
Workshop Report

Patricia T. Raynor
*Coordinator, USDA National Biological Impact
Assessment Program, Michigan State University*

Thomas L. Thorburn
*Program Director of Food Systems, Rural
Development and Water Resources, Kellogg Foundation*

The stated purpose of this workshop was to identify areas of agriculture in which biotechnology is most likely to be beneficial to the public, and to formulate recommendations that could encourage such applications. Two invited speakers presented background material with thought-provoking views of how decisions that shape the agricultural biotechnology agenda are made and who should be making them. Susan Offutt, Executive Director of the Board on Agriculture of the National Research Council, described how a fourth criterion has been added to the public dialogue of agricultural biotechnology. In addition to quality, safety and efficacy, the socioeconomic and environmental impacts of agricultural biotechnology must also be evaluated. In other words, the agenda-setting process needs to be modified to consider non-market aspects of technology adoption and use.

Garth Youngberg, Executive Director of the Henry A. Wallace Institute for Alternative Agriculture, noted that public involvement has not progressed into the planning and decision-making phases of biotechnology research and development. He emphasized that companies need to take a serious look at how to bring farmers, public interest groups and other citizens into their strategic planning.

These ideas set the stage for subsequent discussions during the workshop sessions. Rather than identify agricultural products or research areas in which biotechnology is most likely to be beneficial to the public, the group focused on the process of setting the agenda. The unifying theme that emerged from the discussions was that participatory decision-making was essential to ensure that applications of biotechnology serve the public good.

Nearly fifty people participated in this workshop. Five breakout groups were formed to present and discuss individual issues; from these, the entire workshop group identified three issues of greatest interest or concern: public participation, availability of information, and the regulatory framework. Each was then addressed by a breakout group which developed recommendations.

PUBLIC PARTICIPATION

There is a need to increase public participation in both public and private sectors of the agricultural biotechnology community to create an agenda-setting environment (process) that more accurately reflects the diversity of values, interests and priorities in our society. Public participation would enhance communication among interested parties, promote better understanding of issues from all perspectives, and encourage the development of mechanisms to open up the agenda-setting process.

This issue raises further questions that need to be addressed such as: who should define the public good? who is accountable to the public good? how do you involve people who are affected by the outcome of decisions, but lack the expertise to contribute meaningfully to the process? These questions prompted a comment that in a democracy, government is the entity is responsible for defining the public good.

Recommendations

All of the recommendations for increasing public participation formulated by the breakout group were strongly supported by the entire workshop group.

Review and assess existing public and private advisory structures and modify them as necessary to ensure representative input into the development of the agricultural agenda including biotechnology applications.

Review and define the mechanisms for establishing truly responsible public participation with input focusing on broad areas of societal concern that may benefit from agricultural biotechnology.

Encourage the integration of environmental and social science into biological sciences programs.

AVAILABILITY OF INFORMATION

There is a need to promote ready access to and active dissemination of information relevant to agricultural biotechnology issues. There is also a need to foster educational reform that will enhance the effective use of that information in the decision-making abilities of all citizens. Enhanced availability of information will increase effective dialogue and lead to better decision-making by establishing feedback to, and cooperation with, those who set the agenda.

Education should address both specific issues and broader processes associated with setting the agricultural biotechnology agenda. Procedures need to be developed that will integrate biotechnology information into overall agriculture policy and address the impact of funding sources and allocations. It was noted that information about opportunities to participate in decisionmaking is an important component of education efforts.

Funding to support information and education programs needs to be provided. Because education is distinct from advocacy, the source of funds is important. Information for the public needs to be made available by agencies

or organizations that do not have a vested interest in the outcome. Otherwise, decisions that shape the agricultural biotechnology agenda will, by default, be made by the advocacy groups having the biggest bankrolls.

Recommendations

Recommendations proposed by the breakout group were strongly or unanimously supported by the entire workshop group.

Send a representative to the National Association of Biology Teachers (NABT) and the National Science Teachers Association (NSTA) annual meetings to provide a list of resources and experts in agricultural biotechnology that teachers may contact locally.

Include agricultural biotechnology in K-12 science curricula.

Develop an agricultural bioethics course for land-grant institutions and establish it as a requirement for U.S. Department of Agriculture (USDA) training grant programs.

Continue and expand research on risk assessment and the socioeconomic impact of agricultural biotechnology.

IMPLEMENTING AN ACCESSIBLE, EQUITABLE AND CONSISTENT REGULATORY SYSTEM

The agricultural biotechnology agenda encompasses not only research directions and priorities but also the regulatory framework within which the technology is applied. Does the existing regulatory system ask the right questions and give the right answers? In the ensuing discussions far-ranging ideas were proposed to address some of the deficiencies in the current regulatory system.

Difficulties in obtaining bureaucratically held information could be improved by providing access to information using innovative technologies that allow information on demand. Inequitable distribution of benefits derived from biotechnology products, developed in part by publicly supported research, could be remedied by revamping regulatory agency mandates to include consideration of who profits. In other words, agencies could exercise conscience as well as oversight.

The fragmented regulatory framework, in which the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA) and USDA share overlapping authorities for biotechnology products, could be streamlined by establishing a centralized monitoring agency to serve as a clearinghouse for information from all the agencies. In order for people to have information about how new technologies will affect their daily lives, regulatory agencies could be required to address the socioeconomic aspects of biotechnology applications. It could be argued, however, that such a requirement would effectively result in political decisions being made by government officials who, not being elected, do not represent the political will of the electorate.

As noted below, the recommendations put forth by the breakout group received variable support from the entire workshop group.

Recommendations

Implement prior recommendations on regulations put forth at the NABC 4 meeting in 1992. (This call for action had almost unanimous endorsement.)

Those recommendations (Fessenden MacDonald 1992) were:

- The regulatory gaps delineated deserve serious investigation NABC may wish to establish a committee or other mechanism to assist this investigation.
- A more acceptable policymaking process for rules of broad applicability would be clearly understood or known (not ad hoc), transparent and participatory. The group viewed the process leading to the recent FDA food safety decision as falling short of the goals for an acceptable process.
- Social, economic and ethical questions need to be explored. What role do/should these issues have in research, development and approval processes for commercial use of new products? When should these factors be considered, relative to, but not necessarily as a part of the regulatory process?
- With broader representation (such as food processors and consumer groups), NABC should conduct further exploration of the relationship between the government's regulatory role, particularly the safety statutes and issues of choice such as labeling provisions.

Codify statutory requirements for socioeconomic analysis, (strongly controversial; about fifty percent of the participants supported this recommendation and fifty percent were opposed)

Require that regulators consider equitable allocation of intellectual property rights so that the regulatory process includes consideration for individual compensation, (strongly controversial; the group was divided, with about half in favor and half opposed)

Establish a single regulatory agency clearinghouse monitoring EPA, FDA and USDA for biotechnology applications. (The majority of the group was strongly opposed to the recommendation. Concerns were raised that it would simply create another level of bureaucracy, or that it would undermine existing authorities)

CONCLUSION

At the outset, the stated purpose of this workshop was "to identify those areas of agriculture in which biotechnology is most likely to be beneficial to the public and to formulate recommendations that could encourage such applications." In actuality, however, the discussions addressed the process of setting the agenda rather than the identification of specific products or areas of research. This broader focus produced very general recommendations for im-

proving what was termed “the decision-making process.” Most participants agreed that decisions about the application of biotechnology are more likely to be for the public good when there is greater participation by an informed public in setting the agenda.

REFERENCES

Fessenden MacDonald, J. 1992. *NABC Report 4, Animal Biotechnology: Opportunities & Challenges*. National Agricultural Biotechnology Council. Ithaca, NY.