An Agricultural Law Research Article

Regulating Agricultural Biotech Research: An Introductory Perspective

by

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REGULATING AGRICULTURAL BIOTECH RESEARCH: AN INTRODUCTORY PERSPECTIVE

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Introduction

In June 1816, Mary Shelly penned a novel while at the Villa Diodati near Geneva, Switzerland.[1] The novel, *Frankenstein: The Modern Prometheus*, was the product of a nightmare suffered by Mary while she was engaged in a storytelling competition with her twenty-year-old husband, Percy Bysshe Shelly, her stepsister Claire Clarement, Lord Byron and John Polidori. On the particular night the idea occurred to her, she had been listening to Byron and Shelly argue over the origin of life and speculate whether it could be artificially created. Although man has been intrigued with the possibility of creating new lifeforms, Mary's creation of Frankenstein's monster seems to encapsulate the nightmares and fears of us all that man might actually succeed in his quest and in the process unleash upon the world an uncontrollable force that might spell its doom.

That such a thing could be accomplished through re-engineering of biologic processes has been a favorite theme of the science-fiction/horror movie makers.[2] As a child I remember that one of my own favorite horror movies was *The Beginning of the End* in which grasshoppers that had eaten irradiated tomatoes in a scientist's greenhouse became gargantuan and escaped to wreak havoc upon Chicago. To the great relief of at least one ten-year old, they were destroyed before the city was totally laid waste. Throughout the movie, I remember that I

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1. C. PANATI, EXTRAORDINARY ORIGINS OF EVERYDAY THINGS 180 (1987).

2. In addition to the movie *Frankenstein* (1931) and all of its subsequent variations and progeny (such as *Alraune*, made in 1928, about an artificially created woman who, like Frankenstein, had no soul), the list of movies dealing with man's ability to exploit or control life and the frightening consequence of such power are legion. Some of the more notable include *Them!* (1954); *The Andromeda Strain* (1971); *The Terminal Man* (1974); *Westworld* (1973); *Soylent Green* (1973); *No Blade of Grass* (1970); *The Quartermass Experiment* (1955); *On the Beach* (1959); *The Seven Faces of Dr. Lao* (1964); *The Incredible Shrinking Man* (1957); *The Omega Man* (1971); *The Last Man on Earth* (1964); *A Clockwork Orange* (1971); *Invasion of the Bodysnatchers* (1956); *Fantastic Voyage* (1966). For further discussion, see D. SHIPMAN, A PICTORIAL HISTORY OF SCIENCE FICTION FILMS (1985).

was desperately concerned that in time a way would be developed to destroy the grasshoppers, and I was greatly relieved when the appropriate antidote, which happened to be a particular sound they could not resist, lured them into Lake Michigan where they drowned.

Recent developments in the area of biotechnology have caused us to revisit our favorite nightmares and wonder whether genetic engineering is still the exclusive domain of the movie-makers. As a result of such innovations as patentable mice[3] and oysters,[4] "gene-altered" chickens[5] and Dutch Elm disease resistant bacteria,[6] it now seems well within man's power to at least alter existing lifeforms. This capability has sparked debate as to whether man can or should take the next step, which seems to be the development of totally new lifeforms. There has been no small amount of public concern that pursuit of such a goal will inevitably unleash something truly monstrous on the world for which there will be no antidote. Even now, some are desperately concerned that such a monster might actually trigger a real beginning of the end that is far beyond the wildest imaginations of the movie script writers.

This article deals with some facets of the problems involved with the governmental regulation of the research associated with biotechnology, particularly as it relates to agricultural research. The primary focus will be on government as it struggles to define the responsibility it might have to supervise or control research of this type. In this sense, this article is intended to be an introductory overview to the complex concerns involved.[7] In addition, this article presents a look at how we

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3. U.S. Issues Patent on New Type of Mouse, The Topeka Capital J., Apr. 13, 1988, at 5C, col. 5.

4. *See Ex Parte Allen*, 2 U.S.P.Q.2d (BNA) 1425 (1987).

5. Kiplinger Agricultural Letter, vol. 59, no. 24 at 3 (Dec. 2, 1988).

6. *See* Meeks, *Biotechnology: There's a Challenge Ahead*, STATE LEGISLATURES 12-16 (May/June 1988).

7. For further discussion, *see* Francis, *Recent Developments in Genetic Diagnosis: Some Ethical and Legal Implications*, 1986 UTAH L. REV. 483 (1986); Harlow, *The EPA and Biotechnology Regulation: Coping With Scientific Uncertainty* 95 YALE L.J. 553 (1986); Osborn, *Current Issues in Biologic Regulation*, FDA CONSUMER 58 (June 1981); Cooper, *Regulation: Looking to the Future*, FDA CONSUMER 64 (June 1981); Meeks, *supra* note 6, at 12; Withers, *Biotechnology: An Industry Perspective* 34 U. KAN. L. REV. 665 (1986); Looney, *Emerging Legal Issues Associated with the Application of Embryo Transfer Technology in Livestock Agriculture*, 34 DRAKE L. REV. 321 (1984-85); Wershow, *International Ramifications of BIotechnology*, 1 FLA. INT'L L. REV. (1983); Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177 (1987); Christensen, *Genetic Ark: A Proposal to Preserve Genetic Diversity for Future Generations*, 40 STAN. L. REV. 279 (1987); Whitney, *Regulating Biotechnology Research and Products*, THE ENVIRONMENTAL FORUM 19 (May 1985); Mahinka & Sanzo, *Biotechnology Litigation and Federal Regulation: Status and Implications*, 42 FOOD DRUG COSM. L.J. 500 (1987); Brown, *Feed Biotechnology Reaches Regulatory Crossroads*, FEEDSTUFFS 5 (May 9, 1988); Muirhead, *Views Differ on Federal Approach to Regulation of Biotechnology*,

are currently reacting to the fear that Frankenstein's monster might be more real than we ever imagined, and that it may in fact, be lurking around the corner in some scientist's workshop.

The Biotech Revolution and Agriculture

The history of American agriculture may be described as a history of revolutions. Shortly after the settlement of this country began, the first revolution started. This was a "popular" revolution, culminating in the selection of the "family farm" concept as the national ideal of farmland tenure. It was a revolution that was politically intended to maximize the number of individual landowners which could participate in the public processes of governance and economically focused on concepts of self-sufficiency. It was also a "colonizing" revolution which sought to settle and develop the country from sea to shining sea. The second revolution, a mechanical revolution, began near the end of World War II, moving agriculture from the horse to the tractor. It was also a revolution in production spurred by the development of hybrid seeds, livestock strains and chemicals that could make more efficient use of farm resources. In recent years we have seen two additional revolutions - a revolution in farm management techniques and organizational structures, and an "international" revolution in market relationships. In the management revolution, partnerships and corporations have replaced families and individuals as the dominant farm business format of the largest, most productive farms,[8] and computers, information services and farm managers have replaced the individual farmer as the primary source of expertise in the actual operation of many farms. The latter revolution has been characterized by global concerns and competition over supply and demand for food and resources.

We are at the beginning of still another revolution in agriculture. This revolution involves the manner in which the basic building blocks of nature may be technologically manipulated to create new types of

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FEEDSTUFFS 11 (May 23, 1988); Comment, *Designer Genes That Don't Fit: A Tort Regime for Commercial Releases of Genetic Engineering Products*, 100 HARV. L. REV. 1086 (1987); Comment, *Patents, Plants and Biotechnology—Policy and Law* 14 W. ST. U. L. REV. 529 (1987); Comment, *Biotechnology Regulation Under the Toxic Substances Control Act*, 3 PACE ENVTL. L. REV. 57 (1985).

8. As of January 1, 1988, it was reported that of all farms generating $500,000 or more per year, twenty-three percent were corporations and thirty-two percent were partnerships. In contrast, only forty-three were individuals. At the other end of the spectrum, ninety-six percent of all farms with less than $10,000 in income and ninety-four percent of farms with between $10,000 and $19,000 in income were individuals. Financial Characteristics of U.S. Farms, USDA Economic Research Service, 68 Agric. Info. Bull. No. 551 (Jan. 1988).

plants and animals that will yield more, be more disease and pest resistant, require less care or consume more readily available foods. A major objective of this "biotech" revolution is to develop the capacity to efficiently meet the food and fiber needs of an expanding world population despite a shrinking arable land base. This is to be accomplished either by developing new or modified plants and animals or through the creation of specific-use microorganisms.[9] While such a revolution obviously can change the manner in which agricultural activities are conducted, it undoubtedly will have results that will reach far beyond agriculture as well.

In each of the previous revolutions that have occurred, they have been met with considerable resistance from the "old guard" which has generally been reluctant to give up the "old proven ways." Once the "new" ideas replace the old, they become deeply entrenched and form the basis for resisting the next generation of innovations. Today, for example, there is strong sentiment that farming is somehow better if it is conducted on "family farms," and the call to save family farms has become a battle cry of many who wish to keep corporations out of farming. Similarly, it might be expected that if the new technological developments become widely accepted, they will also become a defended part of agriculture. The problem is *whose* acceptance is required. In the past, it was largely a question of convincing the agricultural sector that the new development was acceptable. However, the new biological developments create more apprehension among the nonagricultural sector than among agriculturists regarding the acceptability of the new developments. This has generated considerable pressure upon government to assume a role in protecting the public's interest.

The development generating the greatest public concern seems to be what is loosely referred to as "biotechnology." This is generally thought of as the ability to move genetic material from one organism to another through a process known as "gene splicing" or "recombinant DNA." In this process, genetic information contained in specific segments of DNA is isolated and then transferred to another organism where it is recombined with that organism's DNA. This is generally done to modify that organism's DNA in order to improve the organism

9. One of the important developments of biotechnology has been the ability to genetically alter bacteria to cause it to perform specific tasks. For example, elm trees might be made resistant to the dreaded Dutch Elm disease through the injection of genetically altered bacteria developed by Dr. Gary Strobel at Montana State University. Similarly, strawberries might be protected from frost damage through inoculation with genetically altered bacteria called "Frostban" developed by Advanced Genetic Sciences Inc. *See* Meeks, *supra* note 6, at 12-16.

or to essentially produce a new or different organism.

In just the past few years, biotechnology has started to develop into a full scale industry. While it is presently conceived as part of the agricultural support sector, it is probably capable of eventually standing on its own. As this industry has grown, it has become the target of increased legislation. This legislation is designed to regulate the risks associated with genetic engineering as well as to protect the industry's economic potential. There is widespread apprehension that the regulations will not be adequate to prevent the release of possibly dangerous organisms. There is also concern within the scientific community that legitimate developments might be stifled by over-inclusive or inadequately developed laws.

An Inventory of the Basic Issues

While biotechnology has the potential to benefit mankind, there is considerable uncertainty as to the risks and social costs associated with its emergence. As a result, a large number of very difficult issues must be dealt with as developments of this type unfold. Although the problem of regulating research requires some understanding of the whole area in order to have an accurate perspective of the complexity of the problem presented by biotechnology, it must be appreciated that most of the issues are not what one might consider truly legal issues. For the most part, these concerns are what the general public might describe as social and ethical in nature. Nevertheless, since law may be conceived as the codified morality or norms of a particular society,[10] law will necessarily play an important role in dealing with these issues, particularly at the policy formulation stage, where government seems to be at present. In addition, it is impossible to separate the social and ethical concerns from the so-called legal concerns in many cases anyway. Finally, it is very difficult to divorce research from the rest of the biotech industry in such a way that the concerns of the researchers are markedly different, for purposes of regulation, from those of the general public, even though their appreciation of the risks may be somewhat more refined.

The issues currently being debated tend to cluster depending on the perspective from which the problem is being viewed. From the perspective of the general public, the concern tends to be predominantly health and safety related. Will uncontrollable organisms be released

10. *See* E. ERLICH, FUNDAMENTAL PRINCIPLES OF THE SOCIOLOGY OF LAW (Moll trans., 1936).

that pose a danger to the public or the environment? Will researchers tamper or experiment with human lifeforms? What happens if the new technology is adopted too quickly? Will ethical considerations play a significant role in regulation? Can existing tort concepts effectively deal with risks and harms of biotechnology? Are risk management procedures adequate to deal with known and unknown risks posed by biotechnology and the release of biotech material? Will biotechnology cause untreatable diseases, radically alter the balance of nature within ecosystems, or develop new strains of super pests? Although answers to many of these questions are unknown, there seems to be an official governmental perception that the new technology will not pose risks that cannot be readily dealt with. A recent report by Office of Technological Assessment concluded that "[n]one of the small-scale field tests proposed or probable within the next several years are likely to result in an environmental problem that would be widespread or difficult to control."[11]

In other cases, the public appears to be skeptical of the answers given by government or by the industry. For example, although the Patent and Trademark Office has announced that it will not consider patent applications for new human lifeforms, this apparently has not alleviated the public's general fear that such a development might eventually occur. This results in part from the fact that when the patent was recently issued for genetically altered mice, the patent actually covered *all mammals* with the specifically described genetic alteration. So far, only a new kind of laboratory mouse has been created using the patented technology. However, at least twenty-one additional patent applications are pending on animals.[12]

The public may take comfort in the fact that the primary basis for governmental regulation in this area is the police power which may legitimately be invoked for the purpose of protecting the public health, safety, welfare and morals of the community. Therefore, the public's concerns are precisely the type that support a governmental effort to protect. The difficult problem of whether public protection is actually needed, however, is still being debated.

From the perspective of the researchers involved, the prospect of government regulation raises different issues. Will research restrictions unduly impinge on rights of researchers and academic freedom?[13] How

11. *Report Boosts Biotechnology Experiments*, Washington Post, May 5, 1988, at E1, col. 2.

12. Chronicle of Higher Education, Apr. 20, 1988, at A1, col. 4.

13. This is a major issue in California Agrarian Action Project, Inc. v. The Regents of the

can the proprietary interests of researchers and the industry be protected against the impact of restrictive regulation? Must currently accepted norms of scientific research be modified to accommodate the risks and fears associated with biotechnology? Recent developments in the area of patents appear to indicate that the innovations of biotechnology may be protected as a specie of property.[14] Moreover, the same may be said of certain secrets of the trade.[15]

On the other hand, property rights are inherently subject to legitimate police power regulation. In fact, the police power may actually be asserted to define, or deny the existence of, property rights in new research developments.[16] In addition, the public may seek, through the exercise of the police power, the creation of standards or codes of ethics that will be binding on biotechnological researchers in ways that may potentially restructure basic research techniques.

From the perspective of the agricultural sector, other important issues are raised. Which products should be regulated? Is there a defensible basis for distinguishing between regulation of human as opposed to animal related biotechnology—particularly food additives and hormone implants? Will biotechnology have a sufficient impact on agriculture to cause fundamental restructuring of the industry? Will the impact of biotechnology be evenly distributed across farms, regions or time? What is the impact of biotechnology on formal policy institutions such as the "family farm"?[17] Should governmental regulatory authority over the biotechnology industry be used to direct or redirect the future of agriculture?

One particularly troublesome issue for agriculture is whether government regulation of biotechnology will consist of new or just more regulation. This, of course, makes a difference both in terms of how the regulation is justified, as well as in how those affected deal with it. At this point, the apparent official position of some governmental agencies is that regulation of biotechnology is not a new type of regulation. "The USDA policy position is that products of genetic engineering fundamentally are no different than those produced by conventional methods

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Univ. of Cal., 210 Cal. App. 3d 1245, 258 Cal. Rptr. 769 (1989).

14. *See* Wadley, *Patent Rights in Biotech Developments*, 4 AGRIC. L. UPDATE 4-6 (Aug 1987).

15. *See* Abramson, *Confidential Business Information Versus Public's Right to Disclosure—Biotechnology Reviews the Challenge*, 34 U. KAN. L. REV. 681 (1986).

16. *See* Wadley, *The Emerging "Social Function" Context for Land Use Planning in the United States: A Comparative Introduction to Recurring Issues*, 28 WASHBURN L.J. 22 (1988).

17. The latter two issues are raised in *California Agrarian Action Project, Inc.*, 210 Cal. App. 3d 1245, 258 Cal. Rptr. 769 (1989).

and therefore, existing statutes are adequate for regulating the products of agricultural biotechnology."[18]

Agriculture is a major, if not the primary, beneficiary of the development of new plants and animals, pesticides and herbicides. On the other hand, public fear might influence the regulatory responses to the problems posed by biotech research. The greatest apprehension of the agricultural community is that public fear regarding the health, safety, and environmental risks of these new research developments, rather than sound economic considerations, will restructure agriculture as an industry.

Because of the nature of most of these issues, it is premature to expect that many of them can be dealt with effectively within the judicial system at the present time. In some respects the delay is to be expected since law inevitably tends to lag behind technology, and in many cases there simply is no law to be applied. On the other hand, existing case law suggests that not only is there some reluctance on the part of the courts to speculate as to the nature and extent of future harms and risks, but it is also difficult to fashion an effective remedy for events that have not happened.[19]

Presently, the role of the judiciary appears to be one of encouraging candor[20] on the part of the industry, rather than supervising the regulation of genetic experimentation. In the cases decided thus far, the courts have fairly limited their inquiry to the sufficiency of, or need for environmental impact statements,[21] the standing of the parties in-

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18. *See* Muirhead, *supra* note 7, at 11; *see also* Meeks, *supra* note 6, at 14, where the National Academy of Sciences was said to have taken the position that hazards from genetically engineered plants or microbes are no greater than those organisms altered by conventional breeding techniques.

19. Few courts have had an opportunity to deal with these issues. The most important cases include the following: California Agrarian Action Project, Inc. v. Regents of the Univ. of Cal., 210 Cal. App. 3d 1245, 258 Cal. Rptr. 769 (1989); Foundation on Economic Trends v. Heckler, 587 F. Supp. 753, 763 (D.D.C. 1984), *aff'd*, 756 F.2d 143 (D.C. Cir. 1985); Laurel Heights Improvement Ass'n v. Univ. of Cal., 193 Cal. App. 3d 467, 238 Cal.Rptr. 451 (1987); Foundation on Economic Trends v. Lyng, 680 F. Supp. 10 (D.D.C. 1988); Foundation on Economic Trends v. Thomas, 661 F. Supp. 713 (D.D.C. 1986); Foundation on Economic Trends v. Johnson, 661 F. Supp. 107 (D.D.C. 1986); Foundation on Economic Trends v. Block, Civ. No. 84-3045 (D.D.C. slip opinion, Apr 26, 1986); Foundation on Economic Trends v. Weinberger, 610 F. Supp. 829 (D.D.C. 1985).

20. *See, e.g.*, Foundation on Economic Trends v. Johnson, 661 F. Supp. 107, 110 (D.D.C. 1986), where the court refused to require the relevant agencies to complete and clarify regulations controlling the use and handling of genetically modified products; *see also* Foundation on Economic Trends v. Block, Civ. No. 84-3045 (D.D.C. slip opinion, Apr. 26, 1986).

21. In Foundation on Economic Trends v. Weinberger, 610 F. Supp. 829, 841 (D.D.C. 1985), the court ruled that the scope of the environmental impact statement (hereinafter EIS) need only be broad enough to consider those activities actually proposed for present experimenta-

volved,[22] or the ripeness of justiciable issues.[23] The one notable exception is *California Agrarian Action Project, Inc. v. Regents of the University of California*,[24] where the court was presented with the problem of deciding the extent to which federal law controls the class of intended beneficiaries of biotechnological research conducted in land grant universities. To resolve this issue, the court had to determine the extent to which federal law preempts the freedom of the researchers to identify their own target audiences and develop research programs accordingly. The trial court held that the Hatch Act required that the agricultural research be targeted to family farms. The case is presently on appeal.

The judiciary has not adequately addressed the public's concern over the potential environmental harms and unknown risks associated with biotechnological developments. Courts should not be expected to play a major role in the present development of the necessary law and regulation in light of the constraints on review and access.

Many of these issues must be considered to be political issues,

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tion. Although the court found the EIS insufficient, it ruled that the required statement need only research the proposed construction of a new testing laboratory for existing biological weapons. Regardless of the fact that the laboratory would be capable of testing genetically altered pathogens as biological weapons, no EIS would be required so long as such activities were merely "contemplated" and not "proposed."

In Laurel Heights Improvement Ass'n v. Univ. of Cal., 193 Cal. App. 3d 467, 238 Cal. Rptr. 451 (Cal. App. 1987), the court held that the scope of judicial inquiry into an EIS is limited to its sufficiency as an "informational document" regarding the effects proposed experimentation may have on public health and safety, and in certain circumstances, whether the statement considers the presence of reasonable alternatives. In this inquiry, the court may not substitute it's judgment for that of the drafter with respect to environmental conclusions.

In Foundation on Economic Trends v. Heckler, 587 F. Supp. 753, 766-67 (D.D.C. 1984), *aff'd*, 756 F.2d 143 (D.C. Cir. 1985), the court held that an EIS could only be required where there was federal funding. Thus, private laboratories are not required to prepare an EIS.

22. In Foundation on Economic Trends v. Thomas, 661 F. Supp. 713, 718-19 (D.D.C. 1986), the court refused to require the EPA to demand, prior to the issuance of a permit, a demonstration of financial responsibility sufficient to redress potential harms that may possibly result from the release of genetically altered bacteria because of a lack of standing. The court found that the plaintiffs possessed only a general interest in the alleged potential harms and were not within the "zone of interest to be protected or regulated;" *see also* Foundation on Economic Trends v. Johnson, 661 F. Supp. 107 (D.D.C. 1986).

23. In Foundation on Economic Trends, 661 F. Supp. 713, 716 (D.D.C. 1986), the court held that the action was premature. It would seem that the requirement of "unusual hardship" or "serious injury" which must be satisfied in order to have a justifiable case actually promote the public fear that the judiciary is not an effective forum in which to resolve these issues where the public fear is essentially a fear on unknown consequences. The public might likely conclude that the harm must actually be done before the case can ever be brought to court; *see also* Foundation on Economic Trends v. Lyng, 680 F. Supp. 10 (D.D.C. 1988).

24. 210 Cal. App. 3d 1245, 258 Cal. Rptr. 769 (1989).

rather than legal issues, because of the unknown and speculative nature of the public's concern. This focus puts considerable emphasis on the legislative and administrative branches of government to be the legal decision makers. This, of course, is not to say that there are no laws on point nor that one of the critical concerns is how these laws should be interpreted, implemented and enforced. It does suggest, however, that the area of biotechnology has not yet developed into a separate or cohesive area of the law. Therefore, the most effective means of influencing legal decision making in this area is through working with the respective governmental bodies that are actually making the operative law. In a practical sense, this does not mean simply lobbying the legislature. Rather, it means dealing with the specific agencies that have regulatory authority.

The Role of the Government

Determining the appropriate role for government is complicated by the fact that government, at both the state and federal levels, has been an active promoter of biotech research as well as a regulator of some aspects of the industry. These roles are considered by many to be fundamentally in conflict. How can government sponsor the creation of what many consider to be a looming monster, and at the same time adequately protect against the consequences of such a creation? Close analysis of the situation suggests that not only are governmental responses to the problem conflicting in nature, but there is also a lack of a clear consensus as to what the appropriate role of government should be.

The present situation resulted from a variety of factors. The diversity of the biotechnology industry fosters regulation in a very fragmented way with minimal coordination between regulating agencies. For example, five separate federal agencies have authority over the area and tend to divide responsibility based on either the type of genetically altered organism or how that organism is to be used commercially.[25] This structuring of regulation causes each agency to cultivate a somewhat different constituency upon which it is dependent for support and toward whom outputs are targeted. In this case, the relevant constituent groups include the general public (which wants protection from the release of dangerous organisms into the environment), the scientific research community (which wants development support in the form of funding and minimal regulation) and the biotechnology industry

25. *Id.*

(which wants protection for the economic position of the industry against the public clamor for regulation and control). Thus, government may be pursuing somewhat conflicting objectives that are almost entirely the result of attempting to satisfy those disparate constituencies.[26]

The considerable ambivalence among government decision makers regarding what particular regulatory role government should play and how that role should be discharged is also worth considering. Not all governmental decision makers are convinced that biotech research is a dangerous or undesirable endeavor. Some, in fact, see these new developments as critical to our ability to adequately feed and clothe a growing world population. There is concern on the part of some that government is more interested in promoting these developments than in guarding against risks posed by the technology. In some respects, the role of "promoter" was assumed first, and it has been the recent public clamor for government to serve as "protector" that has forced some rethinking. In a sense, this creates something of an identity problem for government. Government must decide what its proper role is while ranking constituency groups in order of importance. Nevertheless, it is one thing to decide that the government shall be the "defender against the nightmare"; it is quite another to decide how to accomplish that goal. Clearly, there are many choices. The least intrusive, as far as researchers are concerned, is to have government act only to prevent the release of dangerous organisms into the environment. The public, however, is somewhat uncomfortable with such a narrow role.[27] At the other extreme, government might determine the research agenda itself and perhaps require permission before significant innovations are undertaken. This role probably makes everyone uncomfortable because it smacks too much of "big brother." As a result, the currently perceived role appears to be, though perhaps not deliberately so, an attempt to accommodate virtually all interests without any attempt to rationalize the areas of potential conflict.

Finally, it should be noted that the regulations that are presently in place are very complex and have resulted in considerable confusion as to which agencies with potential jurisdiction have authority in a specific situation. Federal legislative responses to the biotech problem have been criticized for their overlap in some cases and serious gaps in

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26. For further discussion of bureaucratic theory in the context of government regulation, *see* Wadley, *Small Farms: The USDA, Rural Communities and Urban Pressures*, 21 WASHBURN L.J. 478, 501-508 (1982).

27. *Id.*

others.[28] This has resulted in the claim that there is a lack of a coordinated or a comprehensive approach to the problem at any level of government.[29]

As a result of these and other factors, the role for state governments has largely been confined to development and promotion, while regulation has primarily been the federal responsibility.[30] However, these roles are not irrevocably assigned and, in fact, there is considerable debate at both levels of government as to what the proper role of each should actually be. As public concern over biotech developments increases, there is frustration on the part of the states that the federal government is not doing enough or not doing the right things. This suggests the need for a more active regulatory role at that level. As more levels of government get involved in the regulatory process, the more important it will become to be able to block out areas of concern. This, in turn, requires that each level of government develop and articulate a more precise sense of responsibility than has been evident in the past.

The Current Regulatory Framework

For the most part, regulation of biotechnology and associated research, is presently seen as primarily a federal responsibility. A number of different federal or quasi-federal agencies have been given regulatory authority in this area. Both the National Institutes of Health (NIH) and The National Science Foundation (NSF) promote basic research, including biotech research. NIH regulates bio-medical research and recombinant DNA research financed either by federal funds or at institutions or facilities that receive NIH monies. NSF monitors environmental research and finances research with grants. These grants are subject to NIH regulations and guidelines which prohibit some types of experiments and mandate physical containment. NIH created a Recombinant DNA Advisory Committee (RAC) to review and approve all r-DNA research subject to NIH jurisdiction. NIH basic guidelines are contained in what is called "Guidelines for Research Involving Recombinant DNA Molecules." Compliance with NIH guidelines by private research companies, which is a major aspect of biotech research, is presently considered voluntary and is therefore generally thought to be outside the scope of federal regulation by NIH. Similarly, the guidelines and RAC approval apply only to recombinant DNA technology,

28. *See* Meeks, *supra* note 6, at 12-16.
29. *Id.*
30. *Id.*

and do not affect what might be described as classic genetic engineering techniques.

The United States Department of Agriculture (USDA) regulates some research, testing, and production of agricultural biotech products. Areas likely to be affected are genetically engineered plants, insects, animals and microbes that are considered by USDA to be helpful or harmful to agriculture. The Food and Drug Administration (FDA) regulates the development of new drugs, vaccines, food additives, medical devices, etc. These are reviewed primarily for safety and effectiveness. The Environmental Protection Agency (EPA) reviews primarily non-food and non-drug biotechnology products in order to assess risks and benefits to society.

The current statutory framework for regulation involves a variety of different statutes. The National Environmental Policy Act (NEPA),[31] The Federal Food, Drug and Cosmetics Act (FFDCA),[32] The Occupational Safety and Health Act (OSHA),[33] The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA),[34] The Toxic Substances Control Act (TSCA)[35] and The Resource Conservation and Recovery Act (RCRA),[36] are frequently identified as the major statutory basis for federal regulation. Although each of these statutes contains important provisions that facilitate federal jurisdiction over various aspects of the biotech problem, of perhaps even greater significance is the current policy framework that has been specifically developed for biotechnology regulation.

This framework was published as the "Coordinated Framework for the Regulation of Biotechnology"[37] (hereinafter Framework) and represents an effort to coordinate regulatory efforts undertaken by a variety of governmental agencies under authority of the various statutes noted above. These include the Office of Science And Technology,[38] Food and Drug Administration,[39] United States Department of

31. 42 U.S.C. §§ 4321-4370(a) (1970).

32. 21 U.S.C. §§ 301-392 (1938).

33. 29 U.S.C. §§ 651-678 (1970).

34. 7 U.S.C. §§ 136-136(y) (1980).

35. 15 U.S.C. §§ 2601-2629 (1976).

36. 42 U.S.C. §§ 6901-6987 (1976). *See* 49 Fed. Reg. 50, 867 (where EPA identified this act as a potential source of regulatory authority).

37. 51 Fed. Reg. 23, 301 (1986).

38. *Id.*

39. FDA Final Policy Statement for Regulating Biotechnological Products, 51 Fed. Reg. 23, 309 (1986).

Agriculture[40] and The Environmental Protection Agency.[41] This Framework is significant for several reasons. First, it provides a common definitional framework for determining which new organisms or products are subject to regulation.[42] Second, it suggests an intention to use the existing statutory framework for most of the regulation that is anticipated.[43] Finally, it suggests that the focus of regulation will be on the products produced rather than on the process by which these new biotech products are developed.[44] Although the Framework has been criticized as a hodgepodge arrangement that has fallen victim to the same case-by-case trap allegedly established by the NIH guidelines,[45] the framework must be recognized as an important articulation of the position several agencies intend to take in dealing with the problem. While the Framework itself may not be adequate to deal with all of the facets of the problem, it does help structure efforts to deal with the agencies. Since the agencies are the current arena for most legal decision making, it is significant that the agencies involved in the Framework have a publicly announced policy position.

Because the problem of government regulation of biotech research and development is generally thought of as the responsibility of the federal government, very little legislative activity has occurred at the state level. It appears that most of the state activity has been largely due to frustration with the federal approach or of fear that the federal response has been incomplete or inadequate.[46] As of May, 1988, it was reported that only thirteen states had even considered regulating the biotechnology industry and of those thirteen, only Hawaii, MIchigan, New York, Oregon and Rhode Island had established any rules.[47] Environmentalists criticize the rules as not being stringent enough,[48] and that they appear to deal primarily with the release of organisms into the environment rather than with other matters of research and development. Since much of the state activity may be seen as the result of

40. USDA Final Policy Statement for Research and Regulation of Biotechnology Processes and Products, 51 Fed. Reg. 23, 340 (1986).

41. EPA Statement of Policy for Regulating Biotechnological Products, 51 Fed. Reg. 23, 343 (1986).

42. 51 Fed. Reg. 23, 307.

43. Mahinka & Sanzo, *Biotechnology Litigation and Federal Regulation: Status and Implications*, 42 FOOD DRUG COSMETIC L.J. 500 (1987).

44. *Id.* at 502.

45. *See* Comment, *Designer Genes that Don't Fit: A Tort Regime For Commercial Releases of Genetic Engineering Products*, 100 HARVARD L. REV. 1086, 1089 (1987).

46. *See* Meeks, *supra* note 6, at 14.

47. *Id.*

48. *Id.*

perceived weakness at the federal level, it would appear that most states, as well as those within the industry and those without the industry would prefer that regulation occur at the federal level.

On the other hand, states support a considerable amount of biotechnology research. The Office of Technology Assessment estimates that states are spending at least $150 million a year to support research or to attract biotech related industries. This may actually generate a conflict of interest concerning the regulation issue in states where biotechnology is seen as an important part of local economic development. States may see themselves as having to choose between jobs and economic growth on the one hand, and public safety on the other. Where little is known about the risks posed by the new technologies, there may be a tendency to avoid the issue or shift it to the federal level without seriously considering state-level regulation at all.

Government Regulation of Research

Much of any type of governmental regulation—whether of research, of agriculture, of land use—must be seen as an attempt by government to assert, by force of law, a particular codification of value judgments which are supposed to represent the common goals, values and assumptions of the slice of society to which the governmental entity is responsible. This conceptualization of the problem is significant for at least three reasons: First, these "values" are sometimes only emotionally derived. That is, there is no empirical reason why a particular position should be taken but there may be a strong, perhaps popular sense that the regulation is appropriate. Second, to be successful over the long run, *how* the particular values are identified is as critical as the actual regulatory approach. If the underlying values are miscalculated, the resulting regulation will be very difficult to enforce through voluntary compliance. Third, problems necessarily arise when the values are challenged as not representing collective values. In this regard, it might appear that one of the major difficulties with the issue of government regulation of research is that not enough is known about some of the technologies involved. This means that some of the regulations are probably based on nothing more than emotionally derived value judgments. This is unfortunately the case even where the regulation could be grounded on data regarding, for example, health and safety concerns. The more that is learned, the less this should be a problem. Unfortunately, as a matter of fact, law invariably lags behind what is known and does not always adjust quickly to new information. In this regard, the position of government necessarily needs to be somewhat

flexible.

Problems regarding government regulation of research will obviously vary somewhat depending on whether the research to be regulated is privately or publicly sponsored. In a sense, public fears play a larger role in regard to regulation of private research because of the need to ground that regulation on widely recognized values, such as health and safety. On the other hand, if the government is "hiring" the research, it can perhaps impose whatever conditions it wants so long as researchers are willing to work under those conditions. Governmental sponsored research encounters difficulty when the purpose of the research is seen as being tied to values, such as the promotion of the family farm, that may be accepted as basic by one group (the consumers, perhaps) and not by others (such as large-scale agriculture).

Problems regarding regulation of research also vary depending on how the actual regulatory function is considered within a bureaucratic model of government.[49] Bureaucracy, of course, is government by employee, as opposed to government by elected representative. It is acceptable in our system to delegate to governmental agencies (and even others) the responsibility to adopt specific rules and regulations which have the force of law. These rules are essentially developed by employees within the various agencies. The adoption process is typically structured such that unless there is significant negative response to the regulations when they are proposed for public comment, they are considered lawfully adopted. Therefore, much of the actual operative law enforced by agencies is actually made by the bureaucracy rather than by elected lawmakers. Despite the fact that the laws are not the result of any legislative process carried out by elected representatives (as that concept is understood by most people), the public is not deprived of a very meaningful opportunity to participate in the lawmaking process. The vehicle for participation, however, is not what one might expect since it is not involved with the notice-public, comment-adoption of regulations process at all. Rather, it has to do with how bureaucratic clientele are dealt with. According to bureaucratic theory,[50] agencies compete with each other for power and resources. Each agency has its own internal

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49. *See generally* Wadley, *supra* note 26, at 501-08.

50. *See* G. ALMOND & G. POWELL, COMPARATIVE POLITICS, A DEVELOPMENTAL APPROACH (1966); J. BAGWATI, THE ECONOMICS OF UNDERDEVELOPED COUNTRIES (1966); N. RAPHACH, READINGS IN COMPARATIVE PUBLIC ADMINISTRATION (1967); F. RIGGS, ADMINISTRATION IN DEVELOPING COUNTRIES: THE THEORY OF PRISMATIC SOCIETY (1964); F. VON DER MEHDEN, POLITICS OF DEVELOPING NATIONS (1964); C. BLACK, THE DYNAMICS OF MODERNIZATION (1966).

social and political system through which it conducts its activities. These internal systems are comprised of subgroups and subsystems to which the functions of the agency are delegated. These subgroups develop external clients that are the objects of the agencies activities and upon which the agencies depend for support.

Whether the agency is successful in competing with other agencies depends in large measure upon how the specific clientele groups are managed. The greater the dependence of the agency upon its clientele, the more critical it is that the responses of the agency toward the clients be acceptable and correspond to the demands made by the clients of the agency. In an input-output model of bureaucracy, groups rather than individuals tend to be clients. These groups then aggregate and articulate demands which are made of the agency. These demand inputs are then translated by the agency into outputs.

Biotech researchers have become an important client group for several agencies involved in the regulatory process. Research and support for research have also become important agency outputs for this group. Similarly, regulation of research is also an important agency output. It, however, results from the demands of different client groups—the general public and the environmentalists. A critical question, in understanding regulation of biotech research, is which clientele groups are demanding the particular responses and how are the various agencies faring on the competition issue. Where the agencies are directly involved in the lawmaking process, a vital concern is the extent to which the concerns of the general public over safety and environmental impacts are likely to be addressed by the agencies. In this regard, the public might be better advised to attempt to alter the internal and competitive power balances of the bureaucracies rather than resorting to litigation.

Bureaucratic history suggests that one of the most effective ways to influence lawmaking in agencies is to suggest that the outputs of the agencies do not match the public's demands nor expectations. Public influence in the legislative oversight process would appear to be one of the most effective ways to accomplish this. This certainly would put a greater burden on Congress to insure that the collective values of the public are accommodated in the regulatory effort.

It must also be noted that bureaucracies also generate what are called "symbolic outputs."[51] These outputs are exclusively designed to assure the client groups that the agency is attuned to their demands

51. *See* Wadley, *supra* note 26, at 507.

and is acting accordingly. These outputs may not even be true. That does not mater so long as the bureaucracy appears to be doing what the clientele expects, regardless of whether it is or is not true. An example of such a symbolic output may be the statements that have routinely appeared as part of the federal farm program: the family farm is the preferred form of farm tenure.[52] Until the decision in *California Agrarian Action Project, Inc. v. Regents of the University of California*,[53] it was widely thought by many in commercial agriculture that these statements were nothing more than symbolic outputs and that government was more interested in the economic success of agriculture as a whole than it was with the viability of family farms. That position certainly was supported by much of what the government did, particularly the USDA.[54] In a bureaucratic sense, whether the family farm is actually vital is less significant than whether the public is convinced that government believes likewise and acts accordingly. Part of the controversy in the California case revolves around the court's holding that the research conducted at the university with federal funds had to be structured to benefit the family farm. In other words, the court acted as if it believed the government's position on family farms to be more than symbolic.

When government tackles the question of regulation of biotechnology and associated research a number of concerns arise. One concern has been that the public fear of Frankensteinish developments might be translated into nothing more than a symbolic output that leads the public to believe that government is genuinely concerned with the problem and that it will appropriately regulate in a meaningful way, while as a matter of fact, government has neither that intention nor that concern. One commentator has characterized federal attempts to deal with inad-

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52. *See, e.g.*, The Agriculture and Food Act, Pub. L. No. 97-98, § 102(a), 95 Stat. 1213 (1981):

> Congress reaffirms the historical policy of the United States to foster and encourage the family farm system of agriculture in this country. Congress believes that the maintenance of the family farm system of agriculture is essential to the social well being of the Nation and the competitive production of adequate supplies of food and fiber. Congress further believes that any significant expansion of nonfamily owned large-scale corporate farming enterprises will be detrimental to the national welfare. It is neither the policy nor the intent of Congress that agricultural and agricultural-related programs be administered exclusively for family farm operations, but it is the policy and the express intent of Congress that no such program be administered in a manner that will place the family farm operation in an unfair economic disadvantage.

53. 210 Cal. App. 3d 1245, 258 Cal. Rptr. 769 (1989).

54. *See* Wadley, *supra* note 26, at 507.

equacies in federal regulatory approaches as "mostly talk."[55] Unfortunately, there is no litmus test for determining whether an output is symbolic; time alone will tell the extent to which government will be involved.

Conclusion

It appears that agriculture is on the verge of a biotechnological revolution that undoubtedly will be a boon to both the industry and to mankind. Unfortunately, much is still unknown about the human and environmental consequences of the biotechnological developments that are causing this revolution. This uncertainty has generated considerable fear among the public that has been translated into pressure for government regulation. As these demands for regulation are made, many difficult issues must be resolved that appear to depend upon a more comprehensive understanding of the risks and advantages of the new technology than is presently available to lawmakers and to the legal system. This perhaps explains why the legal system has been slow to respond to the public's fears and concerns. Further, the law naturally tends to lag behind technology anyway. As a result, the legislative arena seems to have become the preferable place in which to deal with these issues at least for the present time. This, however, has resulted in giving significant lawmaking authority to the administrative agencies involved with biotechnology. Current agency policies do not appear to unduly restrict researchers; rather, they are more directed at controlling the release of the genetically altered products. This seems to have generated considerable public concern that these agencies have not done their regulatory task as effectively as the public might desire. It would appear from court decisions to this point that the public's concerns in this regard might be more efficiently asserted by targeting the agencies input-output structure than by litigating the issues directly with the agencies—at least until the data is more conclusive as to the risks and benefits of biotechnology.

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55. *See* Meeks, *supra* note 6, at 14.