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THE ROLE OF LOCAL GOVERNMENTS IN REGULATION OF BIOTECHNOLOGY

ABSTRACT

This paper explores the role of local governments in regulation of biotechnology. It evaluates several specific strategies available to local governments. Strategies are designed primarily to respond to experimental field test applications, although regulation of existing research facilities and siting of new research facilities are considered as well. Both Federal and California state regulations are reviewed to determine if they achieve regulatory goals and respond to local government needs. Lessons learned from local government involvement to date are considered in developing regulatory strategies. Particular attention is given to Advanced Genetic Sciences attempts to test "Frostban" in Monterey County and the City of Brentwood in Contra Costa County.

The paper recommends that local governments adopt procedures now which will standardize information flows when applications are submitted. It concludes that local governments should not engage in additional technical and scientific review unless there is a clear need for this review due to a lapse in Federal or State regulatory procedures. Local governments should, however, play a key role in educating the public and receiving and responding to public comments. In addition, Federal and State regulatory officials should change their view of the importance of public opinion. Public comment should be viewed as a legitimate decision making criterion to be balanced against other criteria.

TABLE OF CONTENTS

ABSTRACT.....	i
1.0 INTRODUCTION.....	1
2.0 PRINCIPLES OF REGULATION.....	3
2.1 Efficiency Considerations.....	3
2.2 Equity Considerations.....	5
3.0 STATE AND FEDERAL REGULATORY FRAMEWORKS.....	10
3.1 The Federal "Coordinated Framework".....	10
3.2 California State Regulations.....	11
3.2.1 Biotechnology and the California Legislature.....	11
3.2.2 Biotechnology and the California Executive Agencies.....	14
3.2.3 The Interagency Task Force on Biotechnology.....	15
3.3 Key Elements of State and Federal Regulatory Systems.....	16
4.0 HISTORY OF LOCAL GOVERNMENT INVOLVEMENT.....	22
4.1 Advanced Genetic Sciences in Monterey County.....	23
4.2 Advanced Genetic Sciences in Brentwood.....	27
4.3 University of California in Tule Lake.....	31
4.4 Siting New Research Buildings: UCSF and Stanford.....	32
4.5 Cambridge, MA and Berkeley Ordinances Regulating Research.....	33
4.6 Lessons Learned From Local Government Experiences.....	33
5.0 OPTIONS FOR LOCAL GOVERNMENTS.....	38
5.1 Selection of Criteria.....	38
5.2 Alternatives.....	41
5.3 Assessment of Alternatives.....	46
6.0 CONCLUSIONS.....	51
LIST OF INTERVIEWS.....	56
BIBLIOGRAPHY.....	57
APPENDIX A: A Discussion of Compensation.....	60
APPENDIX B: Alternatives Assessment Matrix.....	67

1.0 INTRODUCTION

Are products developed through genetic engineering techniques really very different from any other products? This question has been debated by scientists, public officials, citizens and industry representatives since the explosion of molecular and genetic science techniques in the mid-seventies. On the one hand, biotechnology products are merely an extension of selective genetic products, such as hybrids of grains, that have been used for decades (Davis 1987). On the other hand, the specific genetic mutations being proposed are different than those which would occur through natural mutation and selective breeding, and potentially can be transferred to other organisms (Sharples 1987, Alexander 1985, McGarity 1985). Both arguments have merit and are supported by highly credible scientists. The debate is unlikely to be resolved in the near future.

Whether or not biotechnology is indeed "new" has important implications for how research and use of products are regulated. If biotechnology is not new, then existing regulatory mechanisms should be reasonably adequate at minimizing risks, forcing internalization of externalities, and providing the desired level of protection of public health and safety and the environment. If biotechnology is new, then it is possible that it creates new risks

which are not detected and analyzed in the current regulatory network. In addition, whether or not these risks are "real" may be irrelevant: if the public is anxious about the dread and unknown nature of biotechnology risks, then this fact alone could justify proceeding with extreme caution.

As federal agencies and California state agencies position themselves to regulate the new range of biotechnology research and products, local governments have been closest to public concerns about biotechnology. County and city governments in California have several options for responding to and/or preparing for increases in biotechnology research and product development applications. This paper explores alternative strategies available to local governments. Strategies are developed in light of existing Federal and State regulatory systems, and lessons learned from local involvement in biotechnology decisions to date.

2.0 PRINCIPLES OF REGULATION

Before examining existing regulations, it is helpful to review theoretical reasons for regulation of biotechnology activities. Reasons related to both economic efficiency and equity are discussed.

2.1 EFFICIENCY CONSIDERATIONS

Ideally, a cost benefit framework can be applied to biotechnology regulation: benefits of the proposed product should outweigh costs. Government regulation is required where health and safety and environmental costs are external to the cost functions of biotechnology firms. In the most simple terms, the regulatory process is intended to deny permits for proposals which have social costs in excess of social benefits.

In the case of biotechnology, the simplicity of this idea quickly becomes obscured by the difficulties of calculating both costs and benefits. Many of the environmental and health consequences of biotechnology are difficult to imagine, much less price. In most of the case-by-case reviews, regulators are able to rule out high probability, moderate cost outcomes. The review questions focus on the low probability of very costly outcomes. For this reason, state and federal regulations focus on the process of risk assessment: estimating the low probability of a very costly event. Accordingly, regulatory actions consist of requiring firms to further minimize risks through tests for pathogenicity, containment

and disposal requirements, etc., rather than determining whether the minimized risks are acceptable.

Whether or not small risks are acceptable is an efficiency consideration which frequently becomes lost in the regulatory process. This consideration is based on the premise that risk itself is costly. In other words, most people would rather choose a sure payoff than a gamble with the same expected gain. The difference between the utility of the sure payoff and the utility of the expected gain is the cost of risk, or the risk premium. Thus, the efficiency criterion for a risk benefit analysis is slightly different than for a cost benefit analysis: benefits must outweigh costs as calculated through expected values plus costs of the risk itself.

A recent Office of Technology Assessment report, "Public Perceptions of Biotechnology," points out that events with completely uncertain outcomes are even more "costly" than events with known probabilities and outcomes:

Perhaps what is more important than the acceptable level of a known risk is the way the public reacts to unknown risk. If the risk is truly unknown, nearly two-thirds (65 percent) of the public say they do not approve of the environmental application (of genetically engineered organisms). In fact, more people approve at a high level of known risk, such as 1 in 100 (40 percent) than at an unknown risk level (31 percent). (Office of Technology Assessment 1987, p. 64)

Two additional efficiency concerns may be important to regulation of biotechnology. First, permit applicants should not be required to submit scientific information which has no probability of changing the regulatory (licensing) outcome. In other words, a State or Federal agency should not require the applicant to conduct and submit tests which are totally unconnected to the decision. (This "value of information" idea does **not** mean that negative findings, eg. on toxicity and dispersion rates, are not an important part of a permit application.)

Second, the regulatory outcome (in most cases, permit issuance or denial) should be reasonably predictable from the vantage point of the applicant. Some level of predictability is necessary to enable firms to make rational research and development decisions. This issue is especially important in biotechnology since research and development time frames are presently very long. Principles of biotechnology regulation based on efficiency considerations are listed in Table 1.

2.2 EQUITY CONSIDERATIONS

A regulatory outcome can be deemed inequitable if some people bear more risks and/or receive less benefits of the regulated activity than other people. In the area of biotechnology, it is unclear whether scientifically calculated risks of activities which use bioengineered organisms are greater for local citizens or not. Although this burden could be calculated on a case-by-case basis,

the history of local involvement to date shows that local citizens usually bear more costs in terms of anxiety and fear.

Whether or not public fear and anxiety represent some rational but incalculable measure of risk is a matter of considerable debate. As scientific risk assessment has become a routine method of analysis in several policy areas (e.g. nuclear power, toxic chemicals) it has become evident that many scientific risk assessments are considerably less conservative than many public perceptions of risk. The question is whether the public operates on "bounded rationality", the inability to understand the true magnitude of small risks, or whether it perceives some valid measure of risk which scientists do not.

Paul Slovic (1986), a leading researcher in risk perception, has shown that the public responds to both "dread" risks and "unknown" risks. He ranks biotechnology extremely high on both of these scales. The "unknown" factor could be considered a measure of risk aversion. Baruch Fischhoff et al (1984) find that, in addition to scientific criteria, risk depends on the decision maker's values about the relative importance of different outcomes. He suggests a framework for systematically addressing these value components of risk.

To what degree it is appropriate or possible to "educate" the public regarding risk assessment is debatable. The term education is misleading in this context because even an educated public's

risk estimates are likely to be quite different than those of scientists. It is increasingly popular, however, to provide some context when discussing risks. For example, the risk communicator can present scientifically calculated risks of many more familiar activities (eg. flying, driving, eating peanut butter) in addition to the risk of the proposed project. This method is limited for two reasons: 1) the daily risk categories presented are usually for voluntary risks whereas the proposed project is involuntary; and 2) risks due to biotechnology are extremely conjectural and uncertain compared to other types of risks. For these and other reasons, the local public may not be sympathetic to risk communication and education efforts.

Research on risk perception and risk communication has implications for assessing risks of biotechnology. If risk analysis contains value laden components, and if the local public's perception of risk depends on legitimate factors which science can not assess, then local opinion should be given weight in the decision making process if the decision is to be equitable. Local opinion should be measured after the public has received information on risks (theoretical outcomes, probabilities of each outcome and ranges of uncertainty). This equity principle is included in Table 1.

Direct compensation for risk is a different means of achieving equity. In order for an activity to be socially beneficial, theoretically "winners" (society, initially by way of a private firm's profits) can compensate "losers" (local citizens). While

attractive conceptually, implementation of a compensatory scheme (other than through the courts) is fraught with difficulties and is not politically palatable. Arguments in favor and opposed to using compensation are presented in Appendix A. A compensation principle is included in Table 1.

Another explanation of frequent local opposition to biotechnology projects rests not on the idea that local citizens bear more of the risk, but rather on the premise that people self-sort according to how risk averse they are. Some communities (perhaps more affluent ones) are less willing to tolerate any probability, no matter how low, of a costly outcome. If this is the case, it is inefficient to force these risk averse communities to accept a risk. On the other hand, if level of risk averseness depends to a large degree on income level, it may be undesirable to sanction risky activities only in less affluent communities.

Table 1.

Regulatory Principles for Biotechnology Activities

Efficiency Considerations:

1. The regulatory process should detect and prohibit biotechnology products/processes which have costs greater than their benefits. The process also should not unduly discourage products/processes which have benefits greater than costs.
2. Societal risk aversion (if there is any) should be included in the cost benefit analysis, either formally or informally.
3. The regulatory process should not require applicants to submit tests and information unless they have some chance of changing the regulatory outcome.
4. The regulatory outcome (permit acceptance or denial) should be reasonably predictable from the vantage point of the applicant, such that rational research and development investment decisions can be made.

Equity Considerations:

5. If, following some reasonable period of education, local citizens perceive that health and safety and/or environmental risks outweigh the benefits of a proposed activity, this perception should be an important criterion in the government's decision to issue a permit, or the local public should be compensated for bearing the risk.

3.0 STATE AND FEDERAL REGULATORY FRAMEWORKS

The State and Federal regulatory environments set the stage for local governments to assess needs and options for local regulation. The term "biotechnology" encompasses a wide range of research activities and potential products. The Association of Bay Area Governments (ABAG) Bioscience Task Force has specified the following categories of activities: therapeutic products, vaccines, genetic probes, monoclonal antibodies, drug delivery systems, industrial and agricultural application systems and molecular research centers (ABAG 1987). Each potential product has at least some coverage under existing Federal and State regulations.

3.1 THE FEDERAL "COORDINATED FRAMEWORK"

Although Congress has considered new, centralized regulation of biotechnology, no new statutes specific to biotechnology have been passed. The Reagan Administration, consistent with its general opposition to new regulation, has determined that all biotechnology activities can be regulated through existing statutes. In order to clarify agency jurisdictions and eliminate redundancy, the President established the Biotechnology Science Coordinating Committee within the Office of Science and Technology Policy in October of 1985.

In June of 1986, the "Coordinated Framework for Regulation of Biotechnology" was published in the Federal Register. The

regulatory framework clarifies which products and processes fall under the jurisdiction of which agencies and statutes. The coordinated policy addresses regulatory policies of the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the Occupational Safety and Health Administration (OSHA), and the United States Department of Agriculture (USDA). In addition, it addresses the research policies of the National Institute of Health (NIH), EPA, OSHA, and USDA. Table 2 lists the agencies and relevant authorizing statutes.

3.2 CALIFORNIA STATE REGULATIONS

Biotechnology regulation on the State level has paralleled that of the federal government. The State relies on an interagency task force to coordinate existing agencies' regulatory actions. Although the Legislature has a history of considering new legislation, no new legislation specific to regulation of biotechnology has been passed.

3.2.1 Biotechnology and the California Legislature

In the early to mid 1980's, State leaders began to compare the promise of biotechnology industries to the computer microchip industry. Members of the Legislature and government officials expressed and continue to express a strong sentiment that California should capitalize on its good fortune of attracting biotechnology industries by providing incentives for these industries to stay and grow. Members of the California Legislature

Table 2.**Select Federal Agencies and Relevant Statutory Authority**

Food and Drug Administration (FDA)		
Food, Drug and Cosmetic Act	21 USC	301-392
Public Health Service Act	42 USC	262
Environmental Protection Agency (EPA)		
Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)	7 USC	136-136y
Toxic Substances Control Act (TSCA)	5 USC	2601-2929
Clean Water Act	33 USC	1251-1376
Safe Drinking Water Act	42 USC	300f
Marine Protection, Research and Sanctuaries Act	33 USC	1401-1445
Clean Air Act	42 USC	7401-7642
Resource Conservation and Recovery Act (RCRA)	42 USC	6901-6987
Comprehensive Environmental Response, Compensation and Liability Act (Superfund)	42 USC	9601-9657
United States Department of Agriculture (USDA)		
Federal Plant Pest Act	7 USC	150 aa-jj
Plant Quarantine Act	7 USC	151-164a, 166-167
Federal Noxious Weed Act	7 USC	2801-2813
Organic Act	7 USC	147a, 148a-e
Plant Variety Protection Act	7 USC	2321
Federal Seed Act	7 USC	1551-1611
Virus-Serum-Toxin Act	21 USC	151-158
Federal Meat Inspection Act	21 USC	601
Poultry and Poultry Products Inspection Act	21 USC	451
Assistant Secretary for Science and Education Research Guidelines	51FR	23336-233347
Occupational Safety and Health Administration (OSHA)		
Occupational Safety and Health Act	29 USC	651

were cognizant of the new environmental and safety issues which biotechnology raised. They started introducing bills which would either promote or regulate biotechnology in 1982. A brief summary of the legislative history follows. This history is summarized from the Assembly Office of Research's ACR 170 Report entitled, "Biotechnology: A Regulatory Overview" (April 1985, pp. 46-50).

In 1982, Assemblyman Torres introduced AB3549. This bill would have required all research conducted by the State or receiving State funds to comply with National Institute of Health guidelines. The bill was passed by the Legislature but vetoed by the Governor.

In 1983, the Joint Legislative Advisory Committee on Biotechnology was formed. This committee was supposed to contain representatives from both government and industry. Eight legislative members were appointed; but the committee never met.

In 1984, Assemblyman Terry Goggin introduced a bill which would have created a biotechnology Task Force within the Environmental Affairs Agency. The bill also would have required all State agencies to comply with the California Environmental Quality Act for any project involving DNA technology. The bill was dropped by its sponsor in August 1984.

Also in August 1984, Assemblyman Sam Farr, Chair of the Committee on Economic Development and New Technologies, introduced ACR 170. This resolution passed in less than a month. ACR 170 required the

Assembly Office of Research to "review all existing, pending, and elapsed state and federal regulations affecting California biotechnology such that the State can make informed decisions about how to promote biotechnology while protecting health and safety and the environment."

In February 1985, Sam Farr created a standing Subcommittee on Biotechnology within the Committee on Economic Development and New Technologies. In April 1985, The Assembly Office of Research submitted the completed ACR 170 study to the Assembly. One of the study's numerous recommendations was that the Governor establish an interagency task force on biotechnology. The report further stated that if the Governor does not create the task force, then the Legislature should consider omnibus legislation.

3.2.2 Biotechnology and the California Executive Agencies

Simultaneous to the Legislature's actions, several of the executive agencies were taking notice of the new economic promise and the potential regulatory burden of biotechnology. In 1983, the Chamber of Commerce issued a report entitled, "Job Creation for the Eighties." Biotechnology industries were identified as some of the most likely "growth" industries (interview, Ervin). In September of 1984, the Chamber of Commerce held a workshop in Los Angeles to discuss the future of biotechnology. The workshop was attended by representatives of industry, academia, and financial institutions (California Assembly Office of Research 1985).

In 1985, the first biotechnology permit applications were submitted to both the California Department of Health Services (DHS) and the California Department of Food and Agriculture (CDFA). These agencies reportedly found themselves "in the thick of it" without much prior warning. Because of public pressures and internal debate, both agencies welcomed the creation of the Interagency Task Force.

3.2.3. The Interagency Task Force on Biotechnology

In November 1985, Governor Deukmejian signed Executive Order D-46-85 which created the Interagency Task Force on Biotechnology. This executive order established the California Department of Commerce as the lead agency and the California Department of Food and Agriculture (CDFA), California Department of Health Services (DHS), the California Department of Fish and Game, the Environmental Affairs Agency, and the Water Resources Control Board as member agencies. (Cal-OSHA also was named as a member agency but has since been disbanded.)

The Task Force objectives listed in the Executive Order D-46-85 are consistent with the overriding State goal as articulated in ACR 170: "...to promote the biotechnology industry while at the same time protecting public health and safety and the environment."

The specific objectives listed in the executive order are:

1. The Task Force shall serve as a resource and repository for expertise and information on biotechnology that could be utilized by appropriate state agencies.

2. In addition, the Task Force is charged with the following nonexclusive responsibilities:
 - a. To evaluate and determine the adequacy of federal and state regulations affecting the biotechnology industry.
 - b. To coordinate and assist in the formulation of state policies affecting the biotechnology industry.
 - c. To serve as the principle liaison between the State of California and federal agencies, including the President's Cabinet Council on Biotechnology, on matters affecting the biotechnology industry.
 - d. To develop educational programs on biotechnology for the benefit of the general public, to the extent that the Task Force determines that such programs are necessary.
 - e. To provide information to new California biotechnology firms on compliance with California statutory and regulatory requirements.

The Task Force has met regularly to clarify regulatory jurisdictions. With the assistance of member agencies, the Department of Commerce prepared Biotechnology: California Permits and Regulations. This publication contains detailed information on federal, state, and local permitting authority for numerous categories of bioscience products.

3.3 KEY ELEMENTS OF STATE AND FEDERAL REGULATORY SYSTEMS

The following elements of the Federal and State regulatory frameworks are relevant to the development of local strategies. Most of these points are widely agreed upon; some may be controversial.

1. Existing laws provide State and Federal agencies with sufficient authority to regulate a wide range of biotechnology products and processes. Every product is regulated by at least one

existing set of regulations. If nothing else, all new bioengineered microbes will be handled under EPA's Toxic Substances Control Act (TOSCA) as a "new chemical" (interview, Andrews). Interpretation of existing statutes to cover biotechnology has not yet been confirmed through the courts. Therefore, while this system has worked in practice, its long-term viability is still in question. This and other concerns about the Coordinated Framework were presented by Rebecca Goldberg of the Environmental Defense Fund to a Congressional Subcommittee (1987).

2. Some definitional discrepancies and areas of ambiguity remain.

For example, it is unclear whether all products intended for environmental release should be reviewed under a FIFRA (pesticide) procedure rather than the TOSCA (new chemicals) procedure. The courts have concluded that both laws require an implicit weighing of risks and benefits (McGarity 1985). TOSCA places the burden of proof on EPA, however, whereas FIFRA places the burden of proof on the applicant.

3. All state and federal agencies conduct permit application reviews on a case-by-case basis; no written standard operating procedures are used. This flexibility is desirable because of the new and varied scientific questions which must be asked depending on the particular product. On the other hand, this case-by-case review creates an uncertain environment for industry and a decision making process which is difficult for local officials and the public to trace.

4. EPA and the California Interagency Task Force's plans to develop standard operating procedures will greatly benefit permit applicants, local government officials and the public.

For example, EPA has issued a strategy for developing risk assessment guidelines for bioengineered microbes intended for environmental release (Levin 1987). In addition, standard operating procedures could help to clarify implementation details such as whether a site should be visited before a permit is issued. Reportedly, EPA did not visit Advanced Genetic Sciences' proposed Monterey site until after the experimental field test permit was issued (interviews: Lindemann, Suslow, Church).

5. State regulatory agencies do not always rely on federal agency reviews. Several state officials said that they do not trust the federal regulatory review process and, thus, feel it necessary to repeat the scientific review and data evaluation. These same officials, when questioned about the role of local government, however, stated that local government should trust state reviews and decisions.

6. Because biotechnology necessarily has some risk to public health and the environment (although these risks may be very small), the State's goals of promoting biotechnology activities and protecting public health and safety may conflict. The more the industry is promoted, the greater the environmental and safety risks. Implementation of this dual goal requires balancing of

risks and benefits. There are at least three ways which this balancing of risks and benefits could be conducted:

- a. Through a strict cost-benefit or risk-benefit approach.
- b. Through minimizing the risks of the industry which the State wants to promote. Only the most blatantly dangerous industries would be denied permits. Most firms would need only to prove that all reasonable protective measures had been taken.
- c. Through promotion of the industry, which the State assumes to be safe. Existing regulatory channels would be used in order to convince the public that the industry is safe.

The executive order language neither acknowledges this conflict, nor does it provide any assistance in determining how these trade-offs should be made.

7. Although State agencies have designated existing personnel as biotechnology contacts within their agencies, they have not been given new funds to hire people with specific bioscience and risk communication expertise. Both CDFA and DHS officials have submitted budget change proposals to hire these people; both have had these proposals rejected (interviews: Duffey, Jones).

8. State officials seem to believe that local officials should be informed, but that special ordinances and permit procedures would be redundant. State officials admit that lines of communication between themselves and local governments could and should be improved.

9. The California Interagency Task Force on Biotechnology has limited the scope of its activities to helping member agencies and industry; it has not assessed the needs of local governments and the public. The Interagency Task Force has not identified local governments as a target for their public education activities. At the time the Executive Order creating the Task Force was written, no centralized environmental or health interest groups spoke out on the issue. Local government associations such as the League of California Cities and the County Supervisors Association of California have not been active in this area.

10. The Interagency Task Force's review of regulations is confounded by the assumption that it is possible to determine the adequacy of regulations without knowing the specific products to which they will apply. Most regulations are developed for a particular set of products or activities. This specificity does not apply to regulation of biotechnology since the range of products and applications is large, diverse, and, to some extent, unimaginable. Because there are no clear criteria for determining adequacy of regulations, the temptation is to evaluate the volume of regulations. This approach necessarily will lead to the conclusion that present regulations are sufficient because they are voluminous.

11. Some State officials assume that public education will lead to public consent. Although not explicitly stated, some officials view public education as a way to reduce public fears and

opposition to biotechnology which might affect firms' decisions to locate in California. Public education is expected to make the public's perceptions of biotechnology risks conform to the experts' scientific assessment of biotechnology risks. When examined in the light of risk perception literature, this assumption is especially troublesome. Public perceptions of risk are unlikely to conform to scientific assessment of risk even after significant periods of education.

12. The network of State and Federal regulatory agencies will necessarily be perceived as confusing and unpredictable by local government officials and the public. This perception problem is counterbalanced by the advantages of the State and federal coordinated regulatory frameworks including: low adjustment costs of using existing systems, ability to respond to many constituencies, and reduced redundancy.

4.0 HISTORY OF LOCAL GOVERNMENT INVOLVEMENT

Ideally, local governments' strategies would allow them to respond quickly and efficiently to all types of biotechnology proposals - whether they be for pesticide experiments or manufacturing of hazardous waste consuming microbes. Unfortunately, it is difficult to know exactly what types of applications are likely to be submitted in the future. To date, local governments have been involved in three types of regulatory activity related to biotechnology: 1) regulating operations of existing research facilities, 2) granting permits for new research facilities, and 3) reviewing experimental field test permits for agricultural products. At a minimum, local strategies should address these three areas.

This chapter reviews specific cases where local governments have become involved in permitting decisions. Advanced Genetic Sciences' attempts to test "Frostban," first in Monterey County and then in the City of Brentwood, are described in detail. Case histories of the University of California's Tule Lake experiments, and other localities' attempts to regulate new and existing research facilities are also discussed. Finally some "lessons learned" from these case histories are offered.

4.1 ADVANCED GENETIC SCIENCES (AGS) IN MONTEREY COUNTY

California has been home to the first two approved outdoor field tests of bioengineered products in the country. Both of these tests involved modified ice nucleating bacteria. Advanced Genetic Sciences' product "Frostban" was originally proposed to be tested in Monterey County. Because the formal permit application process involved only EPA, CDFA, and CDHS, the firm did not notify or educate county supervisors. Once the test proposal became public, residents expressed significant opposition. AGS eventually pulled out of Monterey County and proposed new test sites in Brentwood (Contra Costa County) and in San Benito County. The site in Brentwood was selected. Despite the reservations of some local residents, local officials endorsed the tests and the experiments proceeded as planned. A more detailed chronology of events follows. (This chronology is based on interviews with Lindemann, Suslow, Caffrey, Church, Duffey, Jones, and others.)

In early 1984, AGS decided to seek approval for field testing their product "Frostban." At this time, neither EPA nor the Office of Science and Technology Policy had issued guidelines for field testing. AGS sent an application to the National Institute of Health's Recombinant DNA Advisory Committee (RAC) to determine whether or not the field test, as designed, would comply with the NIH guidelines. The submittal of this application was voluntary since NIH guidelines are not enforceable for private research firms. The NIH guidelines were not designed to address purposeful release of recombinant organisms to the environment, but rather to

regulate use of these organisms in laboratories. The RAC recommended approval of AGS's application in June of 1984. Official agency approval, which must be signed by the Director, was never granted.

In October of 1984, EPA issued an interim policy on small scale field tests. AGS sent a notice of intent to EPA in accordance with this interim policy. AGS provided EPA with additional data on Frostban throughout November and December. During this period, EPA convened a Scientific Advisory Panel which consisted of experts outside the agency. In January 1985, EPA notified AGS that an experimental use permit would be required under FIFRA. AGS contested this ruling on the grounds that Frostban was not a pesticide. In August of 1985, EPA published notification of AGS's application in the Federal Register and asked for public comment.

Simultaneous to their application to EPA, AGS applied to CDFA for a Pesticide Research Authorization required under State law. The CDFA notified the County Agricultural Commissioner. The Monterey County Agricultural Commissioner visited the test site in November 1985. EPA issued the Experimental Use Permit for the test in Monterey on November 14, 1985. At the time the permit was issued, no EPA official had visited the test site. CDFA issued its permit in December.

At no time during the application process was the exact site in Monterey County disclosed to the Board of Supervisors or to the

public. Although the County Agricultural Commissioner had visited the site, he was bound by CDFA's rules of confidentiality. AGS officials explain that they wanted to keep the site secret as long as possible in order to avoid vandalism.

In December of 1985, there were several articles in a local newspaper which called attention to the tests. By January 3, 1986, a letter of opposition to the tests signed by several prominent community members was sent to the Monterey County Board of Supervisors. At least one County Supervisor and the County Health Commissioner took an active role in responding to public concerns. Approximately two weeks after the letter was sent, County staff approached Jeremy Rifkin (of the Washington, D.C. Foundation on Economic Trends), regarding the legitimacy of public concerns. Rifkin reportedly sent the Monterey County Health Commissioner, Walter Wong, a large amount of information.

The first public meeting on the tests was held by the County on January 27, 1986 (AGS). According to Glen Church, an active local citizen, this meeting was attended by approximately 175 people and lasted from 9:00 am to 6:00 pm. It also was attended by several national media representatives. Comments from local citizens were uniformly in opposition to the tests. At the meeting AGS voluntarily agreed not to proceed with the tests for 30 days. This meeting was followed by one two weeks later at which the Board of Supervisors voted to place a 45 day moratorium on AGS' field tests.

Also in January 1986, EPA sent a team of scientists to the test site for the first time in order to develop a monitoring strategy. The team observed that the site was closer to adjacent residences than they had thought. They informed AGS that the firm would have to receive permission from land owners to monitor adjacent lands. According to AGS officials, this requirement eventually convinced AGS to look for a new site within Monterey County.

Throughout January and February, the original Monterey County test site was not disclosed by AGS despite numerous requests to make the site public. In March, the site finally became public due to an adjoining land owner observing experimental equipment on the land. Even at this time, AGS did not confirm that this was the correct site.

Also in March, the EPA discovered that AGS had conducted illegal roof top experiments at its Oakland research facility. Due to this violation, EPA suspended AGS' field test permit for the Monterey site on March 24. CDFA suspended their research authorization on March 25.

A third public meeting was held by the Monterey County Board of Supervisors in March. At this time, the Board voted to extend the moratorium on field testing for nine more months. In August of 1986, AGS officially announced that they would not test Frostban in Monterey County.

Following EPA's notification that adjacent land owner's permission should be attained (January 1986) and before the August pull out date, AGS tried to find a new field test location within Monterey County. Because the moratorium at that time specified no testing within four miles of a residence, the availability of sites was very restricted.

In March of 1987, the Monterey County Board of Supervisors approved the ordinance which is currently in effect. This ordinance prohibits field tests within one mile of a residence. It also gives the County the authority to require an Environmental Impact Report (EIR). Although County officials insist that the ordinance responds to a legitimate local land use issue, CDFA officials believe that it conflicts with their authority to regulate experimental tests of pesticides under the California Food and Agriculture Code section 11501.1A. To date, no suit has been filed to resolve this question.

4.2 ADVANCED GENETIC SCIENCES IN BRENTWOOD

In the Fall of 1986, EPA and CDFA informed AGS that their field test permits could be reinstated once they selected a site. AGS preliminarily selected one site in Contra Costa County (the Brentwood site) and two sites in San Benito County. On December 17, AGS mailed letters to EPA, CDFA, the Boards of Supervisors and the Agricultural Commissioners informing them of the proposed sites. On February 11, 1987 EPA reinstated AGS' experimental

field test permit. CDFA reissued the State permit on April 24, following a 45 day public comment period.

Throughout the months of January and February, AGS sponsored meetings and workshops with citizens and officials of both counties and the City of Brentwood. A chronology of these meetings is provided in Table 3. AGS' approach included a meeting with the agricultural community "to convince them it was in their best interests to support agricultural research" (interview, DeFremery). According to Nancy Andrews of EPA, both Hollister (San Benito County) and Brentwood (Contra Costa County) were enthusiastic about AGS conducting experiments at their sites. AGS eventually attained official endorsements for the proposed tests from all three jurisdictions: the San Benito County Supervisors endorsed the tests February 17, the Brentwood City Council endorsed the tests on March 10, and the Contra Costa County Board of Supervisors gave their endorsement on March 17. The test site in Brentwood was selected in March for technical reasons.

Also in January 1987, the Berkeley Greens, a public interest/ environmental group based in Berkeley, decided to focus their efforts on opposing the upcoming AGS tests. Several representatives of this group attended the initial presentation by AGS to the Brentwood residents on January 10. The Mayor of Brentwood allowed the group to ask questions of AGS, but not to present any information. According to Andrew Caffrey of the Berkeley Greens, the AGS representative was arrogant and did not

Table 3.**PUBLIC NOTIFICATION AND PUBLIC EDUCATION EFFORTS (FROSTBAN)**

December 17, 1986	Notification of Boards of Supervisors and Agricultural Commissioners (written)
January 8, 1987	Meeting with San Benito Co. Frostban Committee
January 9, 1987	Visit to Brentwood neighbors with spanish translator
January 10, 1987	Informational meeting for Brentwood residents near test site
January 22, 1987	Presentation to San Benito Co. Farm Bureau
January 26, 1987	San Benito citizens tour AGS and ask questions
January 27, 1987	Frostban presentation to open meeting of Brentwood City Council
January 29, 1987	Public Workshop on Frostban in San Benito Co.
January 30, 1987	Presentation to Contra Costa Co. Farm Bureau
February 2, 1987	Public hearing at San Benito Co. Board of Supervisors meeting
February 9 - 13	T. Suslow in Hollister all week to answer telephone inquires and distribute information. Daily informational ads in local newspaper.
February 11, 1987	Frostban presentation to Contra Costa Co. Agricultural Resources Advisory Board
February 11, 1987	Presentation to San Benito Chamber of Commerce
February 12, 1987	Frostban presentation to San Benito Lion's Club.
February 16, 1987	Informational open house in San Benito Co. (posters, slide presentation, video)
February 17, 1987	Public meeting of San Benito Co. Board of Supervisors
March 3, 1987	Community Forum, Frostban presentation in Contra Costa Co.

Public education forums utilized a video tape presentation, an oral presentation with slides, and a question and answer period. A six page explanatory fact sheet and copies of representative newspaper articles, both pro and con, were made available.

(This chronology provided courtesy of Julianne Lindemann, Advanced Genetic Sciences.)

respond to his questions. After this meeting, Mr. Caffrey pledged to a reporter that his group would "resist the tests."

The Berkeley Greens attended the Brentwood public hearing on January 27. Before the meeting they were told that they would be allowed to make a presentation of their concerns. The rules were changed, however, and they were not allowed to make a presentation.

Following this second meeting, the Berkeley Greens decided to pursue a legal challenge to the tests on the grounds that an Environmental Impact Report (EIR) was necessary and none had been prepared. Jeremy Rifkin's attorney apparently assisted with this suit. The judge ruled that an EIR was not necessary.

In late March and April, the Berkeley Greens circulated a petition within the City of Brentwood calling for a one year moratorium on the AGS field tests. Within four to five days they obtained 1500 signatures from Brentwood residents. The group presented the signatures to AGS and the Contra Costa Board of Supervisors on April 15. Neither party responded to the petition. On April 24, the scheduled day of the tests, unknown persons broke into the test site and pulled up many of the strawberry plants. AGS proceeded with the tests as planned despite the vandalism.

In early Fall of 1987, AGS announced their plans to conduct a second round of tests at the Brentwood site. The Berkeley Greens (who at this point had changed their campaign name to "Genetic

Alert") circulated 2000 copies of a flyer encouraging Brentwood residents to respond to the tests during CDFA's public comment period. Only five Brentwood residents wrote letters to CDFA in response to the flyer. According to Andrew Caffrey of the Berkeley Greens, CDFA viewed the public comment period as a way to elicit additional scientific information, rather than public opinion.

On November 30, 1987 the strawberry plants at the test site were sprinkled with salt and ammonium. Earth First members claimed responsibility for this action. Both Earth First and Genetic Alert issued separate pledges to resist field tests of bioengineered organisms. AGS proceeded with the second round of tests in early December 1987.

4.3 UNIVERSITY OF CALIFORNIA IN TULE LAKE

A second case of local government response to filed test proposals involves the "ice-minus" bacterium developed by a U.C. Berkeley scientist, Steven Lindow. The experiments, which entailed treating potato plants with the bacterium, were proposed for Tule Lake in Siskiyou County in northern California. Lindow held at least one poorly attended public meeting to discuss the tests in 1985 (before AGS' experiences with Frostban in Monterey County.) By May of 1986, however, about one half of the Tule Lake community had signed a petition opposing the tests. One hundred and fifty people attended a hearing on the tests. The main concern at that time was that the untreated potato crops would be perceived as tainted due to the tests, and would not be marketable. A few people were

concerned about safety and asked the University to conduct an EIR (interview, Church).

A group called Californians for Responsible Toxics Management filed a lawsuit against the University on the grounds that an EIR was necessary. The University agreed to conduct an EIR even though they were convinced there were no technical reasons to do so. The preliminary EIR review yielded all negative findings on the check list of possible impacts (interview, Jones). The tests took place in May of 1987.

4.4 SITING NEW RESEARCH BUILDINGS: UCSF AND STANFORD

Two proposed research buildings have caused considerable controversy during the past year. These are the University of California, San Francisco (UCSF) Laurel Heights campus and Stanford's proposed biological research facility. The UCSF dispute is being settled through the courts. A neighborhood group, the Laurel Heights Neighborhood Improvement Association, sued UCSF over the EIR.

Santa Clara County is now conducting an EIR for the Stanford building. Santa Clara County originally issued a negative declaration (signifying that no EIR would be required) for the building, believing that technical, environmental, and public concerns would be similar to those for other Stanford buildings. The level of public concern caused them to retract the negative declaration, however, and to conduct a full EIR. Juanell Waldo,

Planner for Santa Clara County, does not think that the EIR will provide new technical information but concedes that the EIR is valuable as an educational process. Consultant costs and work delays caused by the EIR are estimated at \$750,000 (interview, Waldo).

4.5 CAMBRIDGE, MA AND BERKELEY ORDINANCES REGULATING RESEARCH

Several cities have passed local ordinances requiring that all research facilities conform with research guidelines issued by the National Institute of Health (Berkeley, Cambridge 1981). All research operations receiving funds from NIH must comply with these guidelines. Most private (non-NIH) funded firms say that they voluntarily comply with these guidelines. The Berkeley ordinance passed with little public debate, although its legality is questionable. It has never been enforced.

4.6 LESSONS LEARNED FROM LOCAL GOVERNMENT EXPERIENCES

The following conclusions are drawn from the above case studies:

- 1. The public expects local governments to be responsive to their concerns regarding biotechnology.** The Monterey County, Cambridge, Berkeley, and Stanford cases illustrate that local citizens look to local governments to intervene on their behalf in cases where they disagree with or mistrust State and Federal regulators. While the Foundation on Economic Trends has been an important actor on the national level, it does not act as a voice for more localized public fears. Similarly, citizens groups do not seem to lobby the

state agencies for changes in their procedures. This situation may change as groups such as Genetic Alert develop long term strategies.

2. The actions of local governments affect both costs incurred by the applicant/research firm and, in some cases, the ultimate decision to engage in an activity. Santa Clara County's decision to require an EIR added expense, in terms of both time and money, to Stanford's construction plans. Monterey County's decision to pass a local ordinance which gave them the power to require an EIR and prohibited testing within a four mile radius of residences was influential to AGS's decision to relocate their test site. Conversely, the Mayor of Brentwood's unwaivering support for AGS reportedly assisted in ultimate selection of Brentwood. Her reluctance to allow opposition groups time to air their opinions, however, may have contributed to the decision to vandalize the site.

3. Local governments are either unable or have not invested a lot of resources (or both) in predicting how they will be involved in review of upcoming permit applications. This lack of foresight was pronounced in the Monterey County case and the Stanford research building case. Other large counties, such as Orange County, which have experienced controversy over biotechnology firms, have no organized indepartmental review mechanism for handling biotechnology applications. Even if local governments plan to play a minimal role in granting permits, they will need to

respond to public concerns. Local governments have not developed these strategies. Where local governments have made concerted efforts to discuss biotechnology, these discussions focus on how to attract the industry to their particular area. One notable exception to this rule is Santa Cruz County which will most likely be home to experimental field tests at some future date. County officials have considered passing an ordinance similar to Monterey County's, but recently have decided to pursue an ordinance similar to the Berkeley and Cambridge ordinances instead (interview, Craft).

4. Local governments do not have biotechnology experts on their staffs who understand either the technical and scientific aspects of permit applications or the larger system of federal and state regulations governing biotechnology. County Health Officers and County Agricultural Commissioners and their staffs can, to some extent, build on their related existing expertise when a biotechnology related application comes before them. For example, County Agricultural Commissioners may be familiar with experimental field test applications for chemical pesticides, if not biological pesticides. Planning staffs have no anticipated expertise in related fields.

5. Local officials and staff who need to respond to public concerns regarding proposed biotechnology projects do not necessarily have access to state and federal regulators who could supply them with useful information. In certain situations, lines

of communication are quite good. For example, when an experimental pesticide permit comes before the State Pesticide Regulatory Evaluation Committee, the CDFA automatically notifies the County Agricultural Commissioner (interview, Jones). Planning staff, on the other hand, may be particularly removed from people with technical information. The state Department of Health seems to have poor lines of communication with County Health Officers as evidenced by the Monterey County case (interview, Duffey).

6. The level of both local and statewide public concern for experimental field tests involving genetically engineered organisms is high. Of the three public meetings held in Monterey County, not one resident commented in favor of the tests. All the meetings were well attended. In Brentwood, 1500 residents signed a petition asking for a one year moratorium on testing. In Tule Lake, 150 people attended a public hearing on the tests.

7. The level of public concern for new research facilities is unpredictable. Certainly, the UCSF Laurel Heights and Stanford cases show that large, new facilities will be controversial. Many smaller firms have been able to locate with any public outcry, however.

8. The applicant's sophistication regarding methods for dealing with local officials and the public is important to the final decision. For example, by notifying the Contra Costa County and San Benito County Supervisors at the same time they notified the

State and EPA and by launching an aggressive public education campaign, AGS was able to avoid some of the problems they had encountered in Monterey County. Their reluctance to listen to the Berkeley Greens comments and respond to these comments in public, on the other hand, may have contributed to the decision to vandalize the test site.

5.0 OPTIONS FOR LOCAL GOVERNMENTS

The review of Federal and California state regulatory systems and the lessons learned from biotechnology activities in California to date suggest several options for local government action. These options are explored in this chapter.

5.1 SELECTION OF CRITERIA

Before developing options for local government action, it is necessary to define the criteria by which these options will be judged. Several of the seven criteria listed below are based on efficiency and equity principles of regulation discussed in Section 2 and listed in Table 1. The principles cannot all be followed realistically, however, in light of existing regulatory and political environments. These principles are recast as more realistic "criteria." In addition, several criteria will be used to assess options which are based on the case histories. These include political and legal constraints.

A local government strategy should contain **(1) limited redundancy with Federal and State regulations.** This self-explanatory criterion is consistent with the efficiency considerations numbered 1 and 3 in Table 1. It should be noted that redundancy is not always inefficient, especially if one system is likely to fail or the consequences of a failure are great. Given that the State's review system serves as a backup to the Federal system in the case

of biotechnology regulation, however, there is little reason to purposefully include more redundancy in the regulatory framework.

In order to satisfy the equity principle listed in Table 1, the regulatory process needs to include: **(2) a forum for local opinions, (3) exposition of the policy components of technical decisions, and (4) a specified means for local public perceptions of risk and risk aversion to enter the decision making process.** A forum can be as simple as the existing public comment periods in State and Federal laws, or as extensive as the public hearings required by CEQA. Exposition of policy components of technical decisions is necessary in order for the public to provide thoughtful and informed comments. This criterion is satisfied through specially designed public education forums or through the State providing the public with detailed standard operating procedures.

Criterion (4) above is especially important to the analysis. This criterion must be satisfied in order for the regulatory process to be equitable to the local public. The wording of this criterion specifically does **not** require that the permit decision depend on local acceptance. Local acceptance was deemed an inappropriate criterion for several reasons. First, if acceptance is necessary it is important to elicit approval of the entire local population, or at least a representative sample of the population. Second, a criterion which allows a small number of people to block a project with large gains for a large number of people is certainly

controversial. In this sense, the criterion selected is a compromise between granting the local public a lot of influence, and granting them no influence.

Criteria 2, 3, and 4, if attained jointly, should ensure that the information necessary to estimate risk aversion and to calculate risks and benefits is brought into the decision making arena. There is no requirement that the benefits be calculated formally; nor that such a calculation be the primary basis of a permit decision.

Actions by local governments should **(5) improve communication and trust between local governments and State and Federal agencies.**

The case histories show that both formal and informal communication channels between local governments and Federal and State agencies could be improved. Improved communication channels would allow local officials to respond more quickly to public inquiries. Improved communication channels would eventually make local responses to proposed biotechnology activities more predictable. Thus, this criterion reflects the principle that regulatory outcomes should be predictable from the perspective of the applicant (number 4 in Table 1).

Any policies which counties and cities choose to adopt should **(6) meet legal constraints and (7) meet political constraints.** The State constitution grants cities and counties limited powers. Most of local government's powers relevant to biotechnology activities

relate to their ability to adopt land use controls through General Plans and zoning requirements. When a proposed activity requires a zoning change and is deemed potentially to have significant environmental effects, the city or county is usually designated as the lead agency under the California Environmental Quality Act (CEQA). CEQA requires the lead agency to hold public hearings as well as provide notice to the public and hold a public comment period. (Certain State actions must meet CEQA requirements as well. Most State review procedures related to biotechnology activities have been determined to be "substantially similar" to CEQA, however.)

Local governments are not entitled to adopt any zoning restriction they please. Certain powers are reserved for the State. For example, the California Food and Agriculture Code (Section 11501.1A) grants CDFA the authority to regulate experimental use of pesticides. Although Monterey County passed an ordinance which enabled them to define experimental field testing as a land use issue, CDFA officials believe this ordinance would not hold up in court. At least one counsel from a county other than Monterey has examined the Monterey precedent and agrees with CDFA.

5.2 ALTERNATIVES

Local governments may want to consider a number of strategies to prepare for an increase in biotechnology related activities in the California. Four alternative strategies are presented below. In addition, alternatives 5 and 6 below are "add-ons" or program

elements. These elements can be attached to any one of the alternatives; they are not mutually exclusive.

All alternatives listed below are designed to respond to issues arising from proposed deliberate environmental releases of genetically engineered organisms. The alternatives could be modified slightly to respond to technical and public opinion concerns related to other types of biotechnology activities.

1. The Status Quo Alternative. The most obvious alternative available to local governments is to use existing resources and procedures only. To summarize: permits would be reviewed as they are submitted, no new local staff with expertise in biotechnology would be hired, no new ordinances or policies regarding use of EIR's would be adopted, and state and federal permit decisions would only be reviewed as a particular staff member sees fit or as requested by the Board of Supervisors or the Mayor. Comment periods would be conducted according to existing State and Federal regulations.

2. Develop local expertise to conduct a cost benefit analysis of proposed biotechnology projects.¹ This alternative would involve County health and agricultural commissioners improving their

1. During interviews, this alternative was raised by interviewees several times as if it were the preferred alternative of other parties. No party of which I am aware advocates this alternative, however. Since several people seem to fear this alternative, I considered it important to include in my analysis in order to systematically analyze and dismiss it.

technical staffs. In order to conduct the risk assessment and cost benefit analysis they would hire staff with specific expertise including molecular biology, ecology, and economics. The technical staff would balance risks and benefits and make a decision based on their results. In this respect, the process would not be explicitly public. Similar to EPA's process, the balancing of risks and benefits would not include consideration of the public's level of risk aversion.

3. Adopt local ordinances that require EIR reviews for experimental field tests and adopt a policy of requiring EIR's for all new biotechnology research and production buildings. Without passing an ordinance similar to Monterey County's, local governments have no authority to approve experimental field test applications. With a special ordinance, they must approve the field test's compatibility with zoning requirements, and are therefore able to require the applicant to submit an EIR. Counties and cities must approve all new buildings under local zoning and building ordinances. Therefore, they can require an EIR for any building permit which could have significant environmental impacts. Local governments frequently use this authority for major new buildings. Under this alternative, counties and cities would always choose to conduct the EIR, rather than issue a "negative declaration."

4. Adopt a policy through ordinance or resolution requiring a public education and comment process. At a minimum, the program would have three separate elements:

- A. An educational element designed to provide correct scientific information in laypersons terms. The technical information could be provided by federal and state officials or applicant representatives. There is no need to improve greatly the technical staff. This element would also contain some estimates of benefits.
- B. A risk communication element. This part of the process would be designed to put the risks in some perspective with other daily and presumed acceptable risks.
- C. A formal comment period. Officials would receive public comments which provide some insight into whether risks outweigh benefits or benefits outweigh risks. Risk aversion can be inferred presuming that the people providing these broader comments have correctly calculated costs and benefits.

5. Adopt minor measures now to facilitate rapid and standardized information flows when applications are submitted. Examples are given below.

- A. Counties develop standard operating procedures which are designed to become effective as various types of applications are submitted. These could include:
 - * who on the staff and which elected officials to notify,
 - * how to notify the public of the application,
 - * how to prepare a county staff report which documents the federal and state permit decision making process for the application in question,
 - * how to review state and federal scientific evaluations (which questions should have been asked).
- B. Regional workshops and coordination procedures be implemented. The Association of Bay Area Governments (ABAG) is a logical choice for initiating regional measures.
 - * Regional workshops targeted for county and city officials could address: the state and federal regulatory systems, the various types of ordinances that have been passed, the legitimacy of the public's aversion to risk regardless of the scientific and technical review, and risk communication at public hearings.
 - * ABAG could establish a library of biotechnology materials, and could designate one staff person to be a regional coordinator.

- * ABAG could prepare and distribute lists of: Bay Area consultants with expertise in risk communication and biotechnology, and state and federal regulatory resource people.

6. Specify how public comments will be used in the decision making process. None of the four alternatives listed above specify how comments of local citizens should be used to make the permit decision. There are at least three very different ways to use public comments. First, the public comment period could be used to solicit additional scientific and technical concerns. Public opinion would influence the permit decision only if new, significant scientific facts are brought to light. In this sense, "public" opinion would be limited to opinions of scientific experts. Second, decision makers informally could weigh the importance of public comments against the importance of other reasons to issue or deny a permit (eg. opposing opinions stated by a few local people could be weighed against potential large societal benefits). Third, public comments could be used to negotiate compensation for accepting a unknown risk of a costly outcome. Compensation could take the form of direct cash payments. More likely, compensation could include payment for new municipal facilities which would otherwise be paid for with general tax revenues.

5.3 ASSESSMENT OF ALTERNATIVES ²

The scientific components of risk assessment and cost benefit analysis are satisfied through the state and federal review processes. Although these processes are not perfect, it is extremely doubtful that even a highly improved and specialized county level government could add significantly to the scientific and economic analysis which occurs on the federal and state levels. For this reason alone, the county technical staff improvement alternative can be rejected as costly and redundant.

The "status quo" alternative is not practical given statewide trends. Everyone agrees that the biotechnology industry is growing. It has been estimated that, nationally, the biotechnology industry will grow from 3.2 billion to 100 billion by the year 2000 (Blakely et al 1988, p.1). California is predicted to maintain a large share of the national industry, especially in research and development (Blakely et al 1988, p. 22). Therefore, building and expansion permits and zoning decisions will have to be made. These undoubtedly fall under local government's purview.

People close to the regulatory system and the industry are less certain of the future of experimental field test permits in California. If the Tule Lake and second round of the Frostban experiments proceed without tremendous controversy, then the

2. The following assessment of alternatives highlights the main advantages and disadvantages of alternatives. For a more exact assessment of the degree to which alternatives satisfy the criteria see Appendix B.

application rate is likely to increase (interviews, Jones and Andrews).

Even if local governments do not wish to pass local ordinances specific to environmental field tests, such as Monterey County's ordinance, they will want to prepare for public concern regarding these tests. In the cases of the Frostban and Ice-minus field tests, the outcomes were dependent on the public relations skills of the applicant and the predisposition of the Mayor or Board of Supervisors to biotechnology. The outcome, or at least the process, could be made more predictable and hence less costly if counties and cities develop policies before applications are submitted.

The acceptability of small risks, especially those associated with organisms designed to be used and to survive in the open environment, is not addressed explicitly in Federal and State regulatory procedures. In order to satisfy both efficiency and equity principles of regulation, local governments and local citizenry should play a role in determining whether or not biotechnology risks are acceptable. Two alternatives potentially satisfy this condition (criterion 4): use of the Environmental Impact Review process and the public education and comment process alternative.

The Environmental Impact Review has been used in the past and could continue to be used as a public education and decision making

vehicle for applications to site new research facilities. The advantage of using the EIR is that it is familiar to both the public and local officials. The disadvantages are: 1) the debate is framed as a scientific/technical debate even when there are no legitimate scientific questions remaining. The public's aversion to risk is not explicitly recognized as a legitimate decision making criterion. 2) The scientific analysis is redundant with the state and federal analysis. 3) EIR's are costly to prepare. 4) The legality of adopting a local ordinance which then provides EIR authority in cases of experimental field tests is questionable.

Elimination of the EIR process leaves the public education and comment process. The advantages of this alternative are that 1) it explicitly includes the public's perceptions of and aversions to risk in the decision making process; and 2) it does not result in redundant scientific review.

The public education component of this alternative is feasible. The field of risk communication has been growing in acceptance in the past few years. There are now consultants who specialize in educating people on how to place risks in perspective. Programs such as EPA's Superfund program have written risk communication and public participation protocols which have been used successfully. Several hazardous waste facilities have been sited using risk assessment and risk communication protocols.

This alternative could be implemented using only existing written comment periods as forums for public comment. Unfortunately, these official written comment periods often precede periods of public concern. Furthermore, local officials may find it difficult to schedule public education sessions before or during the State and Federal comment periods. A revised public comment forum which resembles those used in the EIR process would elicit more comments from a wider sample of the local public.

Three alternative uses of public comments in the decision making process should be assessed. The State presently uses public comment periods only to elicit additional scientific information. Thus, value components of "technical decisions", especially the issue of risk aversion, are now excluded from the decision making process. This exclusion has negative efficiency and equity consequences. In addition, it alienates local officials and members of the public from state and federal technical staff, and diminishes trust.

Public comments can also be used to negotiate with the applicant for compensation. This alternative is unpopular for three reasons: 1) local citizens have incentive to overstate their aversion to risk in order to be substantially compensated; 2) applicants may feel that they are admitting that their project is risky if they agree to compensate the community; and 3) some local citizens may feel it is immoral to negotiate monetary compensation for health and safety and environmental risks. For these reasons, the

compensation alternative is assessed to be politically infeasible. A further discussion of compensation is included in Appendix A.

A third approach to using public comments is to weigh them informally against other reasons for either issuing or denying a permit. This approach satisfies the criterion that public opinion can influence the regulatory outcome. It is also flexible, however, allowing for the costs and benefits of each proposed activity to be considered in addition to the public's perception of risk.

If the public process alternative is going to work, the public must base their recommendations on rational perceptions of risk, rather than irrational perceptions based on faulty information. The only way to have an effective public information program is for the local officials to be able to respond immediately to requests for information. Trust is extremely important. The "minor measures now" alternative would increase the probability that public officials respond correctly and consistently to the public.

6.0 CONCLUSIONS

State officials cling to the myth that assessment and evaluation of biotechnology risks do not involve policy and value judgments. This is, perhaps, best demonstrated through a state official's statement that the purpose of the public comment period is to elicit new scientific information. The State's attempt to base decisions on scientific evidence only excludes the public and local government officials from participating. Since benefits and costs must be implicitly if not explicitly balanced, and since this balancing must include some measure of whether small risks are acceptable if it is conducted correctly, then the public has a legitimate role in the decision making process. The myth of scientific decision making could be changed by hiring new personnel with experience in risk management and risk communication.

The history of local involvement shows that city and county officials have a limited understanding of the larger regulatory environment in which a particular permit application is being processed. While specific people, such as the county health commissioner or the county agriculture commissioner, may have some contacts within the state regulatory structure, these lines of communication are not established enough to be reliable. Thus, local governments are not able to get information to the public in a timely manner; and trust deteriorates. This trust could be

improved through state sponsored workshops explaining the regulatory system.

The development of standard operating procedures for review of biotechnology permit applications also would improve communication and trust between state and local officials. Although a case by case method of review may be needed to evaluate the varied applications which are submitted to the State, this method of review is very difficult for local officials to trace and to understand.

The State could maintain this case by case quality and at the same time satisfy local needs by developing a list of questions which must be asked at a minimum during any biotechnology permit review. These questions could include: is the microbe a pathogen (if using a microbe)? Will a product intended for environmental release survive, multiply, disperse, and/or transfer its genes? How much is known about each of these steps? If this list of questions already exists, it could be circulated among academic and governmental experts and reviewed for completeness. The final list could then be distributed to local officials and citizenry when an application is filed.

The assessment of local government options suggests that the status quo is unsatisfactory. While there is little justification for local governments hiring experts and adopting a strong regulatory stance, there is ample evidence that local citizens look to local

government officials for knowledge and leadership. Cities and Counties which anticipate increased biotechnology activities within their borders may want to adopt the "minor measures now" alternative. This alternative will help to formalize informational and procedural channels to be used when applications are submitted. These improved procedures will increase public trust.

The workshops suggested in the "minor measures now" alternative would provide an excellent opportunity for county and city officials to discuss the specific details of the public education and comment procedure. If workshops are held periodically, a county which tries this procedure could share their experience with other counties.

Cities and counties faced with a potentially controversial application for a biotechnology related activity may want to adopt the public process and comment period alternative. In order for this alternative to work correctly, it is important that the public's comments be based on informed perceptions of costs and benefits. Thus, a public information session should precede a public comment session. The public education and risk communication elements could be modelled after EPA's Superfund program public participation guidelines.

Existing comment periods may be insufficient to elicit informed opinions from a wide sample of local citizens. The public comment process would be improved if cities and counties were to provide

forums in addition to the formal written comment periods used by the State and Federal governments. Local governments could hold hearings which have been advertised in the community. The format for eliciting public opinion could be similar to that required under CEQA.

There is no one best method for incorporating public comments into the decision making process. Rather, decision makers, whether they be State, Federal, or local, can weigh informally public opinion against other reasons to issue or deny a permit. In deciding what weight to give to the public's comments, decision makers might consider: how many people who participated in the educational meeting submitted comments, how many people who did not participate in the educational meeting submitted comments (these comments might be weighted less heavily), and perhaps the strength with which the opinion is stated.

The Environmental Impact Review process is not an optimal approach to reviewing biotechnology permit applications. This procedure should be used, however, if legitimate scientific questions remain. State regulatory officials may help local governments to make this determination.

Biotechnology industry's importance to California is well-recognized. If the industry is to grow in a way which is safe, predictable and publicly acceptable, then a decision making process must be agreed upon. Local governments are in a key position to

facilitate establishment of this process. Local government leaders can show that they are not afraid to open the process to the public, show respect for concerns and nontechnical points of view, and face difficult policy choices in a public forum.

LIST OF INTERVIEWS

Nancy Andrews, Environmental Protection Agency, Region 9	November 6, 1987
Christine Arneson, California Department of Health Services	November 3, 1987
Andrew Caffrey, Genetic Alert	January 29, 1988
Glen Church, Monterey County resident	January 29, 1988
Leonard Craft, Agricultural Commissioner, Santa Cruz County	January 29, 1988
John DeFremery, Agricultural Commissioner, Contra Costa County	November 16, 1987
Paul Duffey, California Department of Health Services	October 26, 1987
Wes Ervin, California Department of Commerce	November 2, 1987
Dan Fricke, Planning Department, Orange County	January 22, 1988
Tobi Jones, California Department of Food and Agriculture	November 13, 1987
Julianne Lindemann, Advanced Genetic Sciences	February 1, 1988
Bob Peterson, Environmental Protection Agency, Region 9	October 30, 1987
Terry Rivasplata, California Office of Planning and Research	October 16, 1987
Jim Stratton, California Department of Health Services	November 3, 1987
Trevor Suslow, Advanced Genetic Sciences	February 1, 1988
Juanell Waldo, Planner, Santa Clara County	November 18, 1987

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APPENDIX A:

A DISCUSSION OF COMPENSATION

One means of incorporating local public opinion in the decision to approve or deny a biotechnology related activity is to allow the local public and the applicant to negotiate for direct compensation. Compensation has basis on both economic theory and legal practice. If a proposed activity is economically "efficient," then benefits must outweigh costs; "winners" (those to whom the benefits accrue) can compensate "losers" (those to whom the costs accrue); and everyone will be better off, or at least as well off, as if the activity had not taken place.

Compensating a few losers for a project which will benefit many is common in legal practice. For example, although eminent domain allows the state to claim land for public projects (eg. roads), the private land owners must be compensated for the fair market value of their land. Compensation of a community for a risky project proves more difficult than either economic theory or legal precedent might make it appear, however.

A useful analogy for approving field tests of genetically engineered organisms can be found in siting hazardous waste treatment and disposal facilities. Bacow and Milkey (1982) divide strategies for siting hazardous waste facilities into two categories: preemption and compensation. Several states have siting laws which preempt local land use authority in the case of siting hazardous waste facilities. All statutes provide for public participation in the preemption decision. Bacow and

Milkey note that: "Preemption represents legal disarmament. It removes obstructionist tactics from the hands of facility opponents, but does not render them powerless or remove their incentive to fight the facility" (pp. 272-273).

Bacow and Milkey (1982) list four weaknesses of the preemptive approach. First, states cannot preempt all forms of local opposition. If the state preempts the municipality's authority to issue zoning restrictions, the municipality can resort to "subtler" strategies such as amending the weight limit on a bridge needed for materials transport. Second, preemptive moves by the state may encourage the municipality or an opposition group to litigate the state's action. Even if the state wins in the end, time delays and legal costs can be substantial. Third, "local governments can often use their power in state government to defeat or prevent the operation of a preemptive statute." (p. 273). State representatives of localities where facilities are likely to be sited usually go to great lengths to prevent preemption. Fourth, and of particular importance to biotechnology field testing, "when political and legal tactics fail, opponents can resort to civil disobedience to thwart unwanted development." (p. 274.) Bacow and Milkey conclude that "preemption operates only on the symptoms of local opposition, not on the causes." (p. 275).

Tarlock (1981) lists five approaches to state preemption which have emerged in hazardous waste facility siting: "(1) straight

state preemption; (2) state preemption of local vetoes upon state review and an extraordinary majority of the siting authority; (3) state preemption after extensive local involvement; (4) straight preservation of local veto authority; and (5) a requirement that the operator and the local community negotiate an agreement that offers rules to the community with arbitration as a last resort (a model much favored by consultants and others who find the adversary process too crude)" (p. 32).

Bacow and Milkey (1982) describe compensation as an alternative to state preemption. Compensation allows for bargaining between the developer and the local government. The developer would start by selecting a "safe" site with a good buffer zone, and providing any necessary infrastructure. The developer could then compensate the local community for remaining impacts or perceived risks through "cash payments, taxes, payments in lieu of taxes, and indirect payments such as property value guarantees, parks and jobs and job training" (p. 276). Compensation agreements are problematic for several reasons. First, opponents of the facility may be unwilling to trade health and safety risks explicitly for compensation. Second, the community may be unable to reach a consensus on the amount necessary to compensate them.

Third, neither the developer nor the public may have the data necessary to conduct a "scientific" risk assessment. Even if such a risk assessment is conducted, the public may still perceive a greater risk than the developer. The question arises:

how much public education is necessary before negotiations for compensation begin? A fourth impediment to compensation is its legality. Common law rules generally prohibit a municipality from bargaining away its policy making powers (p.277). If a developer signs an agreement with a local opposition group, community members outside of the group may still oppose the facility. Finally, community members will have an incentive to overstate their need for compensation, thus leading to an inefficient outcome.

States have tried to strike a balance between preemption and local control through adopting hazardous waste siting laws. These laws vary from state to state. Many of these laws allow the community and the developer to negotiate compensation.

The options of state preemption, local control, and compensation are available to those making decisions on whether to approve outdoor tests of bioengineered organisms. As is the case with hazardous waste treatment facility siting, compensation may create an incentive for community members to overstate their willingness to pay for a risk-free environment. The incentive to distort preferences is not expected to be as large as the hazardous waste analog, however.

First, local government officials, on average, will not overstate preferences since there is considerable competition among cities and counties to attract biotechnology firms. Some elected

officials may want to understate preferences because they have made public commitments to attract new industry. In most cases, firms have several locations from which to chose. Thus, a request for unreasonably high compensation will simply cause the firm to choose another site.

Second, individual revelations of preferences will be made public. Comments will be received in an open arena. Thus, social pressure may limit individuals' tendencies to overstate preferences.

Third, "learning" will only occur to a limited extent. Citizens who participate in the negotiation process will probably learn how to manipulate the process; however, this learning will not spread quickly from community to community. At this time, biotechnology firms are fairly dispersed throughout the Bay Area. Thus, the public's opportunity to negotiate compensation is not likely to occur repeatedly in the same place.

The opportunity for monetary compensation raises the question of whether citizens who are compensated for accepting the risk of a negative event should be compensated again if that event occurs. If a compensation agreement clearly states that the firm would still be liable for damages should a negative event occur, then compensation could be negotiated based on the value of the risk premium. This risk premium should be based on the public's perception of the activity's risk following some reasonable

period of education. It is unlikely that any agreement which limits liability for future event would be legal.

APPENDIX B:

ALTERNATIVES ASSESSMENT MATRIX

CRITERIA

ALTERNATIVES
AND "ADD-ONS"

No redundancy
with Fed &
State
Opinions

Exposition of
Policy Components
of "Technical"
Decisions

Local
Opinion can
Influence
Decision

Improves Fed &
State to Local
Communication
and Trust

Meets
Legal
Constraints
Meets
Political
Constraints

ALTERNATIVES:

1. Status Quo

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2. Develop Local Expertise

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3. Adopt Ordinance or Policy which Requires EIR

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4. Revise Public Education and Comment Process

Comment Process

4A. New Education Program, Existing Comment Periods

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*

**

4B. New Education Program; Additional Comment Forums

**

**

**** Excellent
+++ Good
++ Fair
+ Poor

CRITERIA							
ALTERNATIVES AND "ADD-ONS"	No redundancy With Fed & State	Forum for Local Opinions	Exposition of Policy Components of "Technical" Decisions	Local Opinion can Influence Decision	Improves Fed & State to Local Communication and Trust	Meets Legal Constraints	Meets Political Constraints
ALTERNATIVES:							
1. Status Quo	****	**	*	*	*	****	***
2. Develop Local Expertise	*	**	*	**	*	****	*
3. Adopt Ordinance or Policy which Requires EIR	***	****	*	***	*	*	**
4. Revise Public Education and Comment Process							
4A. New Education Program; Existing Comment Periods	****	**	***	*	**	****	****
4B. New Education Program; Additional Comment Forums	***	****	***	**	**	****	****
**** Excellent							
*** Good							
** Fair							
* Poor							

CRITERIA

ALTERNATIVES
AND "ADD-ONS"No redundancy
with Fed &
State
OpinionsExposition of
Policy Components
of "Technical"
DecisionsLocal
Opinion can
Influence
DecisionImproves Fed &
State to Local
Communication
and TrustMeets
Legal
ConstraintsMeets
Political
Constraints

ADD-ONS:

5. Minor
Measures
Now

NA

NA

6. Specify How

Public Comments
will be used
In Decision

6A. Used only if

NA

NA

*

*

**

New Scientific
Information
Comes to Light

6B. Staff Informally ****

NA

NA

**

Weighs Public
Opinion with
Other Reasons
for Issuance/
Denial

6C. Applicant and ****

NA

NA

NA

**

*

Locals Negotiate
Compensation

**** Excellent

*** Good

** Fair

* Poor

CRITERIA

ALTERNATIVES
AND "ADD-ONS"No redundancy
with Fed &
State
OpinionsExposition of
Policy Components
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DecisionsLocal
Opinion can
Influence
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Communication
and TrustMeets
Legal
ConstraintsMeets
Political
Constraints

ADD-ONS:

5. Minor
Measures
Now

NA

NA

6. Specify How

Public Comments
will be used
In Decision

6A. Used only if

NA

*

*

**

New Scientific
Information
Comes to Light

6B. Staff Informally

NA

**

Weighs Public
Opinion with
Other Reasons
for Issuance/
Denial6C. Applicant and
Locals Negotiate
Compensation

NA

NA

**

*

**** Excellent
*** Good
** Fair
* Poor

CRITERIA

ALTERNATIVES AND "ADD-ONS"	No redundancy With Fed & State	Forum for Local Opinions	Exposition of Policy Components of "Technical" Decisions	Local Opinion can Influence Decision	Improves Fed & State to Local Communication and Trust	Meets Legal Constraints	Meets Political Constraints
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ADD-ONS:

5. Minor Measures Now	****	NA	NA	***	****	****	****
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6. Specify How
Public Comments
Will be used
In Decision

6A. Used only if New Scientific Information Comes to Light	****	NA	NA	*	*	****	**
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6B. Staff Informally Weighs Public Opinion with Other Reasons for Issuance/ Denial	****	NA	NA	****	**	****	***
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6C. Applicant and Locals Negotiate Compensation	****	NA	NA	***	NA	**	*
---	------	----	----	-----	----	----	---

**** Excellent
*** Good
** Fair
* Poor

CRITERIA

ALTERNATIVES
AND "ADD-ONS"

No redundancy
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Exposition of
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Decision

Improves Fed &
State to Local
Communication
and Trust

Meets
Legal
Constraints

Meets
Political
Constraints

ALTERNATIVES.

1. Status Quo

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*

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2. Develop
Local
Expertise

*

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3. Adopt
Ordinance or
Policy which
Requires EIR

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4. Revise Public
Education and
Comment
Process

4A. New Education
Program, Existing
Comment Periods

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4B. New Education
Program;
Additional
Comment Forums

**

**

**** Excellent

*** Good

** Fair

* Poor

