Overview

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Life involves choices. Many of the choices we make require an assessment of the potential benefits and risks associated with our choices. This is particularly true regarding biotechnology. The major objective of the fifth annual meeting of the National Agricultural Biotechnology Council (NABC) was to exchange understanding of the risks associated with agricultural biotechnology and how these risks are perceived and assessed by various segments of society. NABC 5, *A Public Conversation About Risk,* achieved this objective using the NABC format of an open forum for participants to speak, to listen and to learn. Differing views on risks of agricultural biotechnology were expressed and discussed by over 130 agricultural biotechnology stakeholders including consumers; farmers; environmentalists; industry scientists and administrators; journalists; ethicists; government agency professionals; and academic researchers; educators; and administrators.

The meeting topic and the dates for NABC 5 were rather timely, coinciding with the release of Steven Spielberg's blockbuster science-fiction movie *Jurassic Park* which raised questions about the potential dangers of imagined genetic engineering gone awry. Also, the Food and Drug Administration (FDA) issued, in May 1992, a request for comments on labeling of food products that are biotechnologically based. In addition, the risks of another

agricultural technology, pesticides, were being questioned in a National Academy of Sciences report on pesticides in the diets of infants and children since data are not available.

The NABC open forum on the risks of agricultural biotechnology was structured around a roundtable discussion, seven invited plenary speakers, and four concurrent workshops. Each workshop had two co-chairpersons who also served as roundtable discussants. The backgrounds of the plenary speakers and workshop co-chairs were as diverse as those of the participants.

Roundtable: A Public Conversation about Risk

Marshall A. Martin, NABC 5 organizing committee co-chair, moderated a thought-provoking, and often lively and spirited, opening to the NABC 5 meeting. The ideas conveyed in the roundtable set the stage for the remainder of the meeting. (Part IV, page 115, contains a complete transcript of the roundtable discussion.) Different scientific and personal views were expressed about the risks and benefits associated with various technologies, such as alternative modes of travel, consuming dairy products from cows treated with bovine somatotropin (bST) and eating genetically engineered tomatoes. These specific products of biotechnology were selected to draw out a number of issues—such as the role facts, values and emotions play when assessing risk—that were addressed later by the invited speakers and in the workshops. The discussion about the Flavr Savr™ tomato, *Bt* tomato and bST milk, illustrated how individuals can have different tastes and preferences for food, can differ frequently in their environmental concerns, can desire varying levels of information about food products, can have food allergies that might require labeling of transgenic foods, and can display substantial diversity in their knowledge and understanding of agricultural biotechnology. Hence, both technical and other risks and benefits must be considered, though neither is easy to quantify.

PLENARY SESSIONS

During the first full day of the meeting, participants heard presentations from five invited speakers.

Risk Assessment and Communication

Roger A. Balk, an ethicist at the Royal Victoria Hospital in Montreal, spoke on the topic of "Public Values and Risk Assessment." Dr. Balk caught the audience's attention by recalling the story of Henny Penny who concluded, from being hit on the head by an acorn, that the sky was falling—jumping to conclusions that there is a risk without the relevant facts can lead to differ-

ent, but real risks. Drawing examples from the field of medicine, Dr. Balk described a three-tiered system which would allow advanced technology to be supported while protecting those who would be its beneficiaries. Key elements of this system included: 1. the principle of informed consent; 2. the requirement that all applications for support of new technology be subjected to scientific and statistical cost/benefit analysis; and 3. the development of a process through which principles maybe combined with data to guide regulation of the products of new technology. Dr. Balk applied this system to some current, controversial agricultural biotechnologies—bST and Flavr Savr™ tomato.

The next speaker, Sharon Dunwoody, addressed the subject of "Telling Public Stories About Risk." Drawing from her own experiences in dealing with the discovery that her basement may contain asbestos, Dr. Dunwoody, a professor of journalism and mass communications, discussed how people choose information channels when faced with a risky situation. These channels are used to learn about risk as well as to decide how to respond to that risk. She concluded that, given an array of information channels, individuals choose different channels to help them make decisions about different dimensions of a risk. The cost of a channel is also a choice factor. While mass media may be an inexpensive, easily accessible, and important source of information about a risk, persons seeking guidance on appropriate responses to a recognized risk prefer the channel of personal counselors who can take their individual situation into account.

Risk Assessment and Public Perception

During the second plenary session, Roy L. Fuchs spoke on "Risk Assessment: A Technical Perspective." Dr. Fuchs, a Monsanto scientist, presented the perspective of the regulated agricultural biotechnology industry. He began with an overview of the regulatory authority of the various federal agencies and then summarized the approach taken by Monsanto to ensure the safety of one of its biotechnology products: genetically modified potatoes expressing resistance to the Colorado potato beetle. According to Dr. Fuchs, Monsanto's guiding principles were: 1. to establish that the modified potatoes were "substantially equivalent" to the unmodified and widely consumed Russet Burbank potato; and 2. to confirm the environmental, human, and animal safety of the protein products encoded by the two genes introduced via genetic engineering. During the course of his talk, Dr. Fuchs provided numerous examples of the kinds of technical data gathered to evaluate the safety of a genetically modified food.

In his presentation titled "Public Perceptions of the Benefits and Risks of Biotechnology," Dr. Thomas Hoban, a sociologist at North Carolina State University, described results from an extensive national telephone survey and subsequent focus groups. In reviewing conclusions from the survey, Dr. Hoban emphasized that the public is generally optimistic about the potential benefit from and safety of biotechnology in agriculture and desires more information about agricultural biotechnology. However, when specific applications were discussed, considerable variability in perception was uncovered regarding: 1. the public's confidence in sources of information and regulations; and 2. a number of concerns over certain types of products. Survey results indicate that people are more likely to accept plant than animal applications of biotechnology. Views about the morality of biotechnology are very important. Also, respondents want to play a greater role in decisions about biotechnology—he suggested that surveys provide a cost-effective and systematic mechanism for public participation.

Following the Thursday evening dinner, Jerry Bishop, deputy news editor for science with the *Wall Street Journal,* addressed the topic of "Communicating with the Public about Risk." Mr. Bishop recalled the continual stream of risk-associated issues which appears in the news each day. He noted that scientists often criticize journalists for irresponsibility in giving credence to issues, spokespersons, and data which have not been reviewed and evaluated through the critical eye of the scholarly peer-review process. He pointed out that it is often because an issue is controversial that it is of interest to the public and newsworthy. Mr. Bishop reminded the audience that newspapers and other print media must select articles with an eye attuned sharply to what the public wants to read, not what the public should read, if they want to continue publishing.

Risk Assessment and Public Perspective

In the opening plenary session the next morning, Dr. David MacKenzie spoke on "Regulatory Risk Assessment: A View from the Potomac." A U.S. Department of Agriculture (USDA) administrator, Dr. MacKenzie provided an overview of current biotechnology regulation and reviewed the underlying process of risk analysis. In his discussion of risk analysis, Dr. MacKenzie defined such terms as hazard, risk, risk analysis, risk assessment, risk management, risk characterization and risk communication. He emphasized that the science (risk assessment) and the policy/decision-making (risk management) must be kept separate. Dr. MacKenzie also discussed issues regarding the Federal Coordinated Framework for Regulation of Biotechnology. He explained how it has been difficult to fit into the Coordinated Framework

the regulation of agricultural research and product development because this was a previously unregulated area (as opposed to pharmaceuticals). He indicated that, while regulatory gaps exist, the agencies have done a good job of incorporating agricultural regulation and have worked well together. Although the Coordinated Framework focuses biotechnology regulation on the product rather than the process, the issue of how to identify a hazard before the fact has not been resolved. Thus the process by which a specific product is made may need to be considered as the safety of the product is reviewed. Dr. MacKenzie discussed the future challenges for biotechnology regulation. Educating the public about the scientific facts of biotechnology and reaching consensus by reconciling conflicting worldviews about biotechnology through ongoing dialogue are especially important.

The final plenary speaker was Mr. Will Erwin, an Indiana farmer, who spoke on "Risk Assessment: A Farmer's Perspective." In a warm and thoughtful presentation, Mr. Erwin described the farmers' perspective on new technology in general, characterizing farmers as informed risk-takers. He went on to discuss how farmers' concerns are often dichotomous. On the one hand, farmers exhibit personal concerns over the safety of agricultural practices and products for the environment and the public. On the other hand, farmers also have business concerns over regulatory requirements, profitability, the effect of technology on the structure of the industry, and public demand for products. Mr. Erwin emphasized the complexity of the technological issues involved and the need for more information presented clearly to a nontechnical audience. He pointed to the prevailing sentiment of public distrust of what they do not understand and of technology in general, and the pervasive public lack of confidence in government oversight. In his concluding remarks, Mr. Erwin cautioned that people may look to sources other than science for guidance in resolving troublesome technological issues when their culture is saturated with information and hyped with fear.

WORKSHOPS

In addition to attending the roundtable discussion and plenary sessions, NABC 5 participants each took part in one of four workshops: 1. Technical Risk Assessment and Regulations; 2. Public Assessments of Benefits and Risks; 3. Public Values: Benefits and Harms; and 4. Public Communication About Risk. The goal of the workshops, as at all NABC meetings, was to encourage frank discussion and to seek consensus, where possible, on the major issues in order to devise specific and useful recommendations for issue resolution and policy formation. While many of the stakeholders and interest groups represented at NABC 5 had attended previous NABC meetings,

this was the first NABC meeting for the majority of attendees. There were an unusually large number of farmers and representatives of the print and electronic news media at the Purdue University meeting. For many of these people, this was also their first workshop experience.

Participants in each workshop spent six hours identifying and discussing key issues and developing recommendations of appropriate responses. Their recommendations were then presented for discussion by the entire group of participants during the final afternoon. A few highlights from the workshops are outlined below. For complete reports with a full list of recommendations, see Part II beginning on page 19.

Technical Risk Assessment and Regulations

Part of the public debate about agricultural biotechnology has focused on the measurement and regulation of risk. Discussion in this workshop co-chaired by Rebecca Goldburg (Biologist, Environmental Defense Fund) and William Greenlee (Pharmacology and Toxicology, Purdue University), focused on aspects of risk characterization and risk management. Major issues identified by workshop participants included: 1. hazard identification of biotechnology products and processes; 2. establishment of scientific standards for measuring risks associated with biotechnology; and 3. better balancing of benefits and risks. Specific recommendations included:

More input is needed from the scientific community (e.g., commission study by the National Academy of Sciences) to develop hazard identification methodology for agricultural biotechnology products;

Legislative gaps in regulatory authority should be filled (e.g., fish, shellfish);

Land-grant universities need to address issues such as sustainable agriculture, family farms, pesticide use, for which biotechnology now serves as a lightning rod or even a surrogate focus;

Models should be developed to assess the toxicity and allergenicity/antigenicity of expressed products as part of developing risk assessment guidelines.

Public Assessments of Benefits and Risks

Public perceptions may make or break the introduction of agricultural biotechnology products. People's actions will decide which applications ultimately survive and which directions future research will take. Public perception research has shown diverse concerns about the risks associated with agricultural biotechnology. Participants in this workshop co-chaired by Ted

McKinney (Community Affairs and Contributions, DowElanco) and Ann Sorensen (Center for Agriculture and the Environment, American Farmland Trust), discussed public reactions to agricultural biotechnology, societal ties between the people and their leaders, and the public policy formation process. Two major themes emerged from this workshop: 1. a possible paradigm shift in society's view of the role of humanity, science and technology in our world; and 2. the potential for biotechnology to significantly change our lives and our environment. The group's perception was that these themes are conflicting and suggest that the debate over acceptance of biotechnology will be influenced by more than scientific facts alone. Participants agreed on the need for better understanding of public values and attitudes toward biotechnology and its products. Specific recommendations from the workshop participants include the following:

Develop and implement methods of identifying and monitoring public understanding of and awareness about issues and potential changes being brought about through biotechnology;

Place additional emphasis within education and the educational process defining, assessing and understanding risk and decision-making under uncertainty;

Expand the capacity and commitment of the scientific community to more effectively communicate with the public;

Broaden involvement of stakeholders in identification of priority needs to be addressed by biotechnology.

Public Value: Benefits and Harms

Agricultural biotechnology has generated an ethical debate on actual and perceived benefits and harms. In some cases, scientists cannot measure risks because potential hazards have not been clearly delineated. Issues have arisen over the use of particular biotechnology processes (such as genetic engineering), the adoption of individual biotechnology products (such as genetically engineered tomatoes), and over decisions concerning regulation, research, intellectual property rights and other aspects of biotechnology. Each person views these issues through a unique framework of values composed of ethical, religious, economic, scientific and other beliefs. In the workshop on Public Values: Benefits and Harms co-chaired by Rosetta Newsome (Scientific Affairs Information, Food Technologists) and Lilly-Marlene Russow (Philosophy, Purdue University), participants discussed why a diversity of views occurs,

how these diverse views are formed and expressed, why or how they might be changed or harmonized, and who should make these decisions. The major issues identified by participants in this workshop included: 1. who should make decisions regarding biotechnology and its products; 2. what criteria are used to assign value to new biotechnology; 3. how safety is a factor affecting biotechnology; and 4. where communication about biotechnology needs to be improved. Following are some of the recommendations that were made to foster broader participation among stakeholders and to develop institutional mechanisms to enhance such an exchange of information and viewpoints:

Encourage and foster broad participation through a system responsive to stakeholders' input;

Be sensitive to religious concerns and provide information in food labeling accordingly;

Develop information which is clear and understandable, so as to be accessible to people with a variety of educational backgrounds;

Assess the social/economic impacts of specific biotechnology applications at the earliest state possible;

Single out and support land-grant universities and extension offices as particularly appropriate forums for discussion and dissemination of information;

Support better education at all levels, beginning with kindergarten.

Public Communication about Risk

The electronic and print media play a critical role in reporting information and ideas to the public. Editorials, newspaper and magazine articles, books, movies, and news and informational television programming all shape public understanding of and attitudes toward agricultural biotechnology. Effective risk communication requires that persons in the media have an understanding of the technology, the ability to use modern communication systems, and an awareness of people's concerns and interests. Participants in this workshop co-chaired by Karen Bolluyt (Agricultural Information Services, Iowa State University) and David Judson (Gannett News Service) explored ways to conduct an effective dialogue on agricultural biotechnology to help society and consumers make informed long-term evaluations of the risks and benefits of biotechnology. Major issues identified included: 1. circular communication

with effective consumer feedback must be developed and maintained; 2. improvements are needed to enhance the clarity and accuracy of the content of the message communicated to the public about biotechnology; and 3. greater effort is necessary to augment the credibility of biotechnology communicators. Specific recommendations include the following:

Focus on specific products or technologies, discussing risks or benefits for specific groups;

Base information on sound science, identifying the source's qualifications and affiliations;

Provide product information and access to process information;

Use language and concepts that the audience understands;

Share new and existing information from focus groups and surveys as widely as possible;

Employ mass media and targeted media to reach audiences, elicit responses from them, and build coalitions.

TYING IT TOGETHER

At the close of the conference, Dr. Theodore L. Hullar, Chancellor of the University of California, Davis and member of the NABC Council presented wrap-up comments for the group to consider as they returned to their daily professional routines. He noted how the meeting had captured society's frustration with the public policy issues surrounding biotechnology and had illuminated the centrality of social concerns regarding risk. Dr. Hullar commented on the uniqueness of the era in which discussions of biotechnology are held. He also explained the uniqueness of the issues raised by biotechnology. This uniqueness is derived from: 1. the scope and pervasiveness of the technology; 2. from the fact that biotechnology reaches closer to the centrality of life itself than do other technologies; and 3. agricultural biotechnology's enormous power because of its application to multiple potential targets, its dissemination into the environment, and its extension beyond the range of individual control.

In conclusion, Dr. Hullar affirmed his belief that the NABC format was working and that participants in this meeting would leave thinking differently as a direct result of the NABC experience. He challenged the participants to search for new risk evaluation paradigms and to engage in joint

efforts, involving both social and biological scientists, to deal directly with the socioeconomic issues which biotechnology raises. Furthermore, he recommended that USDA proceed with a critical evaluation of socioeconomic issues associated with such topics as agricultural biotechnology and sustainable agriculture by fully funding basic and applied research on these topics through the National Research Initiative. He also supported the desirability of joint public-private partnership in the evaluation of the social implications of proposed new biotechnology products. Dr. Hullar concluded by emphasizing the need for these discussions to move from the realm of theory to the personal/practical level.

The fifth annual NABC open forum concluded with the new Chair of the NABC Council, Bill R. Baumgardt, Director of Purdue University's Agricultural Research Programs, charging the participants to take home with them the information from both the plenary sessions and workshops and from the many conversations in the corridors and over meals, and to implement the recommendations whenever and wherever possible. Reminding those present that individuals matter, he encouraged that broad, meaningful dialogue on agricultural biotechnology continue and wished all participants productive conversations about risk.