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A Broad Perspective on Biotechnology and Environmental Regulation

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A Broad Perspective on Biotechnology and Environmental Regulation

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I think that it is of the utmost importance to keep the political and scientific sides of biotechnology well balanced within the realm of public policy. There are at least two discernible groupings of people regarding biotechnology. There are those who sing its praises and those who ponder how little we really know of basic life processes.

In the public policy arena, government is often caught in a netherworld between promises and realities—where it is often difficult to find truly honest, impartial advisors. While the public expects the government to act on everyone's behalf, interest groups representing the "public" get especially upset when they are slighted. For example, it is hard for anyone to deny a company help that is willing to invest large amounts of money in economically depressed areas. It is equally hard for an elected official to ignore companies who create more jobs than the typical margin of victory in local elections.

Very briefly, environmental regulation in the biotechnology area stems from the efforts in the 1970s of various federal agencies (e.g., National Institutes of Health (NIH), National Science Foundation (NSF), Environmental Protection Agency (EPA). In December, 1984, the White House Office of Science and Technology published in the *Federal Register* a "Proposal for a Coordinated Framework for Regulation of Biotechnology" to standardize and harmonize the federal agencies' regulatory posture (1).

Within this document, the EPA, Food and Drug Administration (FDA), and U.S. Department of Agriculture (USDA) published statements of policy defining the areas of biotechnology with which they would be most concerned. FDA was to be concerned only if undesirable foreign materials are introduced into pharmaceutical or food preparations. USDA saw no difference between recombinant DNA-derived plants and traditional crossbred variants. Finally, EPA considered its role to

be prevention (not abatement), under the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

As soon as the "coordinated framework" was out, it was attacked by representatives of some companies as too restrictive, and by environmentalists as too lax. The federal agencies continued to actively seek out a middle ground on which they could do their work while balancing their public and environmental protection mandates under various federal laws. On June 26, 1986, the *Federal Register* printed an updated "coordinated framework" (2, 3). This report laid out the domain of responsibility for federal agencies based on the existing statutes, which provide a basic framework for agency jurisdiction over research and production. The responsibility for a single product is to be with a single agency, with assistance from others if needed. For example, FDA is to oversee foods/food additives, human drugs, medical devices and biologics, and animal drugs. Animal Protection Health Inspection Service (APHIS) reviews animal biologics. EPA and APHIS will review all microorganisms to be released into the environment. A similar framework is proposed for research work; in this area review is mandatory for federally funded work, and voluntary for nonfederally funded work.

There are several intriguing problems, all too briefly addressed in the 1986 framework. For example, what is a "release"? Containment is often thought of as strict control within a laboratory environment. Yet, according to the 1986 framework, containment can also be "biologic" when an organism's reproductive ability can be curtailed, if not eliminated. "Releases" then involve complexities of physical and biological limitations.

Genetically engineered microorganism types are dichotomized as well in the 1986 framework. EPA has decided that inter-organic (i.e., combinations from source organisms of different genera), not intra-generic combinations (source organisms from same genera), are the most likely to result in new combinations of traits. It is this type of organism that will merit special regulatory attention. But, inter-generic organisms can be excluded from regulation if the added genetic material consists *only* of well-characterized, noncoding regulatory regions. These organisms, they think, will not exhibit new traits, but only quantitative changes in preexisting traits.

If it is not clear yet, environmental regulation is, as William Ruckelshaus once said, a "shotgun wedding between science and law" (4). Commonly, most regulation is of the "command and control" type. We list proscribed behaviors, and fine/incarcerate violators. There is some talk, and experience, with a "reward" based system of regulation that provides tax incentives, grants, etc. to responsible firms. Yet both of these types depend upon some assessment of liability and risk. With regard to biotechnology, the advice regarding risk has been mixed. For example, Martin Alexander, a microbial ecologist, (5) saw the ultimate risk of a genetically engineered organism as a function of six independent probabilities, i.e., probabilities derived from the answers to these questions:

1. Will the organism be released?
2. Will it survive in the natural environment?
3. Will it reproduce?
4. Will its genetic information travel to other organisms?
5. Will it disperse?
6. Will it be harmful?

In my opinion, only the last question is of use to a regulatory agency, and of course, it is the most vague. In fact, 1984 hearings of the House Subcommittee of Investigations and Oversight and the Committee on Science, Research, and Technology ended by saying that there is a small chance of a "high consequence risk" (6, 7). In other words, almost everyone seems to agree that there is a very, very slim chance of a released organism going completely bonkers. Yet, all agree that when it does happen, it is going to be incredibly severe.

What are the problems and opportunities that face us? First, we lack an adequate base in predictive ecology. We cannot expect that to be developed by the state agencies. This help must come from the universities and from the federal agencies. Second, the current case-by-case review procedure is only an interim phase; scale-up is coming. It is when we start spreading otherwise innocuous organisms across millions of acres that we can really determine the ecological effects. Geographers learn that human alteration is pervasive in North America. If the Europeans did not alter an area, the Native Americans surely did. We are now entering a whole new era of landscape alterations. For example, will the distribution of "weed" species significantly change from the ice-minus bacteria?

Minnesota has a strong environmental policy law on the books—Laws 1973, chapter 412, 116D (8, 9). Its purpose is to "(a) declare a state policy that will encourage productive and enjoyable harmony between human beings and their environment; (b) to promote efforts that will prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of human beings; and (c) to enrich the understanding of the ecological systems and natural resources important to the state and to the nation."

Minnesota, like most other states, has no specific regulatory authority regarding biotechnology. But, I think it would be a fairly easy legislative change to grant an agency authority to actively explore this issue with the federal agencies. Wisconsin is the best model we have in this situation.

What can be a positive impact of all this? Since 1977, Cambridge, Mass., has had a strong biotechnology ordinance. Two things have resulted. First, public health safety issues were pushed to a state-of-the-art discussion. Second, informed consent became the standard operating procedure for the community—elected officials are fully informed of what is going on within a company. I think this is where the future of regulation will be.

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CALENDAR OF EVENTS

Editor's note: This calendar is intended to inform MAS members and others about scientific meetings and symposia of interest in Minnesota and surrounding states. Please send notices of upcoming events to The Editor, Minnesota Academy of Science Journal, Suite 916 Pioneer Building, St. Paul, MN 55101.

November

22-24: 20th Annual North Central Junior Science, Engineering, and Humanities Symposium. Kahler Hotel, Rochester, MN. Nancy Zwickey, Lake Crystal High, director.

March

3-5: International Symposium: Man-Health-Environment. Luxemburg. In conjunction with the Departments for Environment and Health of Luxemburg, and, on the occasion of the European Year of the Environment, the International Society for Research on Civilization Diseases and Environment organizes an International Symposium on the topic: Man-Health-Environment. For information about registration, submission of posters, and travel arrangements contact: Secrétariat Année Européenne de l'Environment, c/o Ministère de l'Environment, 5a rue de Prague, L-2341 Luxembourg. Phone: (352 48 8007), Telefax 400 410, Telex: 2536 MINENV-LU

April

17-19: 51st Annual State Science Fair and Research Paper Program. Mankato State University. Wayne Anderson, St. Clair High, director.

29-30: Minnesota Academy of Science 56th Annual Spring Meeting. Macalester College, St. Paul, MN. Wayland Ezell, St. Cloud State University, program chair. Elizabeth Hobbs and Mark Davis, local co-chairs.

August

7-11: 11th North American Prairie Conference, Prairie Pioneers: Ecology, History and Culture. Lincoln, NE. For more information write: 1988 N.A. Prairie Conference, Department of Biology, University of Nebraska at Omaha, Omaha, NE 68182-0040.