers are far too substantial to permit such research to proceed apace at this time. We are told that genetic research and related technological developments may spread pollution and disease, that it may result in a loss of genetic diversity, and that its practice may tend to depreciate the value of human life. These arguments are forcefully, even passionately, presented; they remind us that, at times, human ingenuity seems unable to control fully the forces it creates—that, [as] with Hamlet, it is sometimes better "to bear those ills we have than fly to others that we know not of."
>
> It is argued that this Court should weigh these potential hazards in considering whether respondent's invention is patentable subject matter . . . . We disagree. The grant or denial of patents on micro-organisms is not likely to put an end to genetic research or to its attendant risks. . . .
>
> What is more important is that we are without competence to entertain these arguments—either to brush them aside as fantasies generated by fear of the unknown, or to act on them. The choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot. That process involves the balancing of competing values and interest, which in our democratic system is the business of elected representatives. Whatever their validity, the contentions now pressed on us should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts.

Id. at 316-17 (footnote omitted).

3. In February 1992, the Office of Science and Technology Policy submitted to Congress a supplement to President Bush's fiscal year 1993 budget, entitled "Biotechnology for the 21st Century." In addition to the traditional areas of biotechnology research (such as agriculture, energy, environment, health, etc.), the Biotechnology Research Initiative proposed in this report included four categories of "Social Impact Research":

> **Social and Cultural Impact:**
> EDUCATION & COMMUNICATION

moral values; agricultural, ecological and environmental matters; global competitiveness and economic priorities; and regulatory and public policy issues.

This Comment will focus upon the regulatory and public policy issues associated with the biotechnology industry. Although the specific issue to be discussed is the introduction of genetically engineered organisms into the environment, it will become evident that virtually all the other above-mentioned issues are intrinsically and inevitably linked to regulatory philosophy and public policy values.

This Comment begins with an account of the evolution of federal efforts to oversee biotechnology and genetic engineering; included in this account is a discussion of the federal government's failures—both past and present—in this regard. The emergence of local and state-level initiatives to regulate biotechnology and genetic engineering will then be examined; this discussion will include an analysis of a model approach relative to the four existing categories of state legislative initiatives. Emphasis will be placed upon the choice of regulatory initiatives employed by the State of Maine; this discus-

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Public Understanding of Biotechnology
Expert Advice and Public Choice
. . . .
Ethical Impact:
Impact on Reproductive Choices and Practices
Professional Ethics
Research Ethics
Privacy and Confidentiality
Equity
Legal Impact:
Civil Liberties Implications
Forensics and Criminal Law
Intellectual Property Protection
Regulatory Law
Economic Impact:
Technology Transfer
International Trade
Global Competitiveness

COMMITTEE ON LIFE SCIENCES AND HEALTH OF THE FEDERAL COORDINATING COUNCIL FOR SCIENCE, ENGINEERING, AND TECHNOLOGY, OFFICE OF SCIENCE AND TECHNOLOGY POLICY, BIOTECHNOLOGY FOR THE 21ST CENTURY 65 (1992) [hereinafter BIOTECH 21ST CENTURY].

For a scholarly treatment of these issues, see generally SIR ZELMAN COWEN, REFLECTIONS ON MEDICINE, BIOTECHNOLOGY AND THE LAW (1985); George J. Annas, *Mapping the Human Genome and the Meaning of Monster Mythology*, 39 EMORY L.J. 629 (1990); Stephen L. Carter, *The Bellman, the Snark, and the Biohazard Debate*, 3 YALE L. & POL'Y REV. 358 (1985); Harold P. Green, *The Law-Science Interface in Public Policy Decisionmaking*, 51 OHIO ST. L.J. 375 (1990); Mark Sagoff, *Biotechnology and the Environment: Ethical and Cultural Considerations*, 19 ENVTL. L. RPT. 10520 (1989); Maxine F. Singer, *Genetics and the Law: A Scientist's View*, 3 YALE L. & POL'Y REV. 315 (1985). *See also* John B. Attanasio, *The Genetic Revolution: What Lawyers Don't Know*, 63 N.Y.U. L. REV. 662 (1988) (book review essay); Brett Lockwood, *Genetics and the Law*, 39 EMORY L.J. 875 (1990) (bibliography).

sion will involve an in-depth examination of the decision-making processes prerequisite to the promulgation of rules and regulations. Finally, this Comment will conclude with a plea for a rational and democratic resolution of the regulatory issues associated with biotechnology and genetic engineering.

B. *The Origins of Concern*

The origins of current initiatives by federal and state agencies to regulate deliberate releases of genetically engineered organisms into the environment stem from the concerns of scientists who recognized the far-reaching implications of their research.[4] In the summer of 1973, nearly 100 scientists at the Gordon Conference on Nucleic Acids in New Hampshire expressed a collective concern as to the safety and potential risks associated with the recombinant DNA experiments presented at the Conference. The attendees recognized the potential hazards inherent in the new technology[5] and requested guidance from the National Academy of Sciences.[6]

The Academy convened a committee to evaluate the safety of research on recombinant DNA.[7] The committee's recommendations included a voluntary moratorium on recombinant DNA research while issues of public safety were explored. In addition to the National Academy of Sciences, the National Institutes of Health (NIH) was approached by these same scientists to establish a committee to oversee an evaluation of potential biological and ecological hazards, and to devise guidelines for the practice of genetic engineering technologies.

As a result of the scientific debate in this matter, an international gathering of scientists, policymakers and industrial representatives met at the Asilomar Conference Center in California in February 1975 to discuss the broader ethical and legal implications of genetic engineering, as well as to formulate appropriate safety standards for recombinant DNA research.[8] Those in attendance reached an agree-

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4. John E. Barkstrom, *Recombinant DNA and the Regulation of Biotechnology: Reflections on the Asilomar Conference, Ten Years After*, 19 AKRON L. REV. 81, 85 (1985); Frederick Andrew Spaeth, *Genetic Engineering Research: An Analysis of the Government's Role in Regulation*, 7 U. BRIDGEPORT L. REV. 71 (1986).

5. Judith P. Swazey et al., *Risks and Benefits, Rights and Responsibilities: A History of the Recombinant DNA Research Controversy*, 51 S. CAL. L. REV. 1019, 1020-22 (1978).

6. *See* 181 SCIENCE 1114 (1973) for a letter by Asilomar participants to the National Academy of Sciences and the Institute of Medicine expressing their concerns about recombinant DNA technology in 1973. *See infra*, note 8 and accompanying text.

7. The National Academy of Sciences (NAS) Committee on Recombinant DNA Molecules published its recommendations in Paul Berg et al., *NAS Ban on Plasmid Engineering*, 250 NATURE 175 (1974), and Paul Berg et al., *Potential Biohazards of Recombinant DNA Molecules*, 185 SCIENCE 303 (1974).

8. Paul Berg et al., *Asilomar Conference on Recombinant DNA Molecules*, 188

ment to control their own research until the safety considerations were examined and clarified.

II. The Decision to Regulate Biotechnology at the Federal Level

A. *The Origins of Regulation*

Shortly thereafter, in 1976, the Asilomar recommendations were incorporated into NIH safety guidelines with assistance from a committee of scientists appointed by the NIH as the Recombinant DNA Molecule Program Advisory Committee.[9] The NIH *Guidelines for Research Involving Recombinant DNA Molecules* (hereinafter *Guidelines*) mandated different levels of physical and biological containment for all recombinant DNA research funded by the NIH[10] in an effort to prevent the release of genetically engineered microorganisms into the environment.[11] Because the *Guidelines* pertained only to recombinant DNA research "conducted at or sponsored by" the NIH, they generally allowed private commercial research to proceed unrestricted.[12]

The first version of the *Guidelines* primarily concerned laboratory research and unqualifiedly prohibited the deliberate release of genetically engineered organisms into the environment.[13] From 1978 to 1986 as confidence grew within the scientific community concerning the safety of laboratory research, however, the NIH revised the *Guidelines*. The first of three revisions allowed exceptions to the original blanket prohibition on deliberate release experiments.[14] Three years later, the NIH eliminated the previous ban on deliberate environmental release of any genetically engineered organism.[15] Coincident with eliminating the ban on environmental releases, the NIH relaxed containment precautions initially required by the *Guidelines* to prevent accidental release of genetically engineered organisms. Finally, the NIH delegated both oversight and approval authority to local, institutional peer-review committees known as In-

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Science 991 (1975); Paul Berg et al., *Summary Statement of the Asilomar Conference on Recombinant DNA Molecules*, 72 Proc. Nat'l Acad. Sci. U.S.A. 1981 (1975).

9. Recombinant DNA Research; Guidelines, 41 Fed. Reg. 27,902 (1976).

10. *Id.* at 27,911-43.

11. Swazey et al., *supra* note 5 at 1036-45.

12. 41 Fed. Reg. 27,902 (1976); Guidelines for Research Involving Recombinant DNA Molecules; June 1983, 48 Fed. Reg. 24,556, 24,563 (1983).

13. 41 Fed. Reg. 27,902, 27,914-15 (1976).

14. Guidelines for Research Involving Recombinant DNA Molecules; December 1978, 43 Fed. Reg. 60,101, 60,107-108 (1978).

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

stitutional Biosafety Committees.[16]

The modification of the NIH *Guidelines* to address the deliberate introduction into the environment of certain genetically engineered organisms triggered yet another stage in the development of an oversight initiative at the federal level. This next stage of oversight witnessed several congressional hearings into the potential environmental consequences of deliberate releases into the environment and the adequacy of federal regulatory oversight.

In June 1983, the House Subcommittee on Science, Research and Technology, and the House Subcommittee on Investigations and Oversight conducted a joint hearing, chaired by then Representative Albert Gore, Jr., on the environmental implications posed by commercial application of recombinant DNA technology.[17] No specific legislative initiatives resulted. Shortly thereafter, in September 1984, the Subcommittee on Toxic Substances and Environmental Oversight of the Senate Committee on Environment and Public Works held a second hearing on the potential risks posed by deliberate releases of genetically engineered organisms into the environment.[18] Representatives from the NIH, the Environmental Protection Agency (EPA), and the U.S. Department of Agriculture (USDA) testified that existing statutes, regulations, and guidelines were adequate to address the deliberate release issues without new legislation by Congress.

In fact, just prior to this hearing, the White House Cabinet Council on Natural Resources and the Environment had established a

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16. *Id.* at 59,736; Recombinant DNA Research; Actions Under Guidelines, 47 Fed. Reg. 17,168 (1982). *See generally*, 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).

17. *Environmental Implications of Genetic Engineering: Hearing Before the Subcomm. on Investigations and Oversight and the Subcomm. on Science, Research and Technology of the Comm. on Science and Technology*, 98th Cong., 1st Sess. (1983); Sen. Albert Gore, Jr. & Steve Owens, *The Challenge of Biotechnology*, 3 YALE L. & POL'Y REV. 336, 340-43 (1985).

Apparently, Representative Gore's Investigations Subcommittee then submitted a staff report to the executive branch following the 1983 hearings. The Subcommittee's recommendations were, in part, conceptually responsible for the formation of the White House's Biotechnology Science Coordinating Committee (BSCC) which eventually introduced the current federal Coordinated Framework. *See* Gore & Owens, *supra*, at 342 n.29 & 348-51; *see also infra* notes 21-23. While Gore's initial response to the White House's approach was that "Congress should allow the current Administration['s] effort to proceed for now . . . because it reflects the agencies' intention to do something rather than nothing," *id.* at 350, Gore quickly became disenchanted with the executive branch's regulatory philosophy and ineffectiveness. *See* G. STEVEN BURRILL & KENNETH B. LEE, JR., BIOTECH91: A CHANGING ENVIRONMENT (1990) 145-46 [hereinafter BIOTECH91]. *See also infra* notes 73-76 and accompanying text.

18. *The Potential Environmental Consequences of Genetic Engineering: Hearings Before the Subcomm. on Toxic Substances and Environmental Oversight of the Comm. on Environment and Public Works*, 98th Cong., 2d Sess. (1984).

working group to review biotechnology regulation and begin the process of coordinating the federal agencies. By the end of 1984, the White House Office of Science and Technology Policy (OSTP) proposed an integrated regulatory scheme called the Coordinated Framework for Regulation of Biotechnology (hereinafter Coordinated Framework).[19]

Upon its introduction in 1984, the proposed Coordinated Framework for Biotechnology Regulation was comprised of policy statements by the Food and Drug Administration (FDA), EPA and USDA indicating how these agencies intended to regulate cooperatively biotechnology and genetically engineered organisms.[20] At the time, considerable confusion existed concerning how the federal government would regulate biotechnology, especially research and product development activities that fell outside the existing NIH *Guidelines*.

In 1985, in an effort to address this confusion and facilitate acceptance of the Coordinated Framework's regulatory philosophy, the OSTP announced creation of a White House coordinating committee called the Biotechnology Science Coordinating Committee (BSCC).[21] The BSCC was charged with the responsibility of coordinating the policies of the above mentioned agencies with respect to oversight of biotechnology activities.[22] The OSTP subsequently announced a second version of the Coordinated Framework in 1986 which allocated review of specific products to the USDA, FDA, and EPA based on the proposed use of the regulated products.[23]

The OSTP's 1986 Coordinated Framework policy statement was an effort to clarify regulatory responsibilities in cases of concurrent jurisdiction and to facilitate the agencies' efforts to establish biotechnology regulations.[24] The OSTP attempted to clarify the jurisdiction of each regulatory agency by invoking the concept of a "lead agency," but it failed to designate a specific agency in instances where two or more had concurrent jurisdiction.[25]

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

20. *Id.* at 50,856-57.

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

22. The BSCC had no regulatory or review authority; it was intended merely to coordinate and facilitate interagency communication in matters such as scientific information, review procedures, and risk assessment methods.

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

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

25. *Id.* at 23,302 (1986). Nor did the OSTP attempt to define "lead agency," apparently choosing to defer to the collective wisdom of the agencies involved. This has since proven to be a poor choice given that jurisdictional disputes among the agencies' representatives on the BSCC caused its collapse.

B. *The Federal Coordinated Framework and the Regulation of Biotechnology*[26]

Pursuant to the regulatory matrix set forth by the Coordinated Framework, the USDA and the EPA are the primary agencies responsible for regulating release of genetically engineered organisms into the environment. The USDA purports to derive its jurisdiction of environmental releases of genetically engineered organisms from the Federal Plant Pest Act (PPA)[27] and the Plant Quarantine Act (PQA).[28] The PPA grants authority to regulate importation and interstate transportation of plant pests.[29] The USDA contends that this jurisdiction extends to the environmental release of genetically engineered organisms classified as plant pests.[30] Because the use of

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Shortly before dissolution of the BSCC, Senator Albert Gore, Jr. commented during an interview:

> The BSCC was supposed to ensure that different government agencies worked from similar key definitions. Today, the agencies can't even agree on the definition of genetic engineering or deliberate release. The committee was supposed to resolve disputes between agencies, but instead has actually fueled disputes. It promised Congress that it would stick to questions of science and not policy, but it has become mired in politics. It promised to play a key role in foresight, but it has utterly failed at that mission, as well. I had hoped it would foster public participation, but it has discouraged it. The whole effort [to create a federal regulatory infrastructure] has been seriously flawed and needs to be reexamined.

BIOTECH91, *supra* note 17, at 146.

26. Numerous other commentators have written comprehensively on the subject of the Federal Coordinated Framework, including its virtues as well as its failings. *See, e.g.*, William Allen, Note, *The Current Federal Regulatory Framework for Release of Genetically Altered Organisms into the Environment*, 42 FLA. L. REV. 531 (1990); Valerie M. Fogelman, *Regulating Science: An Evaluation of the Regulation of Biotechnology Research*, 17 ENVTL. L. 183 (1986); Sen. Albert Gore, Jr. & Steve Owens, *The Challenge of Biotechnology*, 3 YALE L. & POL'Y REV. 336 (1985); Diane E. Hoffmann, *The Biotechnology Revolution and its Regulatory Evolution*, 38 DRAKE L. REV. 471 (1988-1989); Gregory A. Jaffe, Article, *Inadequacies in the Federal Regulation of Biotechnology*, 11 HARV. ENVTL. L. REV. 491 (1987); Thomas O. McGarity, *Federal Regulation of Agricultural Biotechnologies*, 20 U. MICH. J.L. REF. 1089 (1987); Norman L. Rave, Jr., Note, *Interagency Conflict and Administrative Accountability: Regulating the Release of Recombinant Organisms*, 77 GEO. L.J. 1787 (1989); Sidney A. Shapiro, *Biotechnology and the Design of Regulation*, 17 ECOLOGY L.Q. 1 (1990); Louis S. Sorell, Note, *Biotechnology Regulation Under the Toxic Substances Control Act*, 3 PACE ENVTL. L. REV. 57 (1985); Frederick Andrew Spaeth, Note, *Genetic Engineering Research: An Analysis of the Government's Role in Regulation*, 7 U. BRIDGEPORT L. REV. 71 (1986); U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, A NEW TECHNOLOGICAL ERA FOR AMERICAN AGRICULTURE 181-270 (OTA-F-474) (1992) [hereinafter OTA REPORT]; Michael P. Vandenbergh, Note, *The Rutabaga That Ate Pittsburgh: Federal Regulation of Free Release Biotechnology*, 72 VA. L. REV. 1529 (1986).

27. 7 U.S.C. §§ 150aa-jj (1988).

28. *Id.* §§ 151-64a, 166-67.

29. *Id.* §§ 150bb-cc.

30. *See* Final Policy Statement for Research and Regulation of Biotechnology Processes and Products, 51 Fed. Reg. 23,336, 23,346 (1986).

plant pathogens to transfer genes to plants is relatively routine, regulations were initially expanded to require that any intentional release, importation, or movement across state lines of any genetically engineered plant pathogen have a permit from the USDA.[31] If a microorganism is a plant pest, the USDA's Animal and Plant Health Inspection Service (APHIS) has regulatory authority as well; APHIS' jurisdiction over microorganisms is also purportedly granted by the PPA.[32]

According to the Coordinated Framework, the EPA regulates genetically engineered organisms if they are comparable in their proposed use to a pesticide. Microorganisms that are designated as pesticides purportedly fall within the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).[33] Additionally, the EPA has ex-

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31. 7 C.F.R. §§ 340.0, 340.1 (1992). Historically, the USDA has maintained a master list of plant pathogens which determines whether a particular organism or vector is subject to regulation. More recently, however, the USDA has introduced a proposed rule that would create categories of exemptions applicable to certain transgenic plants. Genetically Engineered Organisms and Products; Notification Procedures for the Introduction of Certain Regulated Articles; and Petition for Nonregulated Status, 57 Fed. Reg. 53,036 (1992) (to be codified at 7 C.F.R. pt. 340) (proposed Nov. 6, 1992). Thus, all genetically engineered plants otherwise categorized as plant pathogens may no longer be subject to the traditional, permitting-type review conducted by the USDA-APHIS. For a discussion of these proposed rules, see Charles J. Arntzen, *Regulation of Transgenic Plants*, 257 SCIENCE 1327 (1992) (editorial) and Susanne L. Huttner et al., *Revising Oversight of Genetically Modified Plants*, 10 BIO/TECH. 967 (1992); *but see infra* notes 66-71.

32. Organization, Functions, and Delegations of Authority, Final Rule, 54 Fed. Reg. 23,193, 23,195 (1989) (codified at 7 C.F.R. § 371.2 (1992)); the Federal Plant Pest Act (PPA), 7 U.S.C. §§ 150aa-jj (1988). According to the statute, a "plant pest" is any invertebrate, parasitic plant, virus, or similar organism that "can directly or indirectly injure or cause disease or damage. . . ." *Id.* § 150aa(c). APHIS also claims jurisdiction over microorganisms under the Plant Quarantine Act (PQA), 7 U.S.C. §§ 151-167 (1988), which authorizes the USDA to quarantine plants of "any character whatsoever" that are capable of transmitting any plant disease or insect. *Id.* § 161.

33. 7 U.S.C. §§ 136-136y (1988). A "pesticide" is defined as "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant. . . ." *Id.* § 136(u).

The EPA is currently considering amending its regulations governing the testing of new microbial pesticides. The amendment is intended to reduce the regulatory burdens on microbial pesticide testing, and to clarify the scope of EPA's oversight in such matters. In contrast to the EPA's existing requirement, field tests of genetically engineered microbial pesticides would be able to proceed without notification of the EPA unless such microbes "possess new properties that cause significant impacts upon human health or the environment." *Environmental Protection Agency Proposes New Rule for Microbial Pesticide Testing*, NBIAP NEWS REP. (Nat'l Biological Impact Assessment Program, Va. Polytechnic Inst. & State Univ., Blacksburg, Va.), Feb. 1993, at 1-2; Microbial Pesticides: Experimental Use Permits and Notifications, 58 Fed. Reg. 5878 (1993); *EPA to Issue Biotechnology Rule Under FIFRA*, NBIAP NEWS REP. (Nat'l Biological Impact Assessment Program, Va. Polytechnic Inst. & State Univ., Blacksburg, Va.), May 1992, at 1. Apparently, the EPA's efforts to promulgate new regulations for genetically engineered pesticides under the FIFRA were

tended its jurisdiction to other commercial uses of microorganisms under the authority of the Toxic Substances Control Act (TSCA) by defining "chemical substances" to include "organisms."[34] In effect, the EPA regulates non-agricultural uses of biotechnology products, such as genetically engineered organisms, under the TSCA.[35]

Under the TSCA, the EPA currently interprets new chemical substances to include any microorganism that contains genetic material from a genus other than its own.[36] Since some potentially harmful microorganisms fall outside this definition of new microorganisms, the EPA applies significant new use rules[37] to monitor new uses of genetically engineered organisms as well as new microorganisms.

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the subject of negotiations with the Bush administration for more than a year. *EPA Biotechnology Rulemaking*, NBIAP NEWS REP. (Nat'l Biological Impact Assessment Program, Va. Polytechnic Inst. & State Univ., Blacksburg, Va.), Aug. 1992, at 1.

34. 15 U.S.C. § 2602(2)(A) (1986). The TSCA defines "chemical substance" as "any organic or inorganic substance of a particular molecular identity, including (i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature. . . ." *Id.*

The EPA justifies including microorganisms within the scope of the statutory 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.'" Proposed Policy Regarding Certain Microbial Products, 49 Fed. Reg. 50,880, 50,886 (1984).

In the case of genetically engineered microbes, the EPA believed that the TSCA requires that such organisms be regulated in the same manner as new chemicals. This interpretation of TSCA's mandate placed the EPA in conflict with the Bush administration's view of proper regulatory scope. In fact, the EPA and the Bush administration were in a "policy deadlock" for months. Apparently, the EPA's pending proposed rules (submitted to the White House's OMB in late 1992) are conceptually closer to the administration's philosophy. *EPA Biotechnology Rulemaking*, NBIAP NEWS REP. (Nat'l Biological Impact Assessment Program, Va. Polytechnic Inst. & State Univ., Blacksburg, Va.), Aug., 1992, at 1; Roger S. Johnson, Ph.D., *EPA Seeks White House's Approval for Including Recombinants Under TSCA*, GENETIC ENG'G NEWS, June 15, 1992, at 3.

While the pending proposed rule would continue its definition of genetically engineered microbes as new chemicals subject to review, the EPA has proposed four categories of exempt organisms, and has proposed to exempt certain environmental research and development activities from the current voluntary notification and reporting requirement. Also, certain proposed uses of genetically engineered organisms would be exempted when such uses are contained. *EPA To Go Ahead with Biotech Rules Under TSCA*, NBIAP NEWS REP. (Nat'l Biological Impact Assessment Program, Va. Polytechnic Inst. & State Univ., Blacksburg, Va.), Oct. 1992, at 2.

35. Statement of Policy; Microbial Products Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic Substance Control Act, 51 Fed. Reg. 23,313, 23,315 (1986).

36. *Id.* at 23,325. *See also* Allen, *supra* note 26, at 543-44; Shapiro, *supra* note 26, at 39-41.

37. 15 U.S.C. § 2604(a)(1)(B) (1988). *See also* Allen, *supra* note 26, at 543-44; Shapiro, *supra* note 26, at 39-41.

Under the FIFRA,[38] the EPA now regulates genetically engineered organisms used as pesticides pursuant to a two-tiered review scheme. Because the EPA has deemed some microbial pesticides to pose less risk than others, the FIFRA provides two levels of review. Level I review[39] applies to pesticides of microbial origin genetically engineered from DNA of a single genus and containing no DNA from a pathogenic microorganism. The FIFRA requires a Level II review[40] for intergeneric microorganisms, naturally-occurring pathogenic microorganisms, and genetically engineered[41] pathogenic microorganisms. An EPA review under the FIFRA apparently does not preclude independent USDA review if specific pathogens are involved. Under both Level I and II review, the EPA presently makes a determination as to whether the applicant's proposed release will be subject to an environmental use permit. The EPA can require such a permit, however, only if the agency meets its burden of proving "unreasonable risk."[42]

With respect to other types of biotechnology products, foods and food additives are also subject to regulation pursuant to the Coordinated Framework, and may be regulated by more than one agency. Foods and food additives are normally regulated by the FDA under the Federal Food, Drug, and Cosmetic Act (FDCA).[43] Yet a food,

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38. 7 U.S.C. §§ 136-136y (1988). *See also* Allen, *supra* note 26, at 543-44; Fogelman, *supra* note 26, at 249-51; Shapiro, *supra* note 26, at 39.

39. 51 Fed. Reg. 23,313, 23,321 (1986).

40. *Id.* at 23,322.

41. Proposed Policy Regarding Certain Microbial Products, 49 Fed. Reg. 50,880, 50,884-85 (1984).

42. 51 Fed. Reg. 23,313, 23,321 (1986). Presently, Level I permits are subject to a 30-day deadline for completion of review and Level II permits are subject to a 90-day deadline. For pending modifications to the current review process, see *supra* note 33.

43. 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). "[F]ood additive" is "any substance" added by someone "the intended use of which results or 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).

Recently, the FDA issued a policy statement "[clarif[ying the] FDA's interpretation of the Federal Food, Drug, and Cosmetic Act . . ., with respect to new technologies to produce foods, and reflect[ing the] FDA's current judgment based on new plant varieties now under development in agricultural research." Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984 (1992). Because this policy statement has been interpreted as having a deregulatory effect, public response has been vigorous. *See, e.g., Biotechnology and the Food Supply: Consumer Information in the New Marketplace*, NBIAP NEWS REP. (Nat'l Biological Impact Assessment Program, Va. Polytechnic Inst. & State Univ., Blacksburg, Va.), Aug. 1992, at 3. In fact, a bill was introduced in the House shortly after the policy's appearance in the *Federal Register* to amend the FDCA to "require that foods derived from plant varieties developed by methods of genetic modification be labelled to identify their derivation." *Id.* at 4. *See also Policy on Bioengineered Foods Draws Support and Opposition*, NBIAP NEWS REP. (Nat'l Biological Impact Assessment Program, Va.

such as a genetically engineered agricultural field crop, apparently may also be regulated by the USDA and APHIS if it is classified by that agency as a plant pest.[44] Jurisdictional overlap may also occur in the case of edible plants genetically modified to express pesticidal substances. In this regard, the FDA recently released a policy statement purporting to clarify the matter of such jurisdictional overlap with the EPA, as did the EPA in an effort to clarify overlap with both the USDA and the FDA.[45]

Polytechnic Inst. & State Univ., Blacksburg, Va.), July 1992, at 1.

44. Delegation of authority to APHIS for plant pests is pursuant to 7 C.F.R. § 371.2(c)(2)(iv) (1989). The first foods to raise the issue of jurisdictional overlap were genetically engineered tomato and genetically engineered squash. In the case of tomato, the FDA exercised jurisdiction pursuant to its current interpretation of the FDCA, *see* 57 Fed. Reg., *supra* note 43, while the USDA-APHIS expressly refrained from exercising its jurisdiction. *See Interpretive Ruling on Calgene, Inc., Petition for Determination of Regulatory Status of FLAVR SAVR™ Tomato*, 57 Fed. Reg. 47,608, 47,615 (1992). *See also USDA Deregulates Calgene's FLAVR SAVR Tomato*, NBIAP NEWS REP. (Nat'l Biological Impact Assessment Program, Va. Polytechnic Inst. & State Univ., Blacksburg, Va.), Nov., 1992, at 2; *Deregulation of Virus Resistant Squash Proposed*, NBIAP NEWS REP. (Nat'l Biological Impact Assessment Program, Va. Polytechnic Inst. & State Univ., Blacksburg, Va.), Oct., 1992, at 1-2.

45. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 23,005 (1992):

> Questions have been raised concerning whether FDA or EPA would have jurisdiction when plants are modified to express pesticidal substances. FDA and EPA are agreed that substances that are pesticides as defined by FIFRA . . . are subject to EPA's regulatory authority. The agencies also agree that FDA's authority under the [FDCA] extends to any nonpesticide substance that may be introduced into a new plant variety and that is expected to become a component of food.

Id. This FDA policy statement goes on to explicitly identify the types of substances subject only to the EPA's or only to the FDA's regulation. *Id.* For example, substances which alter nutritional composition fall within the purview of the FDA, while substances intended to protect plants from insects and viruses fall within the exclusive purview of the EPA. In spite of these fairly obvious examples, the policy statement admits that the "EPA and FDA are aware that there may be cases in which the jurisdictional responsibility for a substance is not clear. . . . The agencies are also aware that, in some circumstances, evaluation of a particular substance . . . may require the expertise of both EPA and FDA." *Id.*

With respect to the EPA's efforts to further resolve or clarify jurisdictional overlap, the EPA has framed the issue as follows:

> The issue here, therefore, is not whether or under what statutory authority a substance will be regulated. Rather, the issue is who will regulate. If a substance is defined by FIFRA as a pesticide, it is subject to EPA's regulatory authority. If the substance is not a pesticide under FIFRA, FDA has regulatory responsibility. EPA believes it is reasonable to develop [an] interpretation for plant-pesticides that provides for FDA to regulate the types of substances that it has experience and expertise in regulating and avoids EPA regulating substances that relate to nutrition and food quality as "pesticides."

EPA, DRAFT EPA PROPOSAL TO CLARIFY THE REGULATORY STATUS OF PLANT-PESTICIDES 13-14 (Nov. 20, 1992). Accordingly, the EPA first proposes a new definition of "plant-pesticides" under FIFRA, and then proposes to exempt certain categories of

According to the terms of the Coordinated Framework, other instances of concurrent jurisdiction also exist. For example, as suggested above, the EPA, USDA, and APHIS technically share jurisdiction when a microbial pesticide may also be a plant pest.[46] At present, this jurisdictional overlap has theoretically been addressed in the following manner. The EPA, USDA, and APHIS have allocated responsibility for microorganisms according to whether they involve an agricultural use.[47] Consequently, an environmental use does not presently appear to be a determinative factor in resolving matters of potential jurisdictional overlap. The rationale for this distinction has not been disclosed.

C. *The Controversy Surrounding the Coordinated Framework*

1. *The White House's Influence—Then and Now*

In sponsoring the Coordinated Framework through the White House's OSTP, the Reagan Administration assumed a fundamentally crucial policy position concerning a regulatory strategy for biotechnology.[48] It determined that biotechnology and genetic engineer-

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"plant-pesticides" from FIFRA's purview pursuant to § 25(b) of the FIFRA. *Id.* at 25-28. In so doing, the EPA obviates most grounds for jurisdictional overlap with the FDA.

In the case of jurisdictional overlap with the USDA-APHIS, a "letter of agreement" allows the EPA to cooperatively review small scale field tests of plant-pesticides even when those tests fall exclusively within the PPA. *Id.* at 57; *see also id.* at 43 & 56, figs. 1 & 4. Apparently, it is contemplated that this EPA review would survive any future categories of exemptions created by the USDA. *Id.* at 57.

46. See 7 U.S.C. §§ 136-136y (1988), for the statutory source of the EPA's regulatory authority and 7 U.S.C. §§ 150aa-150jj, 151-167 (1988), for the statutory source of the USDA-APHIS's regulatory authority.

47. Coordinated Framework for Regulation of Biotechnology; Announcement of Policy and Notice for Public Comment, 51 Fed. Reg. 23,302, 23,304-05 (1986); *see also* 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). This policy statement specifies that, in circumstances of agency jurisdictional overlap, microorganisms used solely for non-pesticidal agricultural uses are to be reviewed by the USDA only.

With regard to the USDA-EPA distinctions which currently govern regulatory oversight, a new draft bill would greatly enlarge the powers of the EPA. Apparently, the proposed bill, which originated in talks between the new White House Office on Environmental Policy and certain members of Congress, would make environmental quality a key factor in any future legislation or regulation by any agency concerning the introduction of genetically engineered organisms into the environment. *Regulatory Update*, NBIAP NEWS REPORT (Nat'l Biological Impact Assessment Program, Va. Polytechnic Inst. & State Univ., Blacksburg, Va.), Mar. 1993, at 1-2.

48. *See generally* U.S. GENERAL ACCOUNTING OFFICE, REPORT TO THE CHAIRMAN, SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS, COMMITTEE ON ENERGY AND COMMERCE, HOUSE OF REPRESENTATIVES, BIOTECHNOLOGY: MANAGING THE RISKS OF FIELD TESTING GENETICALLY ENGINEERED ORGANISMS (1988) [hereinafter MANAGING RISKS]; Gregory R. Jaffe, *Inadequacies in the Federal Regulation of Biotechnology*, 11 HARV. ENVTL. L. REV. 491 (1987); Sheldon Drimsky et al., *Controlling Risk in Biotech*, 92

ing could be adequately regulated under existing legislative authority, and that no new legislation was necessary to protect the public or the environment. Consequently, genetically engineered organisms are now regulated under the purview of numerous preexisting statutes that address the risks of unrelated uses, unrelated experiments, and unrelated products.

The Reagan Administration's rationale for promoting the regulatory concept embraced by the Coordinated Framework was foreshadowed by Executive Order 12,291 of February 17, 1981.[49] Executive Order 12,291 announced the requirement that federal agencies submit *all* proposals, final rules, or *any* other regulatory initiative to the White House Office of Management and Budget (OMB) for approval. At the time of its release, Executive Order 12,291 purported to be an efficiency measure adopted "to reduce the burdens of existing and future regulations, increase agency accountability for regulatory actions, provide for presidential oversight of the regulatory process, minimize duplication and conflict of regulations, and insure well-reasoned regulations . . . ."[50]

In reality, Executive Order 12,291 gravely curtailed agency discretion in matters of regulatory policy and implementation, and effectuated a form of executive "de-regulation." The Order established a cost/benefit standard by which the OMB was to adjudge a particular agency's regulatory proposal(s).[51] By virtue of this standard, the Order "formally" displaced agency discretion by substituting a "mandatory cost/benefit standard for the discretionary rulemaking authority vested in an agency by its authorizing statute."[52] Moreover, critics contended that the Order had become a guise for the administration's "informal" efforts to usurp agency discretion. Pri-

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TECH. REV. 62 (1989). *See also* BIOTECH91, *supra* note 17.

49. Exec. Order No. 12,291, 46 Fed. Reg. 13,193 (1981).

50. *Id.*

51.

> **Sec. 2.** *General Requirements.*
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> . . . .
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> (b) Regulatory action shall not be undertaken unless the potential benefits to society for the regulation outweigh the potential costs to society;
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> (c) Regulatory objectives shall be chosen to maximize the net benefits to society;
>
> . . . .
>
> (e) Agencies shall set regulatory priorities with the aim of maximizing the aggregate net benefits to society, taking into account the condition of the particular industries affected by regulations, the condition of the national economy, and other regulatory actions contemplated for the future.

Id. at 13,193-94.

52. *OMB Has Usurped Agencies' Regulatory Discretion, Watchdog Group Says*, FOOD CHEMICAL NEWS, Aug. 12, 1985, at 31 (quoting OMB WATCH, Aug. 7, 1985) [hereinafter *OMB Usurpation*].

vate undocumented meetings between the OMB and various industry representatives raised serious doubts as to the administration's claims that Executive Order 12,291 promoted "more rational and objective" rulemaking.[53]

One year after the Coordinated Framework's debut, but one year before the OSTP introduced version two of the Coordinated Framework, the Reagan Administration announced further efforts to effectuate "de-regulation." Pursuant to Executive Order 12,498 of January 4, 1985,[54] the OMB's centralized oversight authority was expanded by the administration's implementation of a regulatory planning process. The Order established a highly structured procedure under which agencies were directed to negotiate with the OMB in matters of regulatory policy and implementation. Critics alleged that Executive Order 12,498 permitted OMB "to control virtually all federal agency policies and activities without public knowledge or involvement, . . . in essence, to write federal policy."[55]

As was true of its 1981 predecessor, the 1985 Order was viewed as far more than an efficiency measure to avoid "duplication" and regulatory "burdens" within the federal scheme. In fact, Executive Order 12,498 established an even broader standard by which the OMB was to adjudge agency submissions. Now, OMB could quash any agency action which it deemed to be "inconsistent with [the] Administration position, either reflected by budget submissions to Congress or overall regulatory 'goals.' "[56] Executive Order 12,498 expressly authorized the Director of the OMB to "consider the consistency of the draft regulatory program with the Administration's policies and priorities" and "identify such further regulatory or *deregulatory* actions as may, in his view, be necessary in order to achieve consistency."[57] This language has led critics to claim that Executive Order 12,498 "institutionalizes a review process that conclusively displaces agency discretion and shuts off all forms of public access, including public comment and Congressional oversight."[58]

This tactic of executive "de-regulation" was wholly adopted by the Bush Administration. With respect to biotechnology regulation, the most blatant manifestation of this tactic to emerge from the Bush Administration was the 1991 report issued by the President's Council on Competitiveness.[59] This report embraced "four principles of regulatory review" which unreservedly endorsed the Coordinated

53. *Id.*

54. Exec. Order No. 12,498, 50 Fed. Reg. 1,036 (1985).

55. *OMB Usurpation*, *supra* note 52, at 31.

56. *Id.* at 32.

57. Exec. Order No. 12,498, 50 Fed. Reg. 1,036, 1,037 (1985) (emphasis added).

58. *OMB Usurpation*, *supra* note 52, at 31.

59. THE PRESIDENT'S COUNCIL ON COMPETITIVENESS, REPORT ON NATIONAL BIOTECHNOLOGY POLICY (1991).

Framework's philosophy of regulation.[60] Moreover, this report expressly recommended that the Bush Administration "oppose any efforts to create new or modify existing regulatory structure for biotechnology through legislation."[61]

While the report by the Council on Competitiveness may have been the Bush Administration's most publicized "de-regulatory" effort,[62] it certainly was not the only such one to affect biotechnology. In his State of the Union Address to Congress in 1992, Bush announced a moratorium on regulation. This announcement came at a critical time for the EPA and FDA, both of which were pending release of proposed rules for biotechnology-related activities.[63] Furthermore, while this declared moratorium was in effect, the White House's OSTP published a policy announcement in the *Federal Register* articulating purported "guidelines" for an agency's exercise of discretion in matters of biotechnology.[64]

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60. *Id.* at 12-13.

61. *Id.* at 14. *See also* Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products into the Environment, Announcement of Policy, 57 Fed. Reg. 6,753 (1992); Principles for Federal Oversight of Biotechnology: Planned Introduction into the Environment of Organisms with Modified Hereditary Traits, Announcement of Policy, 55 Fed. Reg. 31,118, 31,118-21 (1990).

Some experts have expressed concern about the long-term effectiveness of the Competitiveness Council's policy position. Rather than engage in a meaningful effort to formulate policy for building public support and awareness, the Council's myopic view has resulted in a "laissez faire environment that could harm the industry." Roger S. Johnson, Ph.D., *Former House Committee Chief Calls for "National Trust for Biotechnology,"* GENETIC ENG'G NEWS, Apr. 15, 1992, at 5; *see also*, BIOTECH91, *supra* note 17, at 143-44 (interview with then Senator Albert Gore, Jr.). In fact, former Congressional Chief of Staff of the Science, Space and Technology Committee, Rob Ketcham, stated that "the policy will not speed biotech products to market." Johnson, *supra*, at 5.

62. *See, e.g.*, Philip J. Hilts, *Bush to Ease Rules on Products Made by Altering Genes*, N.Y. TIMES, Feb. 24, 1992, at A1.

63. *President Declares Moratorium on Regulations*, NBIAP NEWS REP. (Nat'l Biological Impact Assessment Program, Va. Polytechnic Inst. & State Univ., Blacksburg, Va.), Feb. 1992, at 1. This moratorium was subsequently extended, *see Regulatory Moratorium Extended*, NBIAP NEWS REP. (Nat'l Biological Impact Assessment Program, Va. Polytechnic Inst. & State Univ., Blacksburg, Va.), May 1992, at 1, leading to a legal challenge of the administration's persistent adherence to the so-called temporary moratorium on regulation. *Regulatory Moratorium*, NBIAP NEWS REPS. (Nat'l Biological Impact Assessment Program, Va. Polytechnic Inst. & State Univ., Blacksburg, Va.), Sept. 1992, at 2.

64. Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products into the Environment, Announcement of Policy, 57 Fed. Reg. 6753, 6757 (1992). This document claimed to be a finalization of a 1990 "Scope Document," originally prepared as a "common statement" devised by the "Federal agencies work[ing] closely" and subsequently reviewed by the Council on Competitiveness. *Id.* at 6754. *See also White House Issues New Policy to Govern Oversight of Biotechnology Products*, NBIAP NEWS REP. (Nat'l Biological Impact Assessment Program, Va. Polytechnic Inst. & State Univ., Blacksburg, Va.), Mar. 1992,

Several other efforts to "de-regulate" federal biotechnology oversight took hold during the last months of the Bush Administration.[65] The most significant of these occurred in conjunction with the USDA's formal announcement of proposed new rules to provide "regulatory relief" in field-testing transgenic plants.[66] While USDA's proposal to adopt a non-permitting regulatory scheme for some field tests was itself troublesome, the inclusion in this same announcement of a policy to preempt *any* state oversight in such matters was shocking.[67]

Apparently, following an executive review of the USDA's proposed rule pursuant to Executive Order 12,778, it was decided that "[t]his rule would preempt any State or local laws, regulations, or policies that are inconsistent with this rule."[68] On its face, such a regulatory

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at 1-2. For an historical summary of biotechnology regulation in the context of the original "Scope Document," see *Forum*, NBIAP NEWS REP. (Nat'l Biological Impact Assessment Program, Va. Polytechnic Inst. & State Univ., Blacksburg, Va.), Apr. 1992, at 9-10.

65. *See, e.g.*, *EPA To Go Ahead with Biotech Rules Under TSCA*, NBIAP NEWS REP. (Nat'l Biological Impact Assessment Program, Va. Polytechnic Inst. & State Univ., Blacksburg, Va.), Oct. 1992, at 2; *Regulatory Update: Notification Process for Plants*, NBIAP NEWS REP. (Nat'l Biological Impact Assessment Program, Va. Polytechnic Inst. & State Univ., Blacksburg, Va.), Oct. 1992, at 1; *EPA Biotechnology Rulemaking*, NBIAP NEWS REP. (Nat'l Biological Impact Assessment Program, Va. Polytechnic Inst. & State Univ., Blacksburg, Va.), Aug. 1992, at 1; *USDA Guidelines Released*, NBIAP NEWS REP. (Nat'l Biological Impact Assessment Program, Va. Polytechnic Inst. & State Univ., Blacksburg, Va.), July 1992, at 1-2; *Forum*, NBIAP NEWS REP. (Nat'l Biological Impact Assessment Program, Va. Polytechnic Inst. & State Univ., Blacksburg, Va.), Jan. 1992, at 8. *See also* Roger S. Johnson, Ph.D., *EPA Seeks White House's Approval for Including Recombinants Under TSCA*, GENETIC ENG'G NEWS, June 15, 1992, at 3; AGRIC. BIOTECH. RES. ADVISORY COMM., U.S. DEPT. AGRIC., SUPPLEMENT TO MINUTES, GUIDELINES FOR RESEARCH INVOLVING PLANNED INTRODUCTION INTO THE ENVIRONMENT OF GENETICALLY MODIFIED ORGANISMS, Mar. 5, 1992 (Office of Agric. Biotech., Doc. No. 91-04) (Letter of Mar. 5, 1992, from Bennie I. Osburne, D.V.M., Ph.D. to Dr. Harry Mussman) (While "there have been several policy developments at the White House Office of Science and Technology Policy and the President's Council on Competitiveness, that may affect how USDA implements the recommended guidelines," the Committee "stress[es] how important it is . . . to provide guidance to the agricultural research community on the safe performance of research utilizing the newer techniques of biotechnology.").

66. Genetically Engineered Organisms and Products; Notification Procedures for the Introduction of Certain Regulated Articles; and Petition for Nonregulated Status, 57 Fed. Reg. 53,036 (1992). *See also* John Sterling, *USDA Seeks Easing of Field Test Requirement*, GENETIC ENG'G NEWS, Nov. 15, 1992, at 1; *USDA Proposes "Regulatory Relief" for Field Tests*, NBIAP NEWS REP. (Nat'l Biological Impact Assessment Program, Va. Polytechnic Inst. & State Univ., Blacksburg, Va.), Nov. 1992, at 1; *Regulatory Update: Notification Process for Plants*, NBIAP NEWS REP. (Nat'l Biological Impact Assessment Program, Va. Polytechnic Inst. & State Univ., Blacksburg, Va.), Oct. 1992, at 1; *Regulation of Transgenic Plants to Change?*, NBIAP NEWS REP. (Nat'l Biological Impact Assessment Program, Va. Polytechnic Inst. & State Univ., Blacksburg, Va.), Sept. 1992, at 1-2.

67. 57 Fed. Reg. 53,036, 53,040 (1992).

68. *Id.* Insofar as Executive Order 12,778 is concerned, it was issued on October

posture is completely contrary to the USDA's traditional practice of cooperating with the states. Thus it is not unreasonable to speculate that the preemption language originated from within the White House, not the USDA, especially in light of the previous discussion of OMB's centralized and final authority in matters of agency rulemaking and implementation.

Given that a new administration now occupies the White House, finalization of the above mentioned proposed rule must await another executive review.[69] To date, commentary on the new rule has been substantial.[70] In addition to comments by environmental and industrial groups, at least two states—Maine and North Carolina—have expressed in writing their respective concerns about the rule's technical shortcomings, as well as its unexplained language regarding preemption of state oversight.[71]

To what extent the Clinton Administration will perpetuate the regulatory philosophy of its predecessors remains to be seen.[72] There are numerous reasons, however, to assume that it will not. For example, on January 22, 1993, President Clinton dissolved the existing

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23, 1991 by President Bush, and is entitled "Civil Justice Reform." Exec. Order No. 12,778, 56 Fed. Reg. 55,195 (1991). Essentially, the Order purports to announce principles which would lead to the enactment of legislation and promulgation of regulations which do not unduly burden the federal court system. The preamble states that the Order aims "to facilitate the just and efficient resolution of civil claims involving the United States Government . . . [and] to improve legislative and regulatory drafting to reduce needless litigation."

69. *Regulatory Update: Notification Procedure for Specified Crop Plants*, NBIAP NEWS REP. (Nat'l Biological Impact Assessment Program, Va. Polytechnic Inst. & State Univ., Blacksburg, Va.), Jan. 1993, at 1; *Regulatory Update*, NBIAP NEWS REP. (Nat'l Biological Impact Assessment Program, Va. Polytechnic Inst. & State Univ., Blacksburg, Va.), Dec. 1992, at 1.

70. *Regulatory Update: Notification Procedure for Specified Crop Plants*, NBIAP NEWS REP. (Nat'l Biological Impact Assessment Program, Va. Polytechnic Inst. & State Univ., Blacksburg, Va.), Jan. 1993, at 1.

71. Minutes of the Me. Biotechnology & Genetic Eng'g Comm'n, Me. Dept. Agric., at 3 (Jan. 25, 1993) (on file with author).

Letters to Chief, Regulatory Analysis and Development, USDA-APHIS, from James A. Graham, Commissioner; and, Howard Singletary, Director of Division of Plant Industry, and Scott H. Shore, Biotechnologist, North Carolina Department of Agriculture, Raleigh, N.C. (Dec. 29, 1992) (on file with author). *See also USDA's "Regulatory Relief" and the States*, NBIAP NEWS REP. (Nat'l Biological Impact Assessment Program, Va. Polytechnic Inst. & State Univ., Blacksburg, Va.), Nov. 1992, at 1-2.

72. *See Forum—It's Technology. But What About Regulation?*, NBIAP NEWS REP. (Nat'l Biological Impact Assessment Program, Va. Polytechnic Inst. & State Univ., Blacksburg, Va.), Mar. 1993, at 7 (no strong indicators of direction are yet available); Bradie Metheny and Shirley Haley, *New OSTP Director Calls for Competitive Peer Review for National Labs*, GENETIC ENG'G NEWS, Mar. 1, 1993, at 21 ("A Clinton transition team biotechnology meeting was cancelled indefinitely and the administration has not reopened the topic.").

White House Council on Competitiveness.[73] Such an executive act strongly suggests that the Clinton Administration is unlikely to adopt blindly the regulatory stance of its predecessors.[74]

Moreover, while President Clinton's economic strategy could be interpreted as favoring private enterprise at the possible expense of regulation,[75] his choice of Albert Gore, Jr. as his Vice President suggests otherwise. President Clinton's selection of Gore suggests that the President is not insensitive to environmental or public policy concerns.

Furthermore, Vice President Gore has an established expertise in matters of biotechnology policy and regulation. Such expertise certainly favors the possibility that the Clinton Administration will manage the biotechnology regulatory controversy in a more informed fashion than did its two immediate predecessors. With respect to the existing "government infrastructure" for biotechnology regulation, Vice President Gore has stated that "it's time to pronounce at least a major part of that experiment a failure. . . . The whole effort has been seriously flawed and needs to be reexamined."[76]

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73. President's Memorandum for the Acting Director, Office of Management and Budget, Memorandum on Review of Regulations, 29 WEEKLY COMP. PRES. DOC. 93 (Jan. 21, 1993).

74. It is interesting to speculate that President Clinton's dissolution of the Council was prompted, in part, by Vice President Gore's dissatisfaction with the Council. *See* Roger S. Johnson, Ph.D., *Former House Committee Chief Calls for "National Trust for Biotechnology,"* GENETIC ENG'G NEWS, Apr. 15, 1992, at 5 ("Senator Al Gore (D-TN) is reportedly becoming more interested in biotechnology regulatory policy since the administration's recent actions. He is troubled by the Council on Competitiveness' management of scientific decisions at the agencies.").

For further speculation as to Vice President Gore's role in matters of biotechnology policy, see Richard D. Godown & Lisa J. Raines, *Some Thoughts on How President Clinton's Team Might Approach Biotechnology Issues*, GENETIC ENG'G NEWS, Jan. 15, 1993, at 4, 21 (Vice President Gore "will be designated the administration's science and technology czar.").

75. *See, e.g.*, Richard Bock, *Advice to Investors: Stay Focused on Biotechnology's Long-Term Picture*, GENETIC ENG'G NEWS, Jan. 1, 1993, at 14, 15 ("The present political myth on Wall Street is that baby-boomers Clinton and Gore are supposedly enamored of biotech and view the industry as a sacred cow . . . whose cutting-edge technology is exactly what the new Administration wants to push to help America prosper.").

One commentator has attributed the apparent renewed interest among investors in the biotechnology sector to the "Clinton Effect." The Clinton Administration is perceived as looking favorably upon biotechnology as a growth industry "to help support both a shrinking national tax base and declining global leadership in innovative new technologies." John F. Wong, Ph.D., *A Sanguine Perspective on Biotechnology: Past, Present and the Future*, GENETIC ENG'G NEWS, Feb. 1, 1993, at 14-15.

76. *See* BIOTECH91, *supra* note 17, at 146. *See also* Sen. Albert Gore, *Federal Biotechnology Policy: The Perils of Progress and the Risks of Uncertainty*, 20 U. MICH. J.L. REFORM 965 (1987); Albert Gore, Jr., *A Congressional Perspective*, BIOTECHNOLOGY: IMPLICATIONS FOR PUBLIC POLICY 12 (S. Panem, ed. 1985); Sen. Albert Gore, Jr.,

2. *The Existing Statutory Scheme Is Flawed*

Foremost among the problems created by a regulatory approach such as the Coordinated Framework is that it ignores the possibility that the new biotechnologies may pose previously unconsidered threats to the environment and to society. Moreover, this particular regulatory strategy creates several other problems requiring prompt resolution, without which effective regulation will not be possible. First, reliance on existing statutes does not allow comprehensive regulatory coverage of biotechnology's potential breadth of uses. The existing Coordinated Framework fails to regulate some genetically novel organisms by any agency,[77] is limited in current application to only small-scale releases,[78] and creates numerous categories of exempt organisms and activities which remain unjustified.[79] Second, reliance on unrelated, preexisting statutes does not provide for a unitary regulatory approach. Different agencies use different statutory standards to regulate, yet they have concurrent jurisdiction over the same biotechnology products and their environmental releases.[80] Third, reliance on preexisting statutes does not allow precise statutory interpretation or application. In particular, the EPA has been forced to regulate biotechnology under authority given to it by Congress to regulate chemical substances. A lack of statutory specificity and absence of clear congressional intent may render the EPA lacking in sufficient authority to regulate some aspect(s) of biotechnology and genetic engineering.

The principal objection to the existing Coordinated Framework is that the designated statutes are not designed to regulate biotechnology. Interagency efforts to coordinate their regulatory policies can not overcome the fundamental deficiencies inherent in the individual agency's regulatory authority.

& Steve Owens, *The Challenge of Biotechnology*, 3 YALE L. & POL'Y REV. 336 (1985). For related comments by Vice President Gore, see *supra* notes 17 & 25 and accompanying text.

77. *See, e.g., Genetically Modified Fish—Environmental Threat?*, NBIAP NEWS REP. (Nat'l Biological Impact Assessment Program, Va. Polytechnic Inst. & State Univ., Blacksburg, Va.), Nov. 1992, at 4-5. *See also* Margaret Mellon, *The Regulation of Genetically Engineered Animals: Going from Bad to Worse*, NABC REPORT 4, ANIMAL BIOTECHNOLOGY: OPPORTUNITIES & CHALLENGES 165, 167-69 (J.F. MacDonald, ed. 1992); MANAGING RISKS, *supra* note 48, at 38-47, 105-107; OTA REPORT, *supra* note 26, at 210-12.

78. *See generally* MANAGING RISKS, *supra* note 48, at 20, 107; NATIONAL RESEARCH COUNCIL, FIELD TESTING GENETICALLY MODIFIED ORGANISMS: FRAMEWORK FOR DECISIONS 1-6, 69-70, 119 (1989). *See, e.g., EPA Biotechnology Rulemaking*, NBIAP NEWS REP. (Nat'l Biological Impact Assessment Program, Va. Polytechnic Inst. & State Univ., Blacksburg, Va.), Aug. 1992, at 1.

79. *See supra* note 77.

80. In fact, this kind of potential jurisdictional conflict resulted in grid-lock among the BSCC representatives and contributed to its eventual dissolution in 1991. *See supra* note 25.

One source of the EPA's intended statutory authority in biotechnology regulations, the TSCA, was originally enacted to regulate toxic chemicals and is ill-suited to biotechnology and genetic engineering.[81] It is unclear whether the statute, which by its terms covers only "chemical substances," can be legitimately extended to include genetically engineered organisms. Even if a court could be convinced to define the microbial products of genetic engineering as chemicals, litigating that issue would precipitate regulatory delay and uncertainty.[82]

In addition, the TSCA places the burden on the EPA to demonstrate the existence of a risk before it can take regulatory action.[83] Under the TSCA, the EPA must show, as a prerequisite to exercising its regulatory jurisdiction, that a chemical presents "an unreasonable risk of injury to health or the environment" in order to then establish limitations on its use.[84] The EPA must demonstrate that a chemical "presents or will present an unreasonable risk of injury to health or the environment" before it may even require that a manufacturer test a chemical.[85] Because the burden of proof rests with the EPA, it may be difficult to implement the TSCA extension to genetically modified organisms. In contrast, other federal statutes place the burden on the manufacturer to demonstrate that the product is safe and require that the manufacturer obtain a permit or license before such a product can be used or sold. For example, the FDA relies on legislation which places the burden of proof for product safety on the manufacturer.[86]

Given an inadequate database, together with the EPA's current unfamiliarity with the technical uncertainties surrounding all aspects of environmental releases, placing the burden on the EPA favors uninformed approvals. Such technical uncertainties prevent the EPA's unequivocal determination of "unreasonable risk," thereby preventing it from meeting its burden of proof. In sharp contrast, the biotechnology practitioner has no burden of proof in order to proceed with an environmental introduction. Commentators have previously noted that the practitioner consequently enjoys a pre-

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81. William G. Schiffbauer, *Regulating Genetically Engineered Microbial Products Under the Toxic Substances Control Act*, 15 ENVTL. L. REP. 10,279, 10,280 (1985). *See also* Roger S. Johnson, Ph.D., *EPA Seeks White House's Approval for Including Recombinants Under TSCA*, GENETIC ENG'G NEWS, June 15, 1992, at 3; OTA REPORT, *supra* note 26, at 212.

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

83. 15 U.S.C. § 2605(a) (1988). *See also* Allen, *supra* note 26, at 546-47.

84. 15 U.S.C. § 2605.

85. *Id.* § 2603(a).

86. *See, e.g.*, the FDCA, *supra* note 43; *see also* Michael S. Ostrach, *Biotechnology and the FDA Review Process*, BIOTECHNOLOGY: NEW DEVELOPMENTS IN FEDERAL POLICIES AND REGULATIONS (Practicing Law Institute 1988).

sumption of safety.[87] Thus, although the TSCA establishes a reporting requirement,[88] compliance can hardly be called burdensome on the practitioner relative to the EPA.

In the case of the EPA's application of the TSCA to the release of genetically-engineered organisms, the analogy of a microorganism to a chemical is inapt. The ability of an organism to replicate and evolve makes its potential for risk greater than a chemical's. The effects of replication and evolution are unpredictable. Unlike hazardous chemicals for which careful limitations may be placed on quantities and sites of application, the ability of microbes to replicate renders control over quantity and dispersal more complex and difficult. Such regulations are inadequate to monitor complex and subtle interactions of living organisms in dynamic, uncontained ecosystems.[89]

Additionally, it is unreasonable to expect the EPA to review effectively every Level I or Level II organism within the current prescribed FIFRA deadlines.[90] Unlike chemical pesticides for which the EPA has a vast store of data with which to make assessments and develop comparative analyses, no such database exists for genetically engineered pesticides. Thus, compliance with such deadlines may compromise the thoroughness of the EPA's current review process.

Another potential problem is that the TSCA exempts from regulation small quantities of new, experimental chemical substances.[91] Given the EPA's belief that the small quantities standard is inappropriate for microorganisms, it has made efforts to define small quantities in these cases differently than in cases involving chemicals.[92] In so doing, however, it could be alleged that the EPA has not been faithful to congressional intent. A successful legal challenge to an issue like this would render the concept of interagency regulation via the Coordinated Framework ineffectual.

The question as to whether the EPA has adequate regulatory authority under the TSCA is complicated by the following scenario. On the one hand, the scientific community is not in agreement as to

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87. *See, e.g.*, Allen, *supra* note 26, at 546-47 ("This presumption offers no incentive for the manufacturer to resolve uncertainty through further research. In fact, a presumption of safety actually may provide a disincentive . . . since additional research may provide evidence of harm that the manufacturer would rather not confront.").

88. *See* 15 U.S.C. §§ 2604, 2607 (1988).

89. Other commentators have reached similar conclusions; *see, e.g.*, Allen, *supra* note 26, at 544-45. *See also infra* note 93.

90. *See supra* note 42. *See also* Allen, *supra* note 26, at 544.

91. 15 U.S.C. § 2604(h)(3) (1988). *See also* Allen, *supra* note 26, at 545-46.

92. *See, e.g.*, EPA, DRAFT PROPOSED RULE, MICROBIAL PRODUCTS OF BIOTECHNOLOGY; DESIGNATION OF SIGNIFICANT NEW USES (1988). *See also*, OTA REPORT, *supra* note 26, at 195; *supra* note 34.

the magnitude of risk associated with the release of genetically engineered organisms.[93] From the point of view of those believing that there is little probability of risk, the TSCA is adequate. From the point of view of those believing that the magnitude of the risk is great, the TSCA as it currently stands is inadequate.

On the other hand, the extent of reliance on the TSCA in the regulation of genetically engineered organisms is not yet known. Clearly, the TSCA will become important if a large number of organisms fall within its purview. It is highly likely, however, that the biotechnology industry will orient its future genetic engineering efforts to fall within the least regulated sphere(s) of the Coordinated Framework. After all, less regulation results in lower development and production costs, and speedier market entries. If it does appear that the EPA will rely heavily on the TSCA, a permitting scheme that would shift the burden to the industry should be given serious consideration. In this regard, the prevailing sentiments of the biotechnology industry are to oppose any legislation that would establish new regulations for biotechnology.[94]

As other commentators have noted,[95] the wisdom of regulating some genetically engineered organisms under permitting statutes such as those within the purview of the USDA and APHIS, while regulating other organisms under the TSCA's notification-reporting

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93. The report by the U.S. General Accounting Office, MANAGING RISKS, *supra* note 48, clearly illustrates the fundamental scientific disagreement which precipitated the conflict between microbiologists and ecologists; *see also* BROOKINGS DIALOGUES ON PUBLIC POLICY, BIOTECHNOLOGY: IMPLICATIONS FOR PUBLIC POLICY, (Sandra Panem, ed., 1985); *compare* National Academy of Sciences, *Introduction of Recombinant DNA-Engineered Organisms into the Environment: Key Issues* 14-15 (1987) *with* both Ecological Society of America, *The Release of Genetically Engineered Organisms: A Perspective for the Ecological Society of America*, 70 ECOLOGY 297 (1989) and James M. Tiedje et al., *The Planned Introduction of Genetically Engineered Organisms: Ecological Considerations and Recommendations*, 70 ECOLOGY 298, 300-301 (1989).

Other commentators have described this tension within the scientific community similarly. *See, e.g.*, Shapiro, *supra* note 26, at 25; OTA REPORT, *supra* note 26, at 225-27.

94. *See, e.g.*, BIOTECH91, *supra* note 17, at 159, 162; OFFICE OF RECOMBINANT DNA ACTIVITIES, NATIONAL INSTITUTES OF HEALTH, 1992 NATIONAL BIOTECHNOLOGY POLICY BOARD REPORT, E8-E20 (1992); Johnson, *supra* note 74; OTA REPORT, *supra* note 26, at 213-16.

The recently formed Biotechnology Industry Organization sent a letter to President Clinton supporting his effort to bolster the biotechnology industry. The letter identified regulatory issues to which the new administration should give priority. In particular, the Organization encouraged continued support for the USDA's proposal to institute a non-permitting, notification-only regulatory regime for transgenic plants, *see supra* note 31, as well as the EPA's proposed changes in the regulatory regime for microbial pesticides. *See supra* note 33. *Biotechnology Trade Associations Merge*, NBIAP NEWS REP. (Nat'l Biological Impact Assessment Program, Va. Polytechnic Inst. & State Univ., Blacksburg, Va.), Feb. 1993, at 2-3.

95. *See, e.g.*, Shapiro, *supra* note 26, at 25.

regulatory scheme, is dubious. This is especially so since the TSCA places the burden on the EPA first to prove that a particular organism is an unreasonable risk before the EPA can act on its concerns. It is not clear that Congress would have so decided if the question had been specifically presented for consideration. The Coordinated Framework has circumvented congressional involvement, leaving the matter of legislative intent unascertainable. This may prove significant in the future in the context of a legal challenge to the Coordinated Framework.

With regard to the Coordinated Framework's reliance on the USDA, the USDA's regulation by means of the PPA provides another example of the inadequate application of existing regulations to biotechnology. The PPA applies only to those organisms categorized as "plant pests."[96] Thus, the PPA does not encompass the vast majority of potentially genetically engineered hosts,[97] nor does it encompass vertebrate animals.[98] Moreover, the USDA as a regulatory agency is not vested with the statutory responsibility to protect the environment, yet the USDA will oversee certain releases of genetically engineered organisms into the environment. Finally, there is distrust of the USDA's role in the Coordinated Framework because of a perceived conflict of interest: the USDA is the government's principal promotional agency of agricultural technologies.[99]

Noncommercial research is another area where legislative intervention may be needed to fortify regulatory coverage.[100] For example, under the TSCA, the EPA has authority to regulate commercial releases only.[101] Thus, noncommercial research involving release of genetically engineered organisms into the environment would not be subject to regulation unless it was funded by the federal government or it involved a designated plant pest. Furthermore, the TSCA expressly exempts basic research, whether it be commercial or noncommercial.[102] Yet, concern for environmental safety requires regulation of all research regardless of the practitioner's affiliation or intended application. A high-risk organism will cause no less damage when released into the environment merely because the practitioner

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96. *Supra* note 32.

97. A "genetically engineered host" is an organism that has been manipulated to carry the genes of interest, thereby acting as a vector for genetic transmission.

98. Fogelman, *supra* note 26, at 257-58; Mellon, *supra* note 77.

99. Kevin Bastian, *Biotechnology and the United States Department of Agriculture: Problems of Regulation in a Promotional Agency*, 17 ECOLOGY L. Q. 413 (1990); Jaffe, *supra* note 48, at 529; Thomas O. McGarity, *Federal Regulation of Agricultural Biotechnologies*, 20 U. MICH. J.L. REF. 1089, 1144-45 (1987). *See also* OTA REPORT, *supra* note 26, at 218-19, 265.

100. *See* Fogelman, *supra* note 26, at 257-62; Shapiro, *supra* note 26, at 21; Allen, *supra* note 26, at 545-46; OTA REPORT, *supra* note 26, at 212-13.

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

102. 15 U.S.C. § 2604(h)(3) (1988).

was engaged in noncommercial research or basic research.[103]

Thus, in accordance with the Coordinated Framework's current regulatory strategy, the EPA interprets the TSCA to include commercial research that involves the release of genetically engineered organisms,[104] while noncommercial research is exempt from regulation.[105] In the context of biotechnology, however, the distinction between commercial and noncommercial may be moot. In the mid-1980s, private industry sponsored approximately twenty percent of all academic biotechnology research;[106] the biotechnology industry's strategic liaison with the private, academic sector continues to be critical, especially for smaller companies.[107] Whether research qualifies as commercial or noncommercial should not depend solely upon the professional affiliation of the researcher.[108] Furthermore, the TSCA employs a subjective standard to ascertain whether the researcher is conducting basic noncommercial research,[109] making meaningful enforcement problematic.

D. The Need to Reconsider the Coordinated Framework

While the 1986 Coordinated Framework may have attempted to clarify the roles of the various agencies, it did nothing to address the real obstacles created by the Reagan Administration's decision to regulate biotechnology under existing statutory authority. Although the goal of the OSTP's Coordinated Framework was to vest responsibility for a particular product's use in a single agency,[110] currently such is not the case. Private industry often has been unable to predict which federal agency will have regulatory jurisdiction over new applications, especially when biotechnology blurs the traditional distinctions among those categories of products possibly subject to regulation.[111]

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103. Fogelman, *supra* note 26, at 257-59 (1987); Shapiro, *supra* note 26, at 21.

104. *See* Toxic Substances: Revisions of Premanufacture Notification Regulations, Final Rule, 40 C.F.R. pt. 720 (1992).

105. Statement of Policy; Microbial Products Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic Substance Control Act, 51 Fed. Reg. 23,313, 23,331 (1986). (Non-commercial experiments are exempt pursuant to TSCA § 5(g).) *See also* Fogelman, *supra* note 26, at 258 nn.391 & 392.

106. Fogelman, *supra* note 26, at 257.

107. *See* BIOTECH91, *supra* note 17, at 49 & 151; *see also* BIOTECH 21ST CENTURY, *supra* note 3, at 2-3.

108. Fogelman, *supra* note 26, at 257 n.388.

109. *Id.* (distinction between commercial and noncommercial research hinges on intent of experimenters). *See also* Allen, *supra* note 26, at 545-46.

110. 51 Fed. Reg. 23,303 (1986). For a discussion of the current status of jurisdiction and coordination among the federal agencies, see OTA REPORT, *supra* note 26, at 207-10.

111. Examples of regulatory uncertainty deriving from jurisdictional ambiguities include foods containing pesticidal substances and plants containing pesticidal substances. In the case of foods, the FDA's policy statement in this matter acknowledged

In short, regulation by the Coordinated Framework is suboptimal because of concurrent jurisdiction, lack of regulation by any agency in some areas, and the fact that the existing regulatory authority of each agency does not derive from statutes which contemplate the specific applications and possible risks associated with the environmental release of genetically engineered organisms. Furthermore, it does not adequately protect the public or the environment because it does not incorporate proper risk assessment or risk management methodologies.[112]

To date, the Coordinated Framework has yet to address adequately the considerable redundancy which may ultimately result in unworkable biotechnology regulation. An inefficient, ineffective review process is likely to lead to controversies concerning compliance and agency authority. Thus, there appear to be significant grounds for challenging the legitimacy of the Coordinated Framework. If the Coordinated Framework is to remain viable, the designated federal agencies will have to undertake further efforts to address this problem of inefficiency by setting up an effective over-arching coordination program. In so doing, however, a repeat of the BSCC fiasco must be avoided. Recall that the White House's previous coordination efforts were thwarted by the collapse of the BSCC.[113]

Obviously inconsistent, incompatible, and ambiguous regulations engender recourse to litigation. When it is mandated that administratively-independent agencies coordinately apply a collection of unrelated laws to an emerging unfamiliar technology, anything less than a protracted and painful struggle to resolve interpretations would be surprising.[114]

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that "EPA and FDA are aware that there may be cases in which the jurisdictional responsibility for a substance is not clear. . . . FDA and EPA intend to consult closely on such jurisdictional questions, as well as on scientific matters where consultation will be helpful in resolving safety questions." 57 Fed. Reg. 22,984, 23,005 (1992). In the case of plants, the EPA and USDA appear to be in the process of developing a Memorandum of Understanding to govern field tests. "[EPA and USDA] also intend to consult closely on scientific issues related to the safety considerations associated with the environmental impact of field tests of plant pesticides." EPA, DRAFT EPA PROPOSAL TO CLARIFY THE REGULATORY STATUS OF PLANT-PESTICIDES 57-58 (Nov. 20, 1992).

112. Shapiro, *supra* note 26, at 37-49. *See also* OTA REPORT, *supra* note 26, at 227-52.

113. *Id.* at 26, n.160 and accompanying text. *See also supra* note 25.

114. For an introduction to the possible issues surrounding a legal challenge to the federal Coordinated Framework and the dimensions of judicial review in such matters, see generally David L. Bazelon, *Coping with Technology Through the Legal Process*, 62 CORNELL L. REV. 817 (1977); David L. Bazelon, *Governing Technology: Values, Choices and Scientific Progress*, 5 TECH. IN SOC'Y 15 (1983); Maxine F. Singer, *Genetics and the Law: A Scientist's View*, 3 YALE L. & POL'Y REV. 315 (1985); C. P. SNOW, THE TWO CULTURES AND THE SCIENTIFIC REVOLUTION (1959); and William H. von Oehsen III, *Regulating Genetic Engineering in an Era of Increased Judicial Deference: A Proper Balance of the Federal Powers*, 40 ADMIN. L. REV. 303 (1988).

III. The Decision to Regulate Biotechnology at the State Level

A. *Perceptions of an Industry Untamed*

As discussed above, the federal initiative to oversee genetic engineering technologies began in 1974 with the NIH's formulation of research guidelines which were limited in scope to NIH-funded research activities, and did not have the force of law. Not until 1983 did the federal government even contemplate the need for an expanded regulatory scope.[115]

During this interim period of approximately nine years, however, there developed a distinct regulatory vacuum. While the commercial and industrial growth of biotechnology, as well as advancements in the technologies of genetic engineering, underwent an unprecedented surge, no corresponding regulatory standards were available upon which commercial practitioners could rely for guidance, or society could rely for assurance. In fact, the debate at the federal level as to what *should* be done had been virtually nonexistent prior to 1983. Obviously, the perception created by this regulatory dilemma was one of an industry untamed. Such perceptions clearly and directly contributed to the regulatory momentum at the local and state levels which began in the mid-1970s and continues to the present.

Local efforts to regulate technologies such as genetic engineering through the enactment of city or town ordinances began as early as

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For a discussion of "scientific uncertainty" in the federal courts and a critique of the phenomenon of judicial deference in such matters, see generally Kenneth S. Abraham & Richard A. Merrill, *Scientific Uncertainty in the Courts*, 2 Issues In Sci. & Tech. 93 (1986); Warren Ausubel, *Federal Regulation of Genetically Engineered Food Additives and Pesticides*, 4 High Tech. L.J. 115 (1989); Devra Lee Davis, *The "Shotgun Wedding" of Science and Law: Risk Assessment and Judicial Review*, 10 Colum. J. Envtl. L. 67 (1985); Scott D. Deatherage, *Scientific Uncertainty in Regulating Deliberate Release of Genetically Engineered Organisms: Substantive Judicial Review and Institutional Alternatives*, 11 Harvard Envtl. L. Rev. 203 (1987); Norman L. Rave, Jr., *Interagency Conflict and Administrative Accountability: Regulating the Release of Recombinant Organisms*, 77 Geo. L.J. 1787 (1989); Robert Saperstein, *The Monkey's Paw: Regulating the Deliberate Environmental Release of Genetically Engineered Organisms*, 66 Wash. L. Rev. 247 (1991).

For a representative collection of decisions involving issues of "scientific uncertainty" in the federal courts and judicial treatment of related technology issues, see generally Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, 435 U.S. 519 (1978); BASF Wyandotte Corp. v. Costle, 598 F.2d 637 (1st Cir. 1979); Hercules, Inc. v. Environmental Protection Agency, 598 F.2d 91 (D.C. Cir. 1978); Environmental Defense Fund v. Environmental Protection Agency, 598 F.2d 62 (D.C. Cir. 1978); Natural Resources Defense Council, Inc. v. United States Nuclear Regulatory Comm'n, 547 F.2d 633 (D.C. Cir. 1976); Ethyl Corp. v. Environmental Protection Agency, 541 F.2d 1 (D.C. Cir. 1976) (en banc); Sierra Club v. Environmental Protection Agency, 540 F.2d 1114 (D.C. Cir. 1976).

115. *See supra* notes 17-25 and accompanying text.

1976 in Cambridge, Massachusetts.[116] Regulatory initiatives prior to 1986 were strictly local in nature and were generally intended to address small-scale, contained activities. The localities in which these regulatory efforts occurred were generally characterized by the presence of large academic or private research interests, as well as industrial research interests.

Typically, these localities adopted the existing NIH *Guidelines* but broadened them in at least two significant aspects. In a response to the deficiencies in the NIH *Guidelines*, these ordinances were designed to provide for public participation in redefining the scope of biosafety oversight by, first, involving the lay-person in the determination of risk, real and perceived; and second, by forcing non-academic, non-NIH-funded industrial/commercial activities to comply.[117]

The impetus for pursuing regulatory initiatives at the state legislative level emerged in the mid-1980s with the NIH's announcement that it would discontinue its policy of a total ban on the deliberate release of genetically engineered organisms into the environment. As the discussion above indicated, no federal mechanism with the force of law was yet in place to regulate such releases, and the attendant policy considerations had only just begun to receive either executive or congressional attention.[118]

As evidenced by the numerous state-level regulatory initiatives that have since been undertaken, this regulatory vacuum was viewed as precisely the sort which the states, pursuant to their traditional role as the guardian of public safety and welfare,[119] must address, cure or otherwise confront on behalf of their citizens. As in other instances requiring state regulatory oversight, there is a need to ensure that a broad range of both public and private interests are addressed and accommodated. In the case of biotechnology and genetic engineering in particular, however, these technologies most certainly raise issues not previously addressed by the states, including unique socioeconomic concerns, unique ecological concerns, and unique

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116. Diane E. Hoffman, *The Biotechnology Revolution and Its Regulatory Evolution*, 38 DRAKE L. REV. 471, 537-39 (1988-1989); David P. Rosenblatt, *The Regulation of Recombinant DNA Research: The Alternative of Local Control*, 10 B.C. ENVTL. AFF. L. REV. 37, 66-77 (1982).

117. For a discussion of local ordinances and the associated issues of preemption by federal law and a state's application of the home rule doctrine, see Maureen Bessette, *Genetic Engineering: The Alternative of Self-Regulation for Local Governments*, 22 SUFFOLK U. L. REV. 1121 (1988).

118. *See supra* notes 17-25 and accompanying text.

119. Robin Eisner, *State Legislators Seek to Broaden Regulation of Biotech Products*, SCIENTIST, Feb. 18, 1991, at 1; *see also* Scott Veggeberg, *Biotechnology Regs Raise Ruckus*, SCIENTIST, Apr. 13, 1992, at 1, 8 (quoting Dr. Rebecca Goldburg of the Environmental Defense Fund stating that "[i]f the quasi-paralysis continues at the federal level, we will see other states passing laws on genetically engineered organisms.").

moral/ethical concerns.

B. The Development of a Consensus Regulatory Approach

Between 1986 and 1991, numerous state legislatures considered legislation to regulate biotechnology within their respective borders. A few states struggled and succeeded while numerous others did not.[120] Among those states which have thus far succeeded in enacting some form of legislation, a uniformity of regulatory policies and procedures is lacking. It is unfortunate that, in their effort to compensate for the under-regulation perceived to exist at the federal level, states have not adopted a unified policy approach, nor have they adopted a unified procedural approach to biotechnology regulation.

In an effort to aid states in the task of formulating biotechnology regulations, the University of California Systemwide Biotechnology Program and the New Jersey Department of Environmental Protection co-sponsored a policy workshop in Sacramento, California in July 1990.[121] Thirty states were represented.

The purpose of this workshop was to provide a guided process for future biotechnology policy evaluation. Its goal was to adopt a consensus "guidance document," following review and participation by representatives of state and federal regulatory agencies, industry, environmental organizations and universities. It was envisioned that this guidance document would then become a unifying standard for state regulators and policymakers to employ in their regulatory initiatives.

The most significant recommendation set forth by this guidance document is the organization of a task force charged with the evaluation of the existing state and federal oversight frameworks. It is recommended that the task force be composed of "key representatives from [state] government entities potentially responsible for oversight of biotechnology products and activities (e.g., agriculture, environment, health) and who are knowledgeable of biotechnology and the relevant rules and guidelines, and individuals from industry, academia, and public interest groups."[122] It is specifically suggested that the task force acquire an understanding of the nature and scope of the regulatory landscape so that it can "identify strengths and weaknesses in the federal and state oversight systems."[123]

The guidance document further recommends that the task force evaluate "existing state statutes such as food and agricultural codes,

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120. *See infra* text accompanying notes 138-42.

121. UNIVERSITY OF CALIFORNIA SYSTEMWIDE BIOTECHNOLOGY RESEARCH AND EDUCATION PROGRAM, WORKSHOP STEERING COMMITTEE, GUIDANCE FOR STATE GOVERNMENTS ON OVERSIGHT OF BIOTECHNOLOGY (1990) [hereinafter GUIDANCE DOCUMENT].

122. *Id.* at 2.

123. *Id.*

health and safety codes, confidential business information, and environmental codes . . . that provide authority for regulating products and activities."[124] Towards a similar end, the task force should also evaluate "member [state] agencies' past experience with oversight of similar products and other new technological processes" and "assess levels of expertise and resources needed for adequate oversight and timely review both now and in the future."[125]

Finally, and most important, the guidance document expressly recommends that the task force "advise the state legislature and executive branch, including regulatory agencies, on the adequacy of existing state and federal oversight frameworks and recommend needed action at the state and federal level."[126]

Given the debate as to the adequacy of the Federal Coordinated Framework discussed earlier, it is inevitable that state regulatory initiatives will include efforts to fill in the regulatory gaps. The technical inadequacies of the federal oversight mechanism that are likely to receive the most scrutiny at the state level are those that exempt particular small-scale environmental releases of genetically engineered organisms, and those that exempt entire categories of organisms from federal oversight.[127] A state may also take exception to the federal characterization of what constitutes a "release," given that the term remains undefined under the Federal Coordinated Framework.[128] Given the novel applications of biotechnology, the statutory scope of existing state rules and regulations will require careful scrutiny and elaboration. This will be particularly so in determining liability and fashioning remedies—policy matters that should receive specific legislative consideration.[129]

Although the guidance document is a consensus document, there is evidence of an underlying reservation that accompanies endorsement of state legislation for the regulation of biotechnology. For example, the document cautions that "[f]ederal . . . oversight already

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124. *Id.*

125. *Id.* at 3.

126. *Id.*

127. *See, e.g., supra* notes 77 & 78; *supra* notes 31-34, 43-45. *See also* Geoffrey M. Karny, *Federal, State and Local Regulation of Biotechnology*, 19 ENVTL. L. REP. 10,492, 10,494 (1989).

128. Karny, *supra* note 127, at 10,493. *See also supra* note 25.

129. *See generally* Joseph L. Amos, Jr., *Advanced Technology and Tort Law: Reasonable Responsible Standards*, 58 DEF. COUNS. J. 198 (1991); William A. Anderson II, *Current Litigation Issues Associated with Biotechnology*, 19 ENVTL. L. REP. 10,503 (1989); David L. Bazelon, *Governing Technology: Values, Choices, and Scientific Progress*, 5 TECH. IN SOC'Y 15 (1983); Barry R. Furrow, *Governing Science: Public Risks and Private Remedies*, 131 U. PA. L. REV. 1403 (1983); Note, *Designer Genes That Don't Fit: A Tort Regime for Commercial Release of Genetic Engineering Products*, 100 HARV. L. REV. 1086 (1987); Richard Kevin Zepfel, *Stopping a "Gruesome Parade of Horribles": Criminal Sanctions to Deter Corporate Misuse of Recombinant DNA Technology*, 59 S. CAL. L. REV. 641 (1986).

exists for a wide variety of biotechnology products and activities," and "[f]ederal and state regulatory operations are most effective when they complement, but do not unnecessarily duplicate or conflict with each other."[130] The document further suggests that the task force "review the role and authorities of federal agencies and consider the state's historical reliance on federal oversight," as well as "consider the value of involving outside experts in task force deliberations."[131] On their face, such comments reflect a real tension between the federal agencies' and the biotechnology industry's acknowledgement that each state has a right to regulate, and a preference that they not exercise that right.

Another significant set of recommendations set forth in the guidance document is that the task force ensure that adequate "communication pathways [exist] among and between responsible state and federal agencies and local communities" and develop a "strategy for informing local community policymakers on the state and federal frameworks and on the roles of local government in the regulations and in communicating with the public."[132] The document perceives the state to have a "unique role in communicating the existence of the regulatory framework and the results of the regulatory oversight, using communication networks with city and county governments that are available through state regulatory infrastructures."[133]

These recommendations on their face strongly suggest that any such endorsed regulatory processes are to originate at the state level and are to be asserted at the state level, not at the local level. This is a reasonable restriction in that the promulgation of local town and city ordinances is likely to be reactionary rather than anticipatory, and would be far too administratively burdensome to be enforced effectively.

Another inference from these recommendations is that it is reasonable for a state to require communications between itself and federal regulatory agencies, especially in matters directly affecting activities within the state's borders. Although this expectation may be reasonable, it may not be readily met since the only federal agency that, as a matter of practice, directly communicates with states in these matters is the USDA. Even though the USDA has to date routinely provided states with notification of the nature and site of a proposed environmental release, and provided the state with an opportunity to comment upon the proposed release,[134] the

130. GUIDANCE DOCUMENT, *supra* note 121, at 2.

131. *Id.* at 3.

132. *Id.*

133. *Id.* at 2.

134. But see *infra* notes 66-71 and accompanying text for a discussion of the USDA's proposed rule to curtail such interaction with the state. For a comparison of agency-state interactions, see Shapiro, *supra* note 26, at 50-54; OTA REPORT, *supra*

state is not statutorily incorporated into the USDA's decision-making process. This lack of meaningful integration of state participation is an area of potential conflict between the states and federal agencies such as the USDA, the EPA, and the FDA.

The third significant recommendation set forth in the guidance document concerns the role of the public. Without reservation, this document clearly embraces a policy of public involvement in the formulation of regulatory guidelines and standards. The recommended composition of the task force includes "public interest groups."[135] The activities of the task force would "consider the importance of involving the public in task force deliberations," "consider mechanisms for effective public involvement in the oversight process," and would "consider the need and adequacy of resources for information programs or materials to assist . . . the public in regulatory matters and related issues."[136]

It is in this regard that the consensus document advocates a dramatic departure from the existing federal regulatory mechanisms. None of the federal agencies involved in the regulation of biotechnology and genetic engineering has a truly compelling congressional mandate to seek broad-based participation, or to educate and involve the public. Although federal agencies announce policies and solicit comments upon proposed rules in the *Federal Register*, fully-integrated public participation and/or debate is not a determinative factor in federal oversight policy.

The guidance document, therefore, provides a valuable management tool to state regulators and decision-makers. It focuses attention on both the procedural and substantive issues associated with developing an oversight mechanism, as well as those associated with formulating informed regulatory policies. The intent was not to provide model legislation, but rather to provide a rational framework with which regulators could "demystify" the formidable process of regulating biotechnology.[137]

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note 26, at 210, 265.

135. GUIDANCE DOCUMENT, *supra* note 121, at 2.

136. *Id.* at 3.

137. As to its proposed purpose, the guidance document reads in pertinent part as follows:

> This document is intended to provide general guidance to states on ways to address common key issues of biotechnology oversight. It describes a useful process by which regulatory agencies and state legislators can effectively assess the status and adequacy of existing regulatory frameworks. It is not intended to provide model legislation or regulation, or to dictate a particular end product of state assessments. It was formulated in a manner that would provide flexibility to accommodate a variety of regulatory, political, research, and economic development environments.
>
> Advances in biotechnology are providing traditional industries with new strategies for producing useful products. Molecular biology has transformed research, providing an array of new techniques for solving problems of im-

IV. The Status of State Biotechnology Oversight Nationally

At present, twenty-five states have not undertaken any effort to regulate biotechnology and genetic engineering activities, either at the research or commercial level.[138] After being given due consideration, specific biotechnology regulatory initiatives were deemed unnecessary in seven states (Alabama, Louisiana, Maryland, Montana, Rhode Island, South Carolina and South Dakota).[139] In two other

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portance to society. Recognizing the potential economic impact of these new technologies, many states have funded strategic initiatives to support development of biotechnology research and growth of biotechnology-related industries.

Advances in biotechnologies have posed challenges. These arise from health, safety, and environmental issues, differences among existing state and federal regulatory systems, social and economic concerns, and scientific complexity.

States are considering how best to ensure that the broad range of public interests are addressed. Particular attention is being focused on the adequacy of existing state and federal regulatory frameworks.

This document:

- recommends that states examine existing oversight structures and consider whether biotechnology's commercial products and research activities fit them;
- encourages close communication linkages with federal agencies and utilization of the extensive resources they offer; and,
- suggests a mechanism for broad participation and stresses the need for communication at state and local levels, and for outreach.

Id. at 1.

138. Search of the National Biological Impact Assessment Program Electronic Bulletin Board, U.S. Dep't. Agric., Washington, D.C. (Information System Contact: Doug King, (703) 231-3747) (Jan. 8, 1993) [hereinafter NBIAP Bulletin Board]. At this point in the discussion of state biotechnology initiatives, it is appropriate to remind the reader of the specific focus of this Comment: regulation of the deliberate environmental release of genetically engineered organisms. *See supra* Part I. For a comprehensive summary of the other biotechnology-relevant initiatives undertaken during the 1991-1992 state legislative sessions, see Industrial Biotechnology Association, Year-End Survey of State Government Legislation on Biotechnology 1992 (R.D. Godown, L.J. Raines and R.J. Briscuso, Jr., eds. 1992). *See also* OTA Report, *supra* note 26, at 202-204 (discussion of state and local government approaches to biotechnology regulation).

As of January 8, 1993, the twenty-five states that have not undertaken any official efforts to regulate biotechnology and genetic engineering are as follows: Alaska, Arkansas, Arizona, Colorado, Connecticut, Delaware, Georgia, Iowa, Idaho, Indiana, Kansas, Kentucky, Michigan, Missouri, Mississippi, North Dakota, Nebraska, New Hampshire, New Mexico, Nevada, Oregon, Pennsylvania, Tennessee, Virginia and Wyoming.

139. NBIAP Bulletin Board, *supra* note 138. In the cases of Alabama, Louisiana, and Maryland it appears that all will rely upon existing state legislation or regulations for management of biotechnology-related matters. Maryland's current reliance on its Plant Disease Laws appears to follow on the heels of an unsuccessful attempt to regulate biotechnology via specific legislation; a five-year enactment authorizing biotechnology regulation in Maryland was allowed to "sunset," and no further initiative to regulate biotechnology is under consideration. *Id.* In the case of Rhode Island,

states, actual legislation has been proposed or introduced, albeit unsuccessfully (Texas and Vermont).[140] To date, twelve states have officially pursued some form of biotechnology initiative,[141] while regulatory initiatives are presently only under consideration in four others (Massachusetts, Ohio, Utah, and Washington).[142]

A. Four Categories of State Legislative Initiatives

Upon reviewing the legislation that has been enacted to date, there appear to be four distinct categories of legislative initiatives. Those in category 1 result in an amendment(s) of existing state agricultural, public health, and/or environmental statutes to encompass biotechnology and genetic engineering. States which have enacted legislation pursuant to a category 1 initiative are Hawaii,[143] Florida,[144] West Virginia,[145] and Wisconsin.[146]

Legislative initiatives in category 2 may also be characterized as elaborations upon existing state laws. This type of initiative, however, culminates in the creation of a state-wide regulatory matrix which integrates existing state laws under the auspices of a special interagency task force. California[147] and New Jersey[148] have em-

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"commercial biotechnology activities" apparently fall within the scope of the Environmental Standards Board's existing regulations; the Board's authority apparently also extends to ensuring compliance with "federal guidelines for work involving recombinant DNA." *Id.* In South Carolina, "a general safety clause" of the state's Public Health Laws designates responsibility to the Department of Health and Environmental Control. *Id.* Montana's efforts to date involve issuance of a statute by the Department of Livestock requiring "a permit for all biologics and animals imported into the state." *Id.* Finally, South Dakota convened an "informal committee" of state officials, university officials, and industry representatives in 1989 who determined that "no state regulation of biotechnology is necessary." *Id.*

140. NBIAP Bulletin Board, *supra* note 138. In Texas, a bill requiring oversight of the release of genetically engineered organisms by the Texas Commission to Study the Release of Genetically Engineered Microorganisms was proposed, but not passed, in 1988 and 1989. As of May 1991, no related bills had been reintroduced. *Id.* In Vermont, a bill was introduced in 1991 to establish a Biotechnology Advisory Board, but it remains in committee. *Id.*

141. NBIAP Bulletin Board, *supra* note 138. As of January 8, 1993, those states that have pursued regulatory initiatives include the following: California, Florida, Hawaii, Illinois, Maine, Minnesota, New Jersey, New York, North Carolina, Oklahoma, West Virginia and Wisconsin. See also Parts IV.A., IV.B., V.A., and V.B. of this Comment for a detailed discussion of each of these enactments.

142. *Id.* While Massachusetts, Utah and Washington appear to have legislative initiatives pending, Ohio's initiative appears to have originated in the executive branch. *Id.*

143. HAW. REV. STAT. § 321-11.6 (Supp. 1991).

144. FLA. STAT. ANN. §§ 581.011, 581.083 (West 1987 & West Supp. 1992).

145. W. VA. CODE §§ 19-12-1 through 19-12-17 (1991 & Supp. 1992).

146. WIS. STAT. ANN. § 146.60 (West Supp. 1992).

147. Executive Order D-46-85 (1985), Assembly Concurrent Res. 170 (1984), creating an Interagency Task Force on Biotechnology to develop CALIFORNIA'S BIOTECHNOLOGY PERMITS AND REGULATIONS: A DESCRIPTION (Sept. 1986).

braced this regulatory approach.

Legislative initiatives in category 3 result in enactments that are specific to the regulation of biotechnology and genetic engineering, and are independent of existing agricultural, health, and/or environmental legislation. States that have enacted legislation pursuant to this type of initiative are North Carolina,[149] Minnesota,[150] Illinois,[151] and Oklahoma.[152]

Legislative initiatives in category 4 are similar to those in category 3 in that their intent is specifically to regulate biotechnology and genetic engineering independently of other existing state regulatory schemes. A legislative initiative in category 4, however, creates a permanent administrative body to which the legislature has delegated authority to promulgate, implement and enforce rules which specifically regulate biotechnology and genetic engineering. That is, apart from enactment of the legislation which creates the rule-making body, delegates its rule-making authority, and articulates the scope of its regulatory and enforcement authority, this category of

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148. An Interagency Biotechnology Committee was formed in New Jersey in 1989. Conceptually, the Committee was patterned after the task force model suggested by the GUIDANCE DOCUMENT, *supra* note 121, discussed in Part III.B. of this Comment. *See supra* notes 121-37 and accompanying text. In fact, the New Jersey initiative was spearheaded by Roger H. Smith, Ph.D., one of the co-chairs of the 1990 state oversight workshop that developed the aforementioned GUIDANCE DOCUMENT; Dr. Smith was assisted in this effort by biotechnology policy specialist, Laura R. Meagher, Ph.D., co-founder of the North Carolina Biotechnology Center.

Initially, members of New Jersey agencies most likely to be involved in biotechnology-related activities (e.g., Agriculture, Environmental Protection, Commerce, Health, and the Commission on Science and Technology) served informally; they were officially appointed later by their respective commissioners to serve on the Interagency Committee. Once formed, the first objective of the Committee was to ascertain how responsibility for biotechnology oversight would be allocated among the several state agencies. This having been accomplished, the Committee then turned its attention to conducting a review of all pertinent existing state laws and regulations. Upon completion of this review, the Committee next planned to address the question of whether specific biotechnology regulations were necessary in New Jersey. At the present time, the Committee has not yet completed its examination of New Jersey's existing laws and regulations. Telephone Interview with Laura R. Meagher, Ph.D., Industry and Government Liaison, AgBiotech Center, Cooks College, Rutgers University, New Brunswick, New Jersey, 08903 (Feb. 16, 1992). *See also* OTA REPORT, *supra* note 26, at 203, 204.

In light of the fact that New Jersey's category 2 initiative has not yet progressed to the policy-making stage, this Commentator has chosen to focus only on California's policy-making process. No further discussion of New Jersey's regulatory initiative will appear in this Comment.

149. N.C. GEN. STAT. §§ 106-765 through 106-777 (Supp. 1992); ADVISORY COMMITTEE ON BIOTECHNOLOGY IN AGRICULTURE, NORTH CAROLINA BIOTECHNOLOGY CENTER, *Advisory Committee on Biotechnology in Agriculture: Process, Conclusions and Resulting Legislation* (1989) [hereinafter NORTH CAROLINA ADVISORY REPORT].

150. 1991 Minn. Sess. Law Serv., ch. 250, §§ 28-30 (West).

151. ILL. ANN. STAT. ch. 111.5, paras. 7600-11 (Smith-Hurd Supp. 1992).

152. OKLA. STAT. ANN. tit. 2, §§ 2011-18 (West Supp. 1992).

initiative does not result in legislation which *per se* regulates biotechnology and genetic engineering. Two states which have pursued this type of legislative initiative are Maine[153] and New York.[154]

B. *Category-by-Category Analysis*

1. *Category 1*

As discussed above, legislative initiatives in category 1 result in an amendment(s) of existing state law. In the case of Florida,[155] the state's Plant Industry Laws were amended such that they now extend to genetically engineered organisms. For example, the definition of "plant pest" has been broadened now to include "any genetically engineered organisms . . . which can directly or indirectly injure or cause disease or damage in any plants or parts thereof or any processed, manufactured, or other products of plants."[156] Under the amended Florida law, "the introduction into or release within this state of any . . . genetically engineered plant or plant pest organism . . . is prohibited, except under special permit issued by the [D]epartment [of Agriculture and Consumer Services] through the [D]ivision [of Plant Industry], which shall be the sole issuing agency for such special permits."[157]

It would appear that the Florida amendments collectively succeed in broadening the Plant Industry Laws to include genetically engineered plants and plant pest organisms. It is clear, however, that regulation may only be imposed on those "which may directly or indirectly affect the plant life of [Florida],"[158] or "which can directly or indirectly injure or cause disease or damage in any plants or parts thereof . . . or products of plants."[159]

This limitation on the scope of regulation to those genetically engineered plants and organisms with known injurious capabilities is too restrictive. In addition, it exempts numerous other categories of releases. The state of Florida also has the burden to classify a plant or organism as a plant pest before it may impose its permitting requirements. This is exactly the same kind of broad-sweeping exemption which is characteristic of the USDA's regulatory scheme under the federal Coordinated Framework, thus leaving the regulation of non-pests and non-plants unaddressed at both the state and federal level.

The Florida amendments do not provide the state with the authority to restrict intrastate movements of genetically engineered

153. ME. REV. STAT. ANN. tit. 7, §§ 231-36 (West 1989 and Supp. 1992-1993).
154. N.Y. Public Health Law §§ 3220-23 (McKinney 1985).
155. FLA. STAT. ANN. §§ 581.011, 581.031, 581.083, 581.101 (West Supp. 1992).
156. *Id.* § 581.011(23).
157. *Id.* § 581.083.
158. *Id.*
159. FLA. STAT. ANN. § 581.011(23) (West Supp. 1992).

plants or plant pest organisms. While certainly it is imperative that a state have authority to regulate the movement of a designated plant pest across its borders and to regulate its release while within its border, it is also imperative that a state have similar authority over intrastate movements for the following reason: Issuance of a special permit such as that contemplated by the Florida Plant Industry Laws is contingent upon a variety of factors, such as the containment capabilities at the site of destination. It is not to be supposed that all such sites within the state are equally suitable. Thus, maintaining effective regulatory control requires authority to oversee any and all movements, introductions and releases within the state's borders.

With regard to the authority to regulate genetically engineered plans and plant pests, Florida's amended Plant Industry Laws do appear to resolve a possible jurisdictional conflict among state agencies, as well as ensure some uniformity in the interpretation and application of the law. It is not difficult to envision a proposed release into the environment that would also fall within the purview of the state's environmental protection agency, natural resources department, fish and wildlife department or forestry service. As amended, however, the law expressly states that "the department [of Agriculture and Consumer Services] through the division [of Plant Industry] . . . shall be the sole issuing agency for . . . special permits" for the "introduction into or release within this state of any plant pest, noxious weed, genetically engineered plant or plant pest organism . . . any arthropod . . . or biological control agent. . . ."[160] Thus, Florida appears to have anticipated disputes as to agency jurisdiction in the matter of regulating genetically engineered plants and plant pests, and the amended Plant Industry Laws expressly vest jurisdiction within the Division of Plant Industry of the Department of Agriculture and Consumer Services.[161]

When assessing Florida's efforts to regulate genetically engineered organisms relative to the model approach proposed by the guidance document discussed above,[162] Florida's amended Plant Industry Laws are incomplete and far too limited in regulatory scope. The Florida laws do not contemplate a comprehensive regulatory program such as that advocated by the guidance document. As written, the Florida laws do not adequately address the regulatory gaps inherent in the existing federal scheme, nor do they address in any fashion the guidance document's policy of public outreach.

Insofar as the other states such as Hawaii, West Virginia, and Wisconsin that have adopted category 1 legislative initiatives are

160. *Id.* § 581.083.
161. *Id.*
162. *See supra* notes 121-26, 130-37 and accompanying text.

concerned,[163] each is similarly limited in its effectiveness because each has adopted an approach which suffers inherent limitations in scope. West Virginia's Agriculture Laws were amended to regulate genetically modified organisms[164] in a manner similar to that of Florida,[165] with one exception. The West Virginia statute exempts environmental release activities proceeding under federal permit from the state permit requirement.[166] Thus, the unsatisfactory regulatory authority created by a Florida-type approach has been even further eroded by the additional deference to federal oversight embodied in the West Virginia legislation.

Even further erosion of state regulatory authority can be found in the category 1 legislative initiatives of Hawaii and Wisconsin. Hawaii extended its Department of Health Laws to include any genetically modified organisms,[167] but the amendment merely requires that Hawaii be notified of any federal permit requests pending approval.[168] Apparently, Hawaii is without authority to do more than receive notice. It would appear that this 1988 amendment was hastily enacted to illustrate some legislative intent not to defer entirely to the federal agencies. Yet, five years later, Hawaii remains seriously handicapped by the lack of enabling legislation in this matter. There are no indications that Hawaii is entertaining any other legislation at the present time.[169]

Like Hawaii, Wisconsin's initiative resulted in amendment of its Public Health Laws.[170] Although Wisconsin's amendment is somewhat broader in scope, it merely provides the Department of Natural Resources or the Department of Agriculture, Trade and Consumer Protection with the authority both to receive notice of,[171] and conduct a "technical review" of,[172] permit requests for environmental release of genetically engineered organisms pending approval by federal agencies.

The Wisconsin amendment improves upon that of Hawaii in that

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163. *See supra* notes 143-46 and accompanying text.

164. W. VA. CODE §§ 19-12-1 through 19-12-17 (1991 & Supp. 1992).

165. *See, e.g.*, W. VA. CODE §§ 19-12-2(g), (q), (s); §§ 19-12-3(a) & (b); § 19-12-14 (1991 & Supp. 1992).

166. W. VA. CODE § 19-12-14 (Supp. 1992) reads in pertinent part as follows:

> No person may sell, barter, expose, offer for sale or move, transport, deliver, ship or offer for shipment into or within this state any plant pest . . . without first obtaining either a federal permit, where applicable, or a state permit from the commissioner. . . . If a permit, which addresses environmental safety, has been issued by the appropriate federal regulatory agency in consultation with the commissioner, no state permit is required.

167. HAW. REV. STAT. § [321-11.6] (Supp. 1991).

168. *Id.*

169. NBIAP Bulletin Board, *supra* note 138.

170. WIS. STAT. ANN. § 146.60 (West Supp. 1992).

171. *Id.* § 146.60(3).

172. *Id.* § 146.60(4)(d).

it requires public notice[173] and creates authority within the state agencies to solicit public comment when conducting its technical review.[174] Unfortunately, although the amendment also creates authority within state agencies to request information directly, including "confidential information"[175] from the federal permit applicant to assist in its technical review, the amendment expressly states that the applicant "is not required to submit that information to the reviewing department."[176]

Wisconsin's amended Public Health Laws in effect leave its state agencies, albeit marginally more informed, handicapped to the same extent as Hawaii's laws. In spite of the fact that the text of Wisconsin's amendment substantially exceeds the five lines of text which comprise the Hawaii amendment, Wisconsin's additional text is mere surplusage with no regulatory consequences. Again, as in the case of Hawaii, the Wisconsin legislature desired perhaps to indicate their intent not to defer to the federal agencies. Yet, this legislation on its face fails to do even that.

As is evident from the above discussion of category 1 legislative initiatives, grafting new issues and new concerns onto old rules and old policies is not a satisfactory solution. One of the reasons such initiatives fail to encompass the outstanding regulatory issues is that the legislature is simply not the body in whom consideration of these matters should solely reside. The technical, jurisdictional, and public policy issues inherent to the regulation of biotechnology and genetic engineering are specialized and highly complex. Although the state legislatures enacting category 1 legislation may genuinely desire to participate in regulation of these matters, their lack of expertise in, and comprehension of, the technology and its attendant issues may prevent them from appreciating how seriously inadequate such legislative initiatives truly are.

2. *Category 2*

A clearly different approach, both in scope and regulatory philosophy, is represented by California's regulatory matrix. In 1984, the California Legislature adopted Assembly Concurrent Resolution 170 (hereinafter ACR 170) "to encourage the California biotechnology industry to grow, while at the same time protecting public health and safety."[177] Pursuant to this resolution was the formation of an

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173. *Id.* § 146.60(3m).

174. *Id.* § 146.60(4)(b).

175. *Id.* §§ 146.60(2)(b), (3) & (6).

176. *Id.* § 146.60(4)(c).

177. INTERAGENCY TASK FORCE ON BIOTECHNOLOGY, CALIFORNIA'S BIOTECHNOLOGY PERMITS AND REGULATIONS: A DESCRIPTION (Sept. 1986), at 2 [hereinafter CALIFORNIA BIOTECHNOLOGY]; Executive Order D-46-85 (1985), Assembly Concurrent Res. 170 (1984), Interagency Task Force on Biotechnology.

Interagency Task Force on Biotechnology to identify, clarify, and coordinate the state's existing regulatory requirements applicable to biotechnology. The Interagency Task Force is composed of the Directors of the Departments of Commerce, Food and Agriculture, Health Services, Fish and Game, Environmental Affairs Agency, Occupational Safety and Health Division of the Department of Industrial Relations, and the Water Resources Control Board. Of interest is the fact that the Department of Commerce is charged with directing the activities of the Interagency Task Force.[178]

While the formation of a task force directly addresses the above-expressed concern that state legislatures may be ill-equipped, if left unassisted, to identify adequately regulatory needs, California's Interagency Task Force cannot be fully operative in this regard for the following reason. In accordance with the legislative desire expressed in ACR 170, the Interagency Task Force adopted a policy of deferring to the federal government whenever possible.[179] As a result, "minor administrative changes" were made to only four permit review procedures throughout the state's nine participating regulatory agencies.[180] With the exception of these changes, no new procedures were adopted and no new regulations were proposed "[i]n accor-

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178. *See* CALIFORNIA BIOTECHNOLOGY, *supra* note 177, at app. A, para. 2. This is entirely consistent with the predominant motivation for ACR 170, which was the development of policies and procedures that encourage the California biotechnology industry to grow, while at the same time protecting public health and safety.

179. *See* CALIFORNIA BIOTECHNOLOGY, *supra* note 177. Among the recommendations set forth by the Assembly Office of Research pursuant to ACR 170 are the following:

> There is a universal expectation that the biotechnology industry will grow as spectacularly as the electronics industry did after the invention of the computer chip. *This new industry must be encouraged to grow and prosper in California.*

Id. at 1 (emphasis added).

> To avoid unnecessary delays in getting new biotechnology products to market, federal and state governmental agencies should make every effort to set policy, adopt guidelines, and clarify regulations as soon as possible. . . . *California should defer wherever possible to the federal government on the development of new regulations for the industry.*
>
> As a general rule, if any biotechnology activity falls within the matrix of federal regulation, then no additional state regulation should be imposed. Exceptions should be made only where there is a clearly identified need for state regulation that is not addressed by federal standards. Even in these cases, state agencies should attempt to cooperate with federal authorities to minimize regulatory procedures and to ensure that they are *flexible and responsive to industry needs* and valid regulatory concerns.

Id. at R-1 (emphasis added).

> The task force should oversee the formulation of individual agency policy statements in order to assure a balanced and predictable regulatory climate for the emerging industry.

Id. at R-3.

180. *Id.* at 3.

dance with the legislative desire expressed in ACR 170."[181] It is without doubt that California's commercial priorities are, in part, directly responsible for the mandated legislative deference to federal oversight, and for the implicit discouragement of any substantive, new regulations. The wisdom of California's decision in this particular regard is debatable. In many respects, California's regulatory matrix suffers from many of the same inadequacies associated with the federal Coordinated Framework. That is, California is reliant upon existing statutory schemes to oversee unrelated activities, to cure unanticipated regulatory crises, and to monitor unforeseen risks.

Although California's Interagency Task Force is indeed seriously handicapped by the legislative prescription of deference, its principal contribution may lie elsewhere. It is within the purview of such a broad-based body to "consider the overall issue of translating risk assessment information into effective policy decisions."[182] This objective of a comprehensive, unified interagency treatment of risk assessment and risk management is precisely what is lacking in the category 1 legislative initiative discussed above.

Thus, relative to category 1, category 2 is clearly the preferred initiative. In fact, the regulatory matrix approach of California closely parallels the approach proposed in the consensus guidance document.[183]

3. *Category 3*

Striving towards an even more comprehensive approach, legislative initiatives in both categories 3 and 4 attempt to evolve further the regulatory scope and philosophies discussed thus far. The feature that sets these initiatives apart is their purported objective to formulate regulatory schemes which are specific to biotechnology and genetic engineering, and which are independent of preexisting state agency rules and regulations. As mentioned above, category 3 differs in that authority to regulate resides within express statutory mandates, while category 4 effects regulation pursuant to authority delegated by the legislature to an administrative body.

Insofar as the four states that have pursued category 3 initiatives

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181. *Id.*

182. *Id.*

183. *See supra* notes 121-26 & 130-37 and accompanying text. This is not entirely surprising since one of the Workshop sponsors was the University of California. Moreover, given the fact that "California is home to a third of the nation's biotechnology industry, and *our universities and colleges provide talented minds and ingenious insight that contribute to this new endeavor*," it is not surprising that the guidance document retains hints of the commercially-biased, industry-favorable posture which dominates the California regulatory regime. CALIFORNIA BIOTECHNOLOGY, *supra* note 177, at app. A (emphasis added). Fortunately, because the guidance document is a true consensus document, the other workshop participants had a tempering effect, thus avoiding adoption of a pure California approach.

are concerned, their success or failure in so doing is readily apparent. Illinois[184] and Oklahoma[185] may clearly be characterized as failing, while North Carolina[186] and Minnesota[187] have been unquestionably successful.

While presuming to enact specific legislation to "protect agriculture and public health from intentional or unintentional release of genetically engineered biological articles into the environment,"[188] the Oklahoma Agriculture Biotechnology Act (OABA) does no such thing. The OABA exempts any activity which is in compliance with federally established guidelines.[189] No notice, technical review or permit provision applies to any exempt activity, including movement into and within the state as well as release into the environment. While in theory the OABA may arguably provide oversight protection in instances that totally escape federal scrutiny, Oklahoma has chosen to defer to the federal standards of the Coordinated Framework which, in turn, employ a policy of exempting certain activities. The perplexing question in the case of legislation like the OABA is whether activities that do fall outside the scope of the federal Coordinated Framework—not because they are recognized exemptions, but because they occupy one of the many regulatory gaps within the federal coordinated framework—will be construed to be "in compliance" simply because they are not "out of compliance."

The situation in Illinois is equally unsatisfactory. The Release of Genetically Engineered Organisms Act[190] merely requires that the state be notified of, and allowed to comment upon, those activities already subject to federal oversight.[191] No state permit requirement is imposed on such activities, and obviously no permit requirement exists for any federally unregulated activity.

Both the Oklahoma[192] and the Illinois[193] Acts became effective as recently as 1990. Thus, there is reason to hope that amendments will be forthcoming to fortify each state's existing authority. There is no information available as to this possibility at present.[194]

It is certainly not the case that states such as Oklahoma and Illi-

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184. ILL. REV. STAT. ch. 111.5, paras., 7600-11 (Smith-Hurd Supp. 1992).

185. OKLA. STAT. ANN. tit. 2, §§ 2011-18 (West Supp. 1993).

186. N.C. GEN. STAT. §§ 106-765 through 106-777 (Supp. 1992).

187. MINN. STAT. ANN. §§ 116C.91-116C.96 (West 1992); 1991 Minn. Sess. Law Serv., ch. 250, §§ 28-30 (West).

188. OKLA. STAT. ANN. tit. 2, § 2012 (West Supp. 1993).

189. *Id.* §§ 2016C, D. In fact, Oklahoma law appears to apply only to those persons "not in compliance with a federal agency." *Id.* § 2016D.

190. ILL. REV. STAT. ch. 111.5, paras. 7600-11 (Smith-Hurd Supp. 1992).

191. *Id.* para. 7603 § 3(a); para. 7601 §§ 1(d), (e).

192. OKLA. STAT. ANN. tit. 2, § 2011 (West Supp. 1993).

193. ILL. REV. STAT. ch. 111.5, para. 7600 (Smith-Hurd Supp. 1992).

194. NBIAP Bulletin Board, *supra* note 138.

nois were wanting for lack of statutory models. Prior to 1990, two other category 3 states had launched widely-publicized regulatory initiatives, namely North Carolina[195] and Minnesota.[196] The legislation eventually enacted in each of these states was pursuant to the recommendations of a legislative advisory body—an Advisory Committee[197] in the case of North Carolina and an Environmental Quality Board[198] in the case of Minnesota—the wisdom of this procedural approach having already been discussed in Part III.B. of this Comment.[199]

The Minnesota Act establishes a comprehensive, permit-requiring regulatory scheme extending to the following categories of release activities: "genetically engineered plant,"[200] "genetically engineered pesticide,"[201] "genetically engineered fertilizer,"[202] and "genetically

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195. N.C. GEN. STAT. §§ 106-765 through 106-777 (Supp. 1992). The North Carolina Biotechnology Center created the Advisory Committee on Biotechnology in Agriculture in June 1988 to consider whether state regulations were needed for releases of genetically engineered organisms into the environment. After deliberation, the Committee proposed legislation vesting authority in such matters to the state's Department of Agriculture. In March 1989, the Department of Agriculture sponsored regulatory legislation which was subsequently enacted in August 1989. *See* NORTH CAROLINA ADVISORY REPORT, *supra* note 149.

196. 1991 Minn. Sess. Law Serv., ch. 250, §§ 28-30 (West). In 1988, Minnesota law established a task force to consider the need for specific regulation of biotechnology and genetic engineering. The task force subsequently determined that the state should establish a permitting system under the auspices of the state's Environmental Quality Board (EQB) for all environmental releases of genetically engineered organisms. Additionally, the task force recommended the formation of a permanent advisory committee whose purpose is to aid the EQB in formulating rules, regulations, and policies in matters of biotechnology and genetic engineering. The task force's recommendations were adopted by the legislature in Minnesota's 1989 legislative session. Establishment of the advisory committee and formal rule-making followed shortly thereafter during the summer of 1989. Specific legislative enactments elaborating upon biotechnology and genetic engineering regulation became effective in 1991. Apparently, after considerable debate, the EQB's proposed rules became effective in August 1992. *See Minnesota Biotech Regulations Kick In*, NBIAP NEWS REP. (Nat'l Biological Impact Assessment Program, Va. Polytechnic Inst. & State Univ., Blacksburg, Va.), Oct. 1992, at 2-3; *State Regulations May Affect Progress Rate in Biotechnology Development*, NBIAP NEWS REP. (Nat'l Biological Impact Assessment Program, Va. Polytechnic Inst. & State Univ., Blacksburg, Va.), May 1992, at 8; Veggeberg, *supra* note 119, at 1, 8.

197. *See* NORTH CAROLINA ADVISORY REPORT, *supra* note 149.

198. MINN. STAT. ANN. §§ 116C.91-94 (West Supp. 1992).

199. *See supra* notes 122-26, 132-37 and accompanying text.

200. 1991 Minn. Sess. Law Serv., ch. 250, [18F.07] (West).

201. *Id.* [18B.285]. The broad definition of "genetically engineered pesticide" includes an "organism" which is defined as "an *animal*, plant, bacterium, cyanobacterium, fungus, protist, or virus." *Id.* [18F.02] subd. 6 (emphasis added). Thus, although not expressly regulated as a distinct category, the Minnesota Act contemplates genetically engineered animals.

202. 1991 Minn. Sess. Law Serv., ch. 250, [18C.310] (West).

engineered soil amendment."[203] The permit-granting process is premised on the applicant's ability to demonstrate adequately the absence of "[u]nreasonable adverse effects on the environment" defined as "an unreasonable risk to humans or the environment, taking into account the environmental costs and benefits of the use of a genetically engineered organism."[204] A permit may be denied if the Board of Environmental Quality or the Commissioner of Agriculture, pursuant to authority to "administer, implement and enforce" the provisions of the Minnesota Act,[205] determines that the use to be made of the genetically engineered fertilizer, soil amendment, plant,[206] or pesticide[207] may cause unreasonable adverse effects on the environment. These provisions place the burden of proof on the applicant and allow the state to formulate the standards as to what constitutes an "unreasonable adverse effect on the environment."[208]

The Minnesota Act contemplates no recognized exemptions. The Board may be petitioned to consider granting an exemption for those releases requiring a federal permit.[209] In this regard, it is important to note that Minnesota retains the right to deny a state permit to an applicant already in possession of a federal permit.[210]

In keeping with its comprehensive intent, the Minnesota Act requires that public notice be given, provides for public comment on the environmental review process, and requires that the Board consult with local units of government and with private citizens before adopting any rules.[211] The Minnesota Act also provides for civil penalties[212] or "enforcement of the general criminal laws" for specified violations of the Act.[213]

North Carolina's Genetically Engineered Organisms Act closely resembles its Minnesota counterpart in terms of regulatory philosophy. In at least two notable respects, however, the North Carolina Act may be considered more complete. The North Carolina Act devotes a considerable amount of text to defining and establishing the state's prerogative to request "confidential business information."[214] Information designated as such is not subject to release pursuant to the Freedom of Information Act. The state is consequently in a posi-

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203. *Id.*
204. 1991 Minn. Sess. Law Serv., ch. 250, [18F.02] subd. 9 (West).
205. *Id.* [18F.04].
206. *Id.* [18C.310] subd. 2(b).
207. *Id.* [18B.285] subd. 1(c).
208. *Id.* [18F.02] subd. 9.
209. *Id.* 116C.94(c).
210. *Id.*
211. MINN. STAT. ANN. § 116C.94 (West Supp. 1991).
212. 1991 Minn. Sess. Law Serv., ch. 250, [18D.325] subd. 1 (West).
213. *Id.* [18D.301] subds. 1 & 2; [18D.331] subds. 1-3.
214. N.C. GEN. STAT. § 106-774 (Supp. 1992).

tion to insist upon receiving additional information in order to complete its permit-granting review process, while, at the same time, avoiding any attempts by the applicant to raise the defense of confidentiality. Although such a provision is absent from Minnesota's Act, it may be unnecessary given that Minnesota requires that the applicant prove an absence of adverse effects on the environment as they are defined by Minnesota. In contrast, the North Carolina Act contains language as to burden of proof and environmental standards which is far less specific and thereby more reliant upon confidential business information for fortification.

Another provision of the North Carolina Act which is absent from the Minnesota Act is a complete ban on regulation at the local level.[215] Such a provision certainly eliminates the administrative ramifications of multiple layers of regulation, and is not unreasonably exclusive since the North Carolina Act does expressly provide for public notice and comment by "each county where the release is proposed to be made."[216] The omission of a similar provision from the Minnesota Act suggests that more stringent requirements at the local county and/or community level may be tolerated. Local activities due to less stringent requirements would be prohibited by the Minnesota Act which defines such activities as violations. Thus, it would not appear that Minnesota's authority to regulate has been compromised by this omission.

The North Carolina Act has been criticized for its apparent deference to the commercial interests of the biotechnology industry.[217] There is language in the North Carolina Act which may be construed as favoring a commercially-biased regulatory approach. It advocates that "minimally burdensome measures" be applied when pursuing the protection of the public and the environment, and that such measures should "simultaneously allow[] biotechnological research and product development to advance."[218] This language is more indicative of an acknowledgement that tension among industry, the public and the environment exists, rather than a deference to that tension. This becomes more evident upon a review of the Advisory Committee's report,[219] which prompted the enactment of

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215. *Id.* § 106-775 (Supp. 1992).

216. *Id.* § 106-773 (Supp. 1992).

217. Robert Saperstein, *The Monkey's Paw: Regulating the Deliberate Environmental Release of Genetically Engineered Organisms*, 66 WASH. L. REV. 247, 257-60 (1991).

218. N.C. GEN. STAT. § 106-765 (Supp. 1992).

219. *See generally* NORTH CAROLINA ADVISORY REPORT, *supra* note 149. Nevertheless, it continues to be suggested that North Carolina's regulatory environment is "pro-biotechnology." Interestingly, in contrast to North Carolina, Minnesota's regulatory environment is perceived to be one in which "it will be difficult to accomplish a promotion of biotechnology." According to those involved, it is not Minnesota's regulations *per se* which create the anticipated difficulties, but rather it is an apparent

the North Carolina Genetically Engineered Organisms Act.

Relative to the various forms of state legislative initiatives discussed thus far, the Minnesota and North Carolina Acts present themselves as exemplary models of considered, comprehensive, and enabling legislation. States, particularly those in which a large number of commercial or academic institutions are conducting experimental releases of any genetically engineered organism, would be well advised to fashion legislative initiatives after those of Minnesota and North Carolina. Having legislation of this scope in place now enables a state to establish a critically needed database concerning the anticipated, as well as the unanticipated, consequences of an environmental release. Moreover, such legislation enables a state to do so while those releases are being conducted on a small, experimental scale rather than on a large commercial scale.

States desiring to subscribe to a hands-off policy in biotechnology and genetic engineering regulation must appreciate that enacting enabling legislation now does not prevent them from returning to a hands-off policy in the future. In practice, it is actually the short-term authority to control activities, such as environmental releases of genetically engineered organisms, which may truly be critical because the nature, probability and magnitude of the associated risks have been heretofore undocumented. Being able to control such activities while they are being conducted on an experimental scale is a fundamental prerequisite to formulating an informed long-term policy. To assume a hands-off posture at this early stage is to compromise future participation irreversibly.

4. Category 4

Legislative initiatives in category 4 are characterized by delegation of authority to a legislatively-created administrative body whose purpose is to prescribe regulations and promulgate rules concerning biotechnology and genetic engineering. The scope of the rules and regulations established by the administrative body is circumscribed to whatever extent the legislature deems appropriate by virtue of the legislation's language.

New York legislation[220] enacted in 1978 expressly limits the Commissioner of Public Health to "prescribe regulations for the conduct of recombinant DNA activity which shall be the substantial equivalent of the . . . DNA research guidelines of the National Institutes of Health. . . ."[221] The Commissioner is also expressly lim-

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adversarial "milieu" which originated during the rule-making process. *See State Regulations May Affect Progress Rate in Biotechnology Development*, NBIAP NEWS REP. (Nat'l Biological Impact Assessment Program, Va. Polytechnic Inst. & State Univ., Blacksburg, Va.), May 1992, at 8; Veggeberg, *supra* note 119, at 8.

220. N.Y. PUB. HEALTH LAW §§ 3220-3223 (McKinney 1985).

221. *Id.* § 3222(2).

ited to prescribing regulations for specified, related activities such as training of personnel and establishing institutional committees to monitor compliance.[222] Moreover, the Commissioner is expressly prohibited from reviewing or otherwise taking exception with any activities proceeding under a federally-obtained permit.[223] Even though such activities automatically receive certification from the state, however, the Commissioner appears to be empowered to revoke any certificate for certain acts of non-compliance.[224]

Clearly, this legislation did not contemplate either a broad regulatory scope or policy, but it did attempt to embrace both academic and commercial research activities[225] which is not the case with the federal guidelines. The one broad-sweeping provision of this 1978 legislation is that which prohibits the enactment of any related regulations by any local authority.[226] Given that this legislation was enacted in 1978, long before the controversy about federal policy towards the environmental releases of genetically engineered organisms, it is most certainly inadequate in the context of current regulatory concerns.[227]

Another example of a category 4 legislative initiative is the State of Maine's legislation creating a Commission on Biotechnology and Genetic Engineering.[228] Relative to the New York legislation in this same category, Maine's legislation represents the opposite extreme in delegation of authority. Maine's legislation vests the Commission with broad powers and duties in a variety of circumstances.[229] This will become apparent in the following section which discusses in further detail Maine's category 4 legislative initiative.

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222. *Id.* § 3222(3)(a), (c).

223. *Id.* § 3222(8).

224. *Id.* § 3223(2).

225. *Id.* § 3221(4).

226. *Id.* § 3222(9).

227. In 1989, a bill was introduced to establish a Committee on the Release of Genetically Engineered Organisms within the New York Department of Health for the purpose of advising the New York legislature; legislation is apparently still pending. NBIAP Bulletin Board, *supra* note 138. "The New York state assembly is considering legislation requiring public notification prior to the release of bioengineered organisms and that provides a state court injunction procedure to block such releases." Veggeberg, *supra* note 119, at 8.

228. ME. REV. STAT. ANN. tit. 7, §§ 231-36 (West 1989 and Supp. 1992-1993) P.L. 1987, ch. 805 §§ 2-5, L.D. 2370 (113th Legis. 1988), represents the text of the original Act to Establish Guidelines for Genetic Engineering and Experimentation; it was enacted on April 28, 1988, with subsections 233, 235, and 236 of ch. 805 becoming effective April 15, 1990. Subsequently, the original Act has been twice amended. First, a 1989 amendment expanded the Commission's membership and further clarified the scope of the Commission's permissible regulatory activities pursuant to P.L. 1989, chs. 486, 503, 798, 878, and L.D. 1751 (114th Legis. 1989); second, a 1991 amendment rectified some definitional errors pursuant to P.L. 1991, ch. 837 and L.D. 2424 (114th Legis. 1990).

229. ME. REV. STAT. ANN. tit. 7, § 233 (West 1989 and Supp. 1992-1993).

V. The Evolution of Biotechnology Oversight in Maine

A. *The Commission on Biotechnology and Genetic Engineering*

In 1988 the 113th Legislature of the State of Maine established the Commission on Biotechnology and Genetic Engineering,[230] the stated purpose of which is:

> [To] address the legitimate concerns of the public about the release of microorganisms into the environment as a result of increased use of biotechnology in agricultural and other industries. The Commission on Biotechnology and Genetic Engineering . . . would be charged with addressing this concern while at the same time providing an atmosphere which promotes this fast growing field of research.[231]

Importantly, the legislation provides for a Commission membership prescribed as follows:

> [O]ne person . . . who has practical experience and knowledge in agricultural procedures, one who has practical experience and knowledge in environmental and conservation issues, a health care professional, a representative from the forest products industry, a representative from the marine fisheries industry, a person . . . to represent the general public, one practicing scientist who shall be a representative of industry and one practicing scientist who shall be a representative of the academic community. . . . The 3 ex officio members are: the Commissioner of Agriculture, Food and Rural Resources . . . the Director of the Maine Agricultural Experiment Station; and the Executive Director of the Maine Science and Technology Commission.[232]

Pursuant to the express language of the legislation, the Commission is authorized to: evaluate the adequacy of federal regulations and state rules concerning biotechnology and genetic engineering,[233] especially as to their adequacy in preventing releases that will have a "substantially deleterious effect" on the health, safety and welfare of the public and the environment;[234] formulate state policies affecting the biotechnology and genetic engineering industries;[235] establish standards for the issuance of permits for environmental releases and conduct of any release activities;[236] assess risks to the public and environment created by the use of biotechnology and genetic engineering;[237] and adopt rules and take such actions as are appropriate

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230. *Id.* §§ 231-236; *see also* Me. Rev. Stat. Ann. tit. 5, § 12004(10) (West 1989 and Supp. 1992-1993).

231. L.D. 2370, Statement of Fact (113th Legis. 1989).

232. Me. Rev. Stat. Ann. tit. 7, § 231(1) (West Supp. 1992-1993).

233. Me. Rev. Stat. Ann. tit. 7, § 233(2) (West 1989).

234. Me. Rev. Stat. Ann. tit. 7, § 233(6) (West Supp. 1992-1993).

235. Me. Rev. Stat. Ann. tit. 7, § 233(3) (West 1989).

236. Me. Rev. Stat. Ann. tit. 7, § 233(7) (West Supp. 1992-1993).

237. *Id.* § 233(5).

to carry out the legislation's purpose.[238] The legislation also provides that the Commission's rules have the force of law,[239] and violations of "any order, rule, decision or permit issued by the commission shall be punished" by a fine.[240]

In terms of express limitations upon either the conduct or authority of the Commission, the current legislation imposes only one procedural restraint on the Commission. The legislation expressly states that the Commission is required to treat all information received as confidential "unless the commission determines that there is a compelling reason to make the information public."[241]

As mentioned above, the scope of the authority delegated to Maine's Commission far exceeds that of the New York category 4 initiative described above.[242] Unlike category 3 legislation, however, which on its face specifies its standards, procedures and stance on federal regulatory policy (as was seen in the cases of the Minnesota and North Carolina legislation),[243] it is not possible to ascertain Maine's regulatory philosophy merely by reviewing the legislation as written. Towards that end, it is necessary to examine Maine's Commission Workplan.[244] Although the Workplan is not a document containing a final policy statement, it is possible to infer the Commission's regulatory sentiments from evaluating its objectives and examining its priorities. The discussion which follows will summarize the critical operational features of the Commission's Workplan, particularly as it relates to the Commission's perception of its role in the formulation and implementation of biotechnology regulation in Maine. Moreover, the discussion will address potential conflicts or ambiguities between the legislation's actual delegation of authority to the Commission and the Commission's assumed authority as reflected by its Workplan.

B. The Formulation of a Workplan by the Commission

1. The Commission's Jurisdiction

The Commission's Workplan begins with a declaration of jurisdiction and summation of its powers and duties pursuant to the legislation. The Commission asserts that its jurisdiction includes the State of Maine and all applications of biotechnology and genetic engineering technologies, including medical uses in agriculture and fisheries

238. ME. REV. STAT. ANN. tit. 7, § 233(8) (West 1989).
239. *Id.* § 235.
240. *Id.* § 236.
241. *Id.* § 234.
242. *See supra* notes 220-27 and accompanying text.
243. *See supra* notes 195-219 and accompanying text.
244. 1990-1991 Me. Comm'n Biotechnology and Genetic Engineering, Final Workplan (January 15, 1990) [hereinafter Workplan].

but excluding medical uses in human medicine.[245] On its face, this is clearly a declaration of exclusive authority to regulate all biotechnology and genetic engineering activities within Maine. In making this jurisdictional assertion, the Commission is obviously attempting to put to rest any ambiguity as to interagency authority in such matters. By doing so, the Commission anticipates that other state agencies, such as Maine's Departments of Environmental Protection, Forestry, and Fish and Wildlife, will refer any and all such matters to the Commission for deliberation.

On the one hand, the Commission's assertion of jurisdictional exclusivity in matters of biotechnology regulation is not entirely inconsistent with the apparent intent underlying adoption of the legislation. The legislation's accompanying Statement of Fact may be reasonably interpreted as endowing the Commission with exclusive authority in matters of biotechnology regulation within the state.[246] Additionally, as has already been discussed, avoidance of jurisdictional conflicts is essential to the Commission's legislative objective of establishing a uniform, state-wide policy of regulation. On the other hand, however, the Commission's declaration of exclusive jurisdiction does not derive from any express legislative provision. In fact, section 233 expressly describes the Commission's powers and duties as "nonexclusive,"[247] even though the Commission is authorized to formulate state policies and establish standards for permits for environmental releases of genetically enginered organisms. Furthermore, it may be argued that the conspicuous absence of other state agency representatives from the Commission's membership strongly suggests a lack of legislative intent to vest the Commission with exclusive regulatory authority outside of the Department of Agriculture.

In an effort to clarify this legislative conflict, the Commission has begun efforts to introduce an amendment to the existing legislation.[248] Having confirmed the legislation's original sponsor's willingness to assist the Commission in this effort, its current Chairman and members are hopeful that the matter will be resolved in 1993.[249] The extent to which the Commission's efforts will be opposed is un-

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245. *Id.* at 1.

246. L.D. 2370, Statement of Fact (113th Legis. 1989). *See supra* note 231 and accompanying text.

247. Minutes of the Me. Biotechnology & Genetic Eng'g Comm'n, Me. Dept. Agric., at 1-3 (Feb. 24, 1992) (on file with author).

248. Minutes of the Me. Biotechnology & Genetic Eng'g Comm'n, Me. Dept. Agric., at 3-4 (Jan. 25, 1993) (on file with author). The first draft of the proposed legislation, dated Feb. 11, 1993, amends § 231 by adding a "Mission" statement; and, repeals the "nonexclusive powers and duties" clause of § 233 by replacing it with a "full authority" clause (draft legislation on file with author).

249. Minutes of the Me. Biotechnology & Genetic Eng'g Comm'n, Me. Dept. Agric., at 2-5 (Apr. 27, 1992) (on file with author).

clear at present.[250]

2. *The Scope of the Commission's Authority*

Pursuant to its delegated powers and statutorily-defined duties, the Commission's Workplan has identified six regulatory categories which have been ranked in order of priority as follows: risk assessment, regulation development/implementation, policy development/implementation, research, liaison, and expertise/information repository.[251] Recognizing the difficulty in segregating its tasks into discrete priorities, the Commission's Workplan outlines the manner in which it intends to manage interdependent tasks yet accommodate its stated priorities. For example, the Commission is acutely aware that perceived risks to the public and the environment are as legitimate as actual risks, and therefore, both must be factored into their risk assessment, risk management, and risk communication strategies.[252] An awareness of both perceived and actual risks, however, will only be incidental to a thorough evaluation of the federal and state rules affecting biotechnology and genetic engineering. Thus, the Commission intends to identify the possible sources of both perceived and actual risks as it progresses through an evaluation of the existing federal and state regulations,[253] and resolve, on a risk-by-risk basis, whether such a risk necessitates a management or a com-

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250. According to Commission Chairman Peter N. Mosher, budgetary considerations have prompted a gubernatorial advisory committee to suggest dissolution of the Commission in 1993. Telephone Interview with Peter N. Mosher, Ph.D., Chairman of the Maine Commission on Biotechnology and Genetic Engineering (Dec. 31, 1992). *See also supra* note 249, at 2.

251. Workplan, *supra* note 244, at 11.

252. With regard to the legislative mandate concerning its duties related to risk evaluation, "the Commission interpreted the legislative intent to mean: to assess the potential risks to the public and to the environment, including perceived risks and public acceptance of biotechnology and genetic engineering technologies and products." *Id.* at 3. Furthermore, the Commission concluded that its responsibilities relating to the development and implementation of regulations "must include the development of not only risk assessment; but also, risk management and risk communication strategies." *Id.* at 4.

In this context, the Commission has formulated the following operational definitions to distinguish between risk assessment, risk management and risk communication. Risk assessment is "[a] determination of the possible harm(s) [both perceived and actual] to the public and/or environment associated with the introduction of a product developed by biotechnology and genetic engineering technologies." *Id.* Risk management is "[t]he action(s) taken to reduce risks to the public and[/]or environment to an acceptable level(s)." *Id.* Risk communication is "[t]he action(s) taken to make known the risks/benefits to the public and/or environment associated with the introduction of a product developed by biotechnology and genetic engineering technologies." *Id.*

253. The Commission's statutory authority to "review other [state] agencies' rules" and "study and analyze the federal [regulatory] process" has been confirmed by the office of Maine's Attorney General. Minutes of the Me. Biotechnology & Genetic Eng'g Comm'n, Me. Dept. Agric., at 2 (Feb. 24, 1992) (on file with author).

munication strategy.[254] Of importance is the fact that the Commission recognizes that risk assessment modalities in the case of biotechnology and genetic engineering will require careful consideration and development.[255]

Insofar as the development and implementation of rules and regulations, the Commission's Workplan indicates a non-deferential stance *vis à vis* the existing federal regulations. The Commission expressly focused on the federal government's lack of oversight in the matter of intrastate movement of biotechnology and genetically engineered products.[256] The Commission also expressly indicated an intention to review the adequacy of existing federal and state laws in three distinct stages of biotechnology product development, namely research, evaluation, and commercialization.[257]

In light of the fact that the Federal Coordinated Framework does not extend to research activities, this suggests that the Commission intends to fill in this gap. Moreover, given that the federal framework has only been extended to small-scale, experimental releases,[258] and has not yet contemplated releases on a commercial scale, this strongly suggests that the Commission intends to be discriminating when determining the "adequacy" of federal regulations in these matters. The Commission has also expressed an intent to establish standards, not only for the issuance of permits for release into the environment, but for conducting research in the laboratory and commercialization of products developed from biotechnology and genetic engineering technologies as well.[259] Collectively, these are clear indicators of a non-deferential regulatory posture.

Another objective articulated in the Commission's Workplan concerns the important matter of public outreach. The Commission has expressly stated that it will "solicit comments from the public . . . regarding the role of the Commission and any policies or regulations that are proposed/promulgated."[260] Moreover, the Commission has

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254. Workplan, *supra* note 244, at 3-4.

255. *Id.* at 3. *See generally*, Charles L. Elkins, *Current Models of Risk Assessment Used in Biotechnology Regulation*, 19 ENVTL. L. REP. 10,496 (1989); Mark W. Lauroesch, *Genetic Engineering: Innovation and Risk Minimization*, 57 GEO. WASH. L. REV. 100 (1988).

256. Workplan, *supra* note 244, at 5.

257. *Id.* at 5-6. Research is defined as "[t]he [d]evelopment of the new product in the laboratory using biotechnology and genetic engineering techniques." Evaluation is defined as "[t]he testing of a new product for it[s] practical application which may involve release into the environment." Commercialization is defined as "[t]he release of the product into commercial channels for sale and use." *Id.*

258. *See, e.g.*, MANAGING RISKS, *supra* note 48, at 20, 107. *See also supra* note 78.

259. Workplan *supra* note 244, at 7. The Commission's statutory authority to "establish standards for the issuance and renewal of permits" has been confirmed by Maine's Attorney General's office. Minutes of the Me. Biotechnology & Genetic Eng'g Comm'n, Me. Dept. Agric., at 2 (Feb. 25, 1992) (on file with author).

260. Workplan, *supra* note 244, at 10.

expressed its intention "[t]o initiate a symposium to encourage the advancement as well as public awareness and understanding of biotechnology and genetic engineering."[261]

3. *The Commission's Dual Role*

Upon review of the Commission's Workplan, tension between the effort to regulate biotechnology and genetic engineering and the needs of related industries to develop and expand within Maine is apparent. In fact, it appears in the legislative Statement of Fact cited earlier.[262] The Commission has assumed the position that its role in the formulation of state policies affecting biotechnology and genetic engineering industries[263] is "to encourage [their] development . . . and insure regulation does not unnecessarily discourage or inhibit the development and practice of biotechnology and genetic engineering in the State."[264]

While such an expressly stated position could foreshadow a possible conflict of interest, it must be evaluated in the context of the Commission's stated priorities, such as addressing both perceived and actual risks to the public and the environment[265] and addressing the "public and private perceptions of existing rules and regulations as well as their perceptions of the need for rules and regulations."[266] Given the reality of the situation, there will inevitably be tension between the regulators and the regulated. The challenge to the Commission is to maintain a balanced perspective when attending the debate between the "Babbitts" and the "Cassandras."[267] When viewed as a whole, it is evident that the Commission's existing Workplan will give rise to a regulatory strategy that sets policies as a consequence of risk, not one that sets risks as a consequence of policies.

4. *The Future of Biotechnology Oversight in Maine*

Based on both the substance and strategy outlined in the Commission's Workplan, as well as a first-hand knowledge of the Commission's activities to date concerning the promulgation of rules,[268] this Commentator believes that Maine will soon have a regulatory scheme in place which closely resembles that of North Carolina.[269]

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261. *Id.*
262. *Supra* note 231 and accompanying text.
263. ME. REV. STAT. ANN. tit. 7, § 233(3) (West 1989).
264. Workplan, *supra* note 244, at 8.
265. *Id.* at 3.
266. *Id.* at 5.
267. *See supra* note 1 and accompanying quotation.
268. The Author of this Comment has been a member of the State of Maine's Commission on Biotechnology and Genetic Engineering since 1989.
269. *See supra* notes 214-19 and accompanying text.

Insofar as the potential adverse ramifications of biotechnology and genetic engineering are concerned, the citizens of Maine will benefit from the foresight of the 113th Legislature. By enacting anticipatory legislation, the state is now well positioned to develop a regulatory scheme with a comprehensive scope, thus safeguarding against ineffective, reactionary legislation in the future.[270] Given the proposed efforts to relax further federal oversight of biotechnology and genetic engineering in 1993, and given that these efforts may result in the virtual exclusion of any state or public participation in the federal process, it is especially important that Maine remain positioned to respond effectively and thoughtfully. The suggestion that Maine's Commission on Biotechnology and Genetic Engineering be dissolved in 1993 is both unwise and irresponsible. This Commentator is hopeful that the successors of the 113th Legislature will demonstrate the same foresight, and the same commitment to the citizenry of Maine, as did their predecessors.

VI. CONCLUSION

The oversight of biotechnology and genetic engineering at any level—federal, state, local—is a unique endeavor requiring an astute appreciation of numerous and diverse considerations. It embraces a multiplicity of competing technical, practical, philosophical, and ethical interests. While the attendant debate has heretofore been confined to participation by those with a specialized knowledge of biotechnology and genetic engineering, it must not remain so.

Perceptions and expectations are elusive phenomena in which all of humankind engages. Even when subsequently found to be premised on pure fiction, perceptions and expectations persist—having acquired a life of their own. Remarkably, moreover, they defy all efforts at remediation. This is particularly so when matters of sci-

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270. For insight into the judicial treatment of environmental and technology-related matters, especially as it pertains to administrative agency decisions, by the Supreme Judicial Court of Maine, see generally Central Maine Power Co. v. Town of Lebanon, 571 A.2d 1189 (Me. 1990); C.H. Rich Co., Inc. v. Board of Envtl. Protection, 567 A.2d 69 (Me. 1989); Swift River Co., Inc. v. Board of Envtl. Protection, 550 A.2d 359 (Me. 1988); New England Whitewater Ctr. v. Department of Inland Fisheries and Wildlife, 550 A.2d 56 (Me. 1988); Secure Environments, Inc. v. Town of Norridgewock, 544 A.2d 319 (Me. 1988); Chandler v. Town of Pittsfield, 496 A.2d 1058 (Me. 1985); State v. Fin & Feather Club, 316 A.2d 351 (Me. 1974); *In re* Maine Clean Fuels, Inc., 310 A.2d 736 (Me. 1973). *See also* THE NEED FOR UNIFORMITY IN PESTICIDE REGULATION: REPORT OF A STUDY BY THE JOINT STANDING COMMITTEE ON AGRICULTURE, 113th Legislature, 1st Sess., State of Maine (1987) [hereinafter PESTICIDE REGULATION].

With regard to the Law Court's affirmative stance on local environmental standards being permissibly more stringent than those of the federal government, see Central Maine Power v. Town of Lebanon, 571 A.2d 1189 (Me. 1990). For a discussion of preemption and application of FIFRA by other state courts, see PESTICIDE REGULATION, *supra*, at 49-57.

ence and technology are concerned, and so too will be the case with biotechnology and genetic engineering.

To ensure that the public's perceptions of biotechnology and genetic engineering will be rational and informed, a campaign for the promotion of scientific literacy must be begun. Likewise, to ensure that the public's expectations from biotechnology and genetic engineering will be realistic, a policy of scientific and technical accountability must be adopted so that attendant risks, as well as benefits, are articulated.[271]

> In the final analysis, the requirement of openness and candor in controlling risky technologies reflects our society's democratic values. Power in the society resides with the people. The freedom enjoyed by scientists and industry to explore is given by the public and can be taken away. In this sense, the prerogatives of a technology depend upon the public good will. False reassurance, unjustified confidence, and hidden agendas will only encourage the public to exercise its ultimate veto power. Our people have always been prepared to accept risks and pursue the greater good of society. Progress can hardly be achieved any other way. It was Thomas Jefferson who once said, "If we think the people not enlightened enough to exercise their control with a wholesome discretion, the remedy is not to take it from them, but to inform their discretion." Choices will be made despite uncertainty and despite their social disruptions and dislocations. To preserve the good will on which biotechnology depends, however, society must be informed about what is known, what is feared, what is hoped, and what is yet to be learned.[272]

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271. For a discussion of scientific literacy and the public's capacity to grasp technological issues, see John Doble & Amy Richardson, *You Don't Have To Be a Rocket Scientist . . .*, 95 TECH. REV. 51 (1992). The authors subscribe to the philosophy that public involvement is inevitable, and they contend that "thoughtful public involvement in decision making about scientifically complex issues is not the impossible task that some suppose." *Id.* at 52. *See also* Mark D. Dibner, Ph.D., *Comment*, NBIAP NEWS REP. (Nat'l Biological Impact Assessment Program, Va. Polytechnic Inst. & State Univ., Blacksburg, Va.), July 1992, at 5-6 (The Director of the Institute for Biotechnology Information of the North Carolina Biotechnology Center advocates a public education campaign).

272. David L. Bazelon, *Governing Technology: Values, Choices, and Scientific Progress*, 5 TECH. IN SOC'Y 15, 23 (1983) (footnote omitted) (quoting Letter from Thomas Jefferson to W. C. Jarvis (Sept. 28, 1820), *reprinted in* 7 WRITINGS OF THOMAS JEFFERSON 177, 179 (H. Washington, ed., 1855)).