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Workshop Report

To set the stage for further discussions, the workshop began with presentations from two speakers who offered alternative viewpoints on the impact of biotechnology on meat and animal product safety. The view of the first speaker, David Berkowitz, Office of Biotechnology, Food and Drug Administration, was that healthy transgenic animals are as safe as traditionally bred animals if the transgene product is safe. Biotechnology provides the potential to predict, understand and control the genetic basis of animal improvement in precise ways.

The perspective of a rural resident, former farmer and member of the Minnesota Food Association, a nonprofit organization interested in food and agricultural issues, was provided by Dianna Hunter. She broadened the definition of safety beyond animal and meat product safety in the marketplace. Ms. Hunter defined safety as "the absence of good honest reasons for fear" and for her, there were many reasons to fear animal biotechnology.

Ms. Hunter also warned against public relations-style communication models which seek to tell in monologue rather than to listen in dialogue. She reinforced the need for dialogue between groups representing divergent views about biotechnology with open and honest communication and mutual respect for alternative viewpoints.

A pre-meeting survey of registrants found over 80 percent of respondents disagreeing that foods derived from the products of agriculture biotechnology will be less safe than today's food. However, workshop participants, after review, did identify some potential safety problems for discussion. These included unanswered questions about bovine somatotropin (BST), allergenicity and questions about a number of products for which there are as yet no data bases, for example, transgenic animals and animals administered recombinant DNA products. On the positive side, the participants acknowledged the promise identified by past NABC attendees for new biotechnologies to produce diagnostic tools for food safety testing of animal products (See *NABC Report 2*, 1990).

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^{*}When this workshop was held, Dr. Harlander was with the University of Minnesota, Department of Food Science and Nutrition.

Finding common ground was more difficult and frustrating once the group moved past the fairly narrow, but controllable, technical hazards to the myriad of intellectual and social elements that people bring to a decision about the safety of any entity, food included. Before moving to the identification of social issues, participants identified elements from three other categories—animal welfare, the environment and social concerns. The first was the topic of another workshop and was not pursued further. Some ecological/environmental problems were mentioned including those arising from the release of transgenic fish, the possible narrowing of the genetic base for domestic animals and the, as yet, unstudied effects of the "short-circuiting" of adaptation in domestic species of animals through genetic engineering.

At this point, participants stepped back to list the major concern of each of the participants about the safety of biotechnologically produced meat and animal products. The items fell into four different areas, each listed and discussed below, including two that had significant social aspects. Small groups were formed to discuss these issues and bring recommendations back to the total workshop group for discussion.

THE SAFETY OF TRANSGENIC ANIMALS AND ANIMALS ADMINISTERED RECOMBINANT DNA PRODUCTS

- Use of transgenic animals to produce pharmaceutical agents for use by humans. Certain transgenic animals are producing pharmaceuticals for use by humans, such as pigs producing human hemoglobin and sheep producing a blood clotting factor. These "pharm" animals may enter the human food supply, but before they do, their safety must be assured. All workshop participants agreed to the need for a data base on the nutrient composition and levels of relevant hormones and residues in these animals to reassure scientists and the public that there are no detectable differences from levels of these substances in traditional animal products. There was not a consensus in the group as to how extensive the data base would be and what it would contain.
- —Animals administered recombinant DNA products: 1. hormones—there are provisions for their regulation by FDA already in place (i.e., regulation of recombinant BST); 2. vaccines of three types—inactivated, gene deletions and live-vectored. The latter two are the ones of concern. None are licensed for release yet although one is being field tested. There was consensus that the regulations under the National Environmental Protection Act (NEPA) and the testing protocols were probably adequate; and 3. direct-fed microbials—these are feed additives such as yeasts, bacterial enzymes and probiotics. FDA has the authority to regulate these but has not been doing so. Participants agreed that FDA should investigate direct-fed microbials more carefully in the future, when applications for recombinant products are received.
- —Long-term consequences of breeding transgenic animals. The concern here is the unknown potential for unexpressed genes to cause other changes

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in animals that may not be expressed for several generations. Some in the group believed that animals should be observed for longer than one generation to detect any such changes. Others believed that observation of the first generation of offspring was sufficient. The group did not agree on whether other data bases should be developed on transgenic animals to assure the public that there are no differences in the levels of various chemical compounds in the meat of these breeds compared to animals now on the market. The final recommendation in this area speaks to the need for remaining aware of the possibility of cloning defects in embryo transfer and cloning experiments.

BIOTECHNOLOGICAL TOOLS TO ENHANCE FOOD SAFETY AND QUALITY

—Animal products are the major source of microbial contamination in the food supply, so that use of DNA probe assays and immunoassays for the detection of pathogens is to be strongly encouraged. Large-scale detection of pathogens is impractical with present technology. Unavailability of rapid and economically effective methods for detection of undesirable materials and contaminants during animal production and processing hinders application of intensive inspection protocols. Biotechnology is the most promising source of tools that can yield rapid, sensitive, specific and cost-effective diagnostic tests for the presence of microbiological pathogens, antigens, toxins and other compounds-of-interest to improve food safety. New diagnostic capabilities can also be used to detect adulterated foods and as a screening method for allergens in the food supply.

The rapid detection of contaminants should lead to the development of improved processing methods and a decrease in the incidence of food borne illness in the population. There was consensus in the workshop that research and application of these tools should move ahead rapidly.

—Genetic markers also offer the potential to improve the healthfulness and safety of the food supply. They allow more rapid and effective application of traditional or conventional genetic selection practices. These new techniques can improve selection for multiple beneficial traits without a substantial loss of progress in other traits of interest. Improvement of resistance to diseases, or colonizations by parasites or human pathogens, decrease the frequency of application of therapeutic drugs and moderate degeneration of animal health, thereby reducing the presence of unwholesome products in the food supply. Genetic markers can also be used to breed for improved macronutrient composition, such as decreased fat in animals. For these reasons the group also endorsed continued research on the use of the genetic markers techniques.

DEFINING FOOD SAFETY

—The larger issue here is how to define food safety. Some participants argued the present definition is too narrow, ignoring quality issues as well as

the fact that food safety is a social construct, as illustrated by the different definitions and standards for food safety held by different cultures and countries. They felt that social, economic and political issues should be evaluated concurrently with the evaluation of efficacy and human and animal safety. Others disagreed with all of these ideas and argued for maintaining the present system of relying solely on technical data for safety decisions. The latter participants did recognize that social, economic and political issues should be discussed. After further comments the workshop debated a recommendation that a mechanism should be set up for formal consideration of the social, economic and environmental ramifications of agricultural biotechnology products. It was noted that there are already regulatory requirements for reviewing environmental consequences, but the group felt it important to state the need for review of environmental consequences. There was not consensus about whether the mechanism should be separate from, or integral to, the present system.

The participants also did not reach consensus on a recommendation that the products of agricultural biotechnology should be continued to be evaluated on a case-by-case basis using current regulations or methods. Some argued that the recommendation was unnecessary; others that we might not want to exclude the possibility of improving or changing the regulatory process.

COMMUNICATING WITH THE PUBLIC

This section of the report and recommendations is premised on a consensus agreement that the public has a stake in maintaining public institutions provided they are responsive to public needs. The decline in the credibility of scientists and public institutions should alert us to the fact that the public does not feel that its needs have been taken into consideration and that one of the reasons is the inability of the institutions and scientists to communicate with the public as equal partners in dialogue.

In the small group discussion the watchwords were: 1. know your audience and 2. listen to what they have to say. This is not as easy as it sounds because many (but not all) scientists have perceptions and biases that are quite different from the various perceptions and biases of public groups which makes it difficult for scientists to be good communicators. There is also the serious problem of lack of support for these activities in the reward structures of institutions and of an imbalance in funding going to high technology research versus research in policy and communications. These were all considered in the following set of recommendations, all of which were endorsed by all workshop participants.

—There is a body of knowledge about communications that scientists should use to improve the dialogue with the public. These include strategies like audience segmentation and use of focus groups. Ongoing survey research on scientist and consumer attitudes could be very helpful.

- —Regional research projects should be promoted and funded and the National Research Initiative should be encouraged to put more funding into its policy and marketing line item to promote public understanding of agricultural biotechnology. Other agencies and entities such as foundations, other nonfederal agencies, industry and academia should be encouraged to promote such research and programs.
- —Interdisciplinary work between the biological and social sciences should be promoted and recognized as critical if serious progress in this area is expected.
- —In all grant proposals the technical significance and relevance of research should be communicated in terms the general public (or anyone outside the particular discipline) can understand. This is part of the ongoing discussion on the balancing of academic freedom versus public input into research priorities. At this point there are inadequate mechanisms for receiving input from those who do not have the knowledge and funds to lobby at the state and federal level. Advisory committees that have a broad representation of the public and heterogeneous interests should be constituted to work with colleges or departments directly.
- —Continuing education programs should be developed for scientists to teach them how to more effectively facilitate two-way communication between scientists and the general public. Scientists need to learn how to recognize and understand the content and validity of a range of social, environmental and economic concepts that include the discussion of food safety issues by the public. They also need training in media relations and the communication process.

The workshop participants also recognized, as has been true in many other discussions of this type, that the public, starting at the grammar school level, would be well served by educational programs on the social, moral, economic, political and scientific issues surrounding biotechnology.

In order to accomplish any wide-ranging change in faculty behavior in these areas it will be necessary to re-envision the mission of the land-grant colleges to serve all their publics and recognize that the responsibility for this is shared by all institutions of higher education. This will change the weight given to public service or extension activities in promotion decisions and bring this area into better balance with research and teaching.

The workshop was quite remiss in failing to discuss in any detail the issue of labeling of products produced through biotechnology, and the contribution and relationship of labeling to communication with the public. We see this as an important topic for a future NABC meeting. [Editor's note: the NABC 5 optional seminar will address the topic of labeling.]