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THE STATE ROLE IN REGULATING BIOTECHNOLOGY

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THE REGULATORY PICTURE

As state governments seek to benefit from the biotechnology industry they are cautiously expanding their role in its regulation. The drive toward regulation is fueled primarily by the lack of knowledge about the risks to the public and the environment from the release of genetically engineered organisms. This regulatory expansion has been limited by the fact that the federal government, which has traditionally been the primary player in regulating the industry, is refining its role. Likewise, it is difficult to apply traditional environmental regulatory methods to biotechnology.

Regulating biotechnology generally means controlling the research, development and application of genetically engineered (altered or changed) organisms. Under the broadest definitions of genetic engineering traditional hybrid agricultural products like tomatoes and corn qualify. These organisms have been available to consumers and in the environment for over 50 years. Most state regulatory efforts are focusing on the transfer/alteration of genetic material through non-traditional methods, primarily the use of recombinant DNA (rDNA). Furthermore, state efforts are focused mostly on the environmental release of altered organisms, as opposed to pharmaceutical applications.

A number of reasons have been suggested for state government action (Moreland, 1987). First, states have primary authority for protecting public health and the environment, as well as implementing the majority of the nation's environmental regulatory programs. The states are in the best position to implement the benefits that biotechnology promises in toxic controls, because the states, as primary regulators, are closest to the environmental problems caused by toxics. States may regulate more stringently than the federal government, which is advantageous to those states that wish to closely monitor environmental releases. State regulation may promote the growth of safer technologies, because the industry will be cognizant of state governmental oversight during releases. State universities conduct much of the research, including that on environmental release. It may be easier for state governments than federal agencies to access this research.

At this time, states are the secondary tier of regulation. The primary regulators of the biotechnology industry currently includes at least six federal agencies; the National Institutes of Health (NIH), United States Department of Agriculture (USDA), Environmental Protection Agency (EPA), Food and Drug Administration (FDA), National Science Foundation (NSF) and Occupational Safety and Health Administration (OSHA) (Fanning, 1988). The NIH, USDA, and EPA are likely to regulate any future industry action which might result in the release of an organism into the environment. The NIH's authority originates from the Public Health Service Act, and is exercised mainly by issuing research and handling guidelines to biotechnological industries. The USDA regulates under the authority of legislation written before modern techniques were developed. These regulations primarily concern the agricultural applications of biotechnology products and transporting of engineered organisms. EPA, on the other hand, regulates under the Toxic Substances Control Act (TSCA) which gives broad authority to oversee "chemical substances" used in commerce. Engineered organisms are usually interpreted as "chemical substances" and are therefore regulated. These regulations are intended to assure the substance in question poses no "unreasonable risks". EPA also regulates engineered organisms under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) if the organisms are used as pesticides.

Unlike many other environmental acts (Clean Air, Clean Water, Resource Conservation and Recovery Act) of the last 20 years, these major authorizing federal acts for biotechnology regulation do not contain provisions for states to assume significant roles in their implementation. The role of the states in these acts is generally limited to commenting on federal agency decisions. Unfortunately, these decisions are often made without adequate time for state responses. Like arrangements made under the Clean Water Act, in which states set water quality standards, states may argue that decisions affecting a release should be made locally or by the state. Furthermore, many states want to play a role in policy making in order to enhance economic development opportunities provided by biotechnology. Thus they have viewed biotechnology as an "economic development" issue, rather than an "environmental protection" one. This policy agenda is focused on first developing the industry rather than controlling or monitoring it.

STATE REGULATORY TACTICS

Existing or proposed state regulatory requirements include several methods that have been successful in other environmental regulatory programs. Registering biotechnology laboratories is a typical

requirement, as is the licensing of rDNA researchers. This action allows the state to create an information base that will assist it in tracking activity. Requiring laboratories to comply with the National Institutes of Health guidelines for releasing or transporting engineered organisms is another common regulatory approach used to assure an acceptable level of technical expertise. Some states are requiring their agencies to comment on proposed federal permits for releasing an engineered organism into the environment. This has always been an option for the state, but due to a very limited response time, has not always been possible.

Another regulatory method is to require an industry to notify the state prior to releasing a genetically engineered organism into the environment, or in the event that an organism is accidentally released. This regulatory technique is similar to that used in hazardous waste regulation. States are also forming oversight commissions, often consisting of representatives from the public, industry representatives, and technical experts. The role of these commissions is most often to assess the necessity for further regulation. Relationships with local governments often are addressed as well. Some states are preempting local government regulations, while others are delegating regulatory authority to local governments. Some states are moving to provide training to fire departments to handle potential emergencies unique to the industry (biological contamination of water supplies, etc.).

The investigation and assessment of economic and environmental impacts are an indicator of the concerns and priorities of state governments with respect to biotechnology. For example, during 1987 six states (California, Maine, Michigan, Minnesota, North Carolina and Wisconsin) studied biotechnology's impact on state economic development. Three states (California, Hawaii and Michigan) were studying environmental effects; seven states (California, Florida, Michigan, Texas, Vermont, Washington and Wisconsin) were studying the need for regulatory authority. California conducted studies on all three subjects, plus a socio-economic study (Stroick, 1987).

Recent state legislative action has focused on the regulation of the environmental release of genetically engineered organisms. As of the end of 1987 five states (Hawaii, Michigan, New York, Oregon, and Rhode Island) regulate the release of modified or engineered organisms. Five additional states (California, Illinois, Texas, North Carolina, and New Jersey) considered such legislation during the 1987 sessions (Stroick, 1987). Table 1 details the content of recent legislation regarding biotechnology in these five states. Of these five, the North Carolina, Texas, New Jersey and Illinois bills died during the sessions. These states and others, including California, have reintroduced bills in the 1988 sessions (Moreland, 1988). Maryland, the first state to pass

environmental release legislation in 1983, allowed the act to lapse in 1987 due to a sunset provision (Stroick, 1987).

Other state actions in 1987 included an attempt by Florida's Department of Agriculture to propose legislation intended to supplement USDA regulations. The Maryland Department of Agriculture proposed to move from a guidance/technical assistance role to a regulatory role. Vermont's agriculture department re-examined its administrative regulations to determine if genetically engineered organisms are included. Wisconsin commissioned a survey to determine what actions other states had taken (Stroick, 1987).

Table 1

Summary of State Biotechnology Legislation Proposed in 1987

California: SB 884 requires private persons and public agencies to obtain a permit from the state department of agriculture as a condition for transporting or releasing a novel organism.

Illinois: HB 1866 establishes a nine member committee to review public policy issues; review existing federal regulation; monitor the release of genetically engineered organisms, and review the status of any federal permit application and make comments on it.

Texas: HB 41 establishes an 11 member committee to study adequacy of state and federal laws governing biotechnology; to assess developing state regulation governing biotechnology; and to prepare a plan on intergovernmental cooperation and public education. Requires the notification of Department of Health of unintended or deliberate release of genetically altered organisms; and provides assistance to biotechnology companies by identifying federal regulatory requirements.

North Carolina: HB 372 authorizes the Board of Agriculture to adopt regulations; cooperate in the management or mitigation of programs; cooperate with other governmental agencies; and to provide confidentiality of information. Prohibits any county or municipality to enact regulations affecting biological organisms.

New Jersey: SB 1123 establishes a nine member committee to study the adequacy of state and federal laws governing biotechnology; review any release that has received federal permit; provide confidentially of information; and preempt all local laws relating to genetically engineered organisms.

Source: Stroick, 1987.

There is no consensus among state governments over which agency should regulate biotechnology. Agriculture departments are being given the lead role in some states because many of the engineered organisms are expected to have applications in food production. Another factor is the "high-profile" federal permit process which resides in USDA. To some extent, agriculture departments may put more emphasis on the economic development aspects of engineered organisms because such organisms may result in improved food production. However, agriculture departments are also concerned in preventing the spread of plant pests or other agricultural threats, and so are interested in any possible risks from releases.

Health departments may be given the lead in the absence of a strong interest from an agriculture department, or if the issue is seen more as a risk to public health than as an industrial development issue. Environmental departments may get the lead because they are seen as experienced regulators of industry. No study results exist which explain why one agency is given a lead over another in biotechnology regulation. Table 2 below outlines the different jurisdictional paths that states have taken in assigning administrative responsibility to biotechnology regulation.

Table 2

Lead Agencies for Biotechnology Regulation

Agriculture Departments:	***Health Departments:***
Alabama	Hawaii
California	Massachusetts
Florida	Michigan
Maryland	New York
North Carolina	Oregon
North Dakota	
New Jersey	***Environmental Departments:***
Rhode Island	Wisconsin
Washington	
Health and Environment Departments:	
Illinois	
Agriculture and Health Departments:	
Texas	

A number of other states may move further in the direction of regulation during the next year as biotechnological research and testing become increasingly commonplace. Environmental releases, such as in Wisconsin and California, have stimulated public concerns and demands for regulation. Alabama, South Dakota and Oregon expect to develop regulations during late 1988 or in 1989. In Oregon's case, such development is an expansion of existing regulations. Hawaii is conducting a study on the possible environmental effects of biotechnology in an effort to determine if the state's statutes are sufficient to provide the desired level of protection (Stroick, 1987).

Two other states might also serve as signals for trends. These are Massachusetts and Missouri, both of which have considerable biotechnological industry in the state and both of which are relatively unregulated at this time. Efforts to adopt regulations in these states might be perceived as a cooling of enthusiasm for the industry. Massachusetts' health department has stated that it expects to develop regulations in the next few years (Stroick, 1987). Table 3 identifies those states which had some form of biotechnology regulation in place or were considering regulation as of December 31, 1987.

Table 3

Status of State Regulation of Biotechnology

States With Biotechnology Programs as of December 31, 1987

Hawaii	New York	Oregon	Rhode Island
Michigan			

States Investigating Biotechnology Regulation

Alabama	Iowa	Missouri	South Carolina
California	Kansas	Nebraska	South Dakota
Connecticut	Maryland	New Jersey	Texas
Florida	Massachusetts	North Carolina	Vermont
Hawaii	Michigan	North Dakota	Wisconsin
Illinois	Minnesota	Oregon	

Both proposed and enacted legislation indicates the concern of the states in regulatory gaps which may threaten public health or the

environment. Legislative action has been initiated by a concern for gaps in shared regulatory responsibilities in the federal system and demonstrates the concern of some states as to whether laws written for other purposes, such as general public health protection provisions, apply to the biotechnology industry.

ECONOMIC DEVELOPMENT AND PUBLIC PROTECTION

The economic health of states varies widely, and many (some would say all) states are actively seeking to develop their economies. A number of states have seized biotechnology as a candidate for this development. There appear to be at least two levels of development states seek. One might be called "primary" research, which includes the laboratories where organisms are actually modified. The second industry might be called "applied" research, for example using the organisms to increase agricultural production.

Economic development proponents and environmental protectionists are often at loggerheads. To date, development has dominated the biotechnology scene at the state level, and there have been few well-publicized battles at the state level between environmentalists and pro-development organizations. Data indicates that in the debate between a climate for easy biotechnological business expansion on one hand and regulation of those businesses for the sake of public protection on the other, that the developmentalists have dominated to date. One estimate shows states spending at least $30-45 million per year on developing this industry (National Governors Association, 1988), while another says 33 states are actively promoting biotechnology, spending $147 million in fiscal year 1987 (U.S. Office of Technology Assessment, 1988). On the other hand, in 1986 no state listed biotechnology programs as line items in their regulatory department budgets (Brown and Garner, 1988). Clearly, the emphasis in state government with respect to biotechnology to date has been in its value as a creator of jobs.

Several states are often cited as examples of leaders in the economic development of biotechnology. In 1986 North Carolina created the North Carolina Biotechnology Center, a non-profit corporation funded by state government as part of an economic development program for the state. In 1986, funding for this Center was $7.7 million (Osser, 1987). Other states with active programs, not necessarily at the university level, are: Arkansas, California, Connecticut, Hawaii, Maryland, Massachusetts, Missouri, New Jersey, New York, Ohio, Rhode Island, Virginia, and Wisconsin (Stroick, 1987). These programs indicate how important the states consider the development of this industry during a time of limited state resources.

Productive relationships with industry are a primary goal of state efforts to capitalize on the investment prospects of biotechnology. Some states protect trade secrets during the permit process when biotech firms file for product research and testing. Another practice requires state regulatory agencies to provide assistance to industry in interpreting federal and state regulations. Finally, some states are requiring facilities to demonstrate adequate technical expertise and fiscal resources to sustain operations, so that the state can minimize its risks of having to expend its resources to correct problems at an abandoned biotechnology facility. These efforts are often made to discourage unstable companies from siting, and to encourage new or existing facilities.

As with many issues in state government, regulating biotechnology calls for a compromise between competing interests. Currently the scale is tipped in favor of development. As state legislative activity suggests, concerns about public health and safety and environmental effects may gradually tip the scale towards protection.

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