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Overview

NABC 4, the fourth annual open forum on agricultural biotechnology, was devoted to issues in animal biotechnology. The May 1992 meeting was held in College Station, Texas and hosted by Texas A&M University. Animal well-being, the safety of animal food products and regulatory issues were on the agenda along with the examination of links between animal biotechnology and new opportunities in human and animal medicine. Previous NABC meetings had focused upon sustainability, food safety and quality, and the financial and regulatory prospects for agricultural biotechnology at a crossroads. Animal biotechnology, especially recombinant DNA research on agricultural animals, however, has opened doors to entirely new areas of human endeavor, many of which were not well understood in the past. The NABC 4 presentations and discussions on animal biotechnology revisited several themes that had been discussed at previous NABC meetings, but also broke ground in identifying several key topics that had not been examined at Ames, Iowa in 1989; at Ithaca, New York in 1990; and at Sacramento, California in 1991.

As in previous meetings, the aim of the National Agricultural Biotechnology Council was first and foremost to establish an open setting in which all perspectives and interests can be represented with participants sharing ideas, asking questions and interacting with one another. Convening under the banner *Animal Biotechnology: Opportunities and Challenges,* more than 150 representatives of industry, interest groups, government and universities opened the conversation on these topics with the goals of establishing a common base of knowledge among all participants, reaching consensus where possible, and specifying a limited number of recommendations to emerge as the product of the workshops. NABC 4 continued the trend of the three previous meetings by expanding the range of views and groups represented. Many of the participants, particularly those concerned with issues of animal well-being, were attending this open forum for the first time. Also, some participants were presented for the first time with viewpoints in sharp contrast to their own. For this reason alone, NABC 4 clearly can be said to have served the NABC mission of promoting dialogue among those with different views.

NEW THEMES

The new topic to the NABC forum was the linkages between human medicine and animal agriculture. Although animal biotechnology was addressed at NABC 1 and at NABC 3, animal well-being as a special theme was a new focus for NABC.

Animal Well-Being

The dialogue on animal well-being had been conceptualized as an opportunity to take up the question of whether developments in animal biotechnology would produce any new or unanticipated issues for the well-being of agricultural animals. Although these topics were, indeed, discussed, presentations by keynoter Michael Fox, Vice President for Bioethics and Farm Animals, The Humane Society of the United States; David Meeker, Director of Research and Education, National Pork Producers Council; and Bernard Rollin, Professor of Philosophy at Colorado State University, moved the discussions into more philosophical and broad-ranging areas. This workshop became a forum in which those who saw themselves as representing animals and those who saw themselves as representing agriculture engaged in energetic dialogue over the criteria and basis for extending concern to animals, without respect to whether biotechnology or, indeed, even agriculture was the topic of concern. As such, participants raised examples from human biomedical research and product testing, familiar forums for animal welfare debates, as a means for sounding out each other's basic views on animal issues.

The question of biomedical applications came up particularly with the "new creation" of: 1. precise animal models for human diseases; and 2. animals as "bioreactors" producing human pharmaceuticals. Rollin prompted a discussion of the dilemma of balancing the relief of great human pain and suffering from genetic diseases with the large numbers of animals that would experience great suffering. He suggested researchers could eliminate the pain centers of such animals, but noted that this, too, raises ethical and aesthetic concerns.

Although the heated discussions in this group produced limited consensus, there was general agreement that it is acceptable under conditions where animals do not experience great suffering, to use animals for human use—whether for food production, as "bioreactors," or as research models for improving human and animal health.

The intensity of discussions in the group was evident to all meeting participants and issues of animal well-being wound up being raised (sometimes briefly) in every workshop. In the shadow of such lively dialogue, the workshop group examining links to human health felt itself to be too homogeneous with few issues on which participants opinions diverged. The group invited a participant from the animal well-being workshop to a session to learn, at least, what the hubbub was about. Although the agenda was broader,

and the consensus achievements occurred in other areas, the 1992 meeting will undoubtedly be remembered as the "animal welfare" meeting of the National Agricultural Biotechnology Council.

Links to Human Health

Recombinant DNA research on farm animals conducted in animal science departments of agricultural universities and in colleges of veterinary medicine, has begun to bring the scientists in these areas into the prospects and controversies that have traditionally been associated with biomedical research. As highlighted by keynote speaker Neal First, Professor of Animal Science at the University of Wisconsin, animal biotechnology continues to establish breakthroughs in reproductive technology, enhance genetic changes in animals and improve animal health. He conveyed to the participants some of the excitement felt by researchers, himself included, as they push the frontiers of animal science forward. It was noted that basic research aimed at disease control in animals often spills over to human applications. Fuller Bazer, Animal Science Department, Texas A&M University, asserted that "When human and animals have diseases with common etiology and genetic markers of the disease, genetic or therapeutic solutions will favorably impact both human and animal health." What is more, Clifton Baile, Director of Research and Development at Monsanto, suggested that intensive public and private funding for research in biomedical applications such as gene mapping and pharmaceuticals will produce techniques, methods and models that will shorten the time for product development for those working on farm animals.

The workshop participants actively discussed the need for connections, or "new linkages," between human medicine, animal medicine and animal agriculture. They saw a major potential for expanding the dialogue and research interaction among these groups, suggesting that soon the justification for animal biotechnology may be its great benefits to human health, not just animal productivity.

It was, however, noted that as agricultural researchers expand their research and interact directly, or even indirectly, with biomedical researchers, they can expect to face some of the problems that have existed in public health and the biomedical research policy arena for some time. These include an intense public interest in reproductive technologies, in part because of their relevance to the abortion issue, and also a level of public concern for the well-being of animals exceeding that hitherto experienced in connection with food animals. As such, the workshop on animal well-being experienced an overlap with the workshop on animal biotechnology links to human health that meeting organizers had not anticipated. When continuing discussions on food safety and regulatory policy were added into the mix, the two-plus days of the meeting proved stimulating.

REVISITED THEMES

Communication and Open Dialogue

The only issue that could rival animal well-being as a main current at the 1992 meeting was the continued call from participants for open communication and the need for all stakeholders to be involved early and continuously in the dialogue on biotechnology. The highly publicized White House announcement of the FDA's policy for evaluating the safety of foods of plant origin made on May 26, 1992, the day before the meeting began, resulted in several diverse groups in attendance at NABC 4 openly expressing concern that if biotechnology is to gain public acceptance, policies must be developed within an open framework with opportunity for input by all interested stakeholders. While most in attendance were not against the announced policy per se, participants on "both" sides of other biotechnology issues followed press coverage of the announcement all week, expressing the view that the announcement reflected little understanding of how public concerns and questions about biotechnology can be addressed in a manner that inspires confidence in the regulatory process.

At the final plenary session, in response to a recommendation by the participants in the Regulatory Issues workshop, several participants spoke forcefully in favor (no one spoke in opposition) of NABC corresponding with appropriate federal officials urging more open dialogue during future deliberations about agricultural biotechnology policies.[1]

Ironically, the announcement of this policy spoke directly to two of the concerns expressed as major themes of the 1991 NABC meeting in California. There, U.S. competitiveness had been linked to a need for clear delineation of regulatory procedures for research and product development. The policy which was, in fact, being announced for comment, was a response to both themes.

The two overarching currents of NABC 4—animal welfare and the call for open dialogue—point toward reiteration of a conclusion that was reached at the 1990 NABC meeting in New York State: concerned parties in the food arena have failed to talk with each other, much less communicate. Regrettably, much the same conclusion was reached by the 1992 workshop on Meat and Animal Product Safety. Participants were in strong agreement that differing groups fail to interact and called on scientists to begin to communicate with the public as equal partners.

Defining Food Safety

This failure to interact and communicate became evident in discussions on *how to define safety.* There were those, mostly scientists, responding to the

[1] Editor's note: Letters were sent to Vice President Quayle and the heads of HHS, FDA, EPA and USDA expressing NABC's belief that the acceptance of government efforts by the public can be enhanced only when policies are developed and perceived to be developed with appropriate input from all interested parties.

presentations of David Berkowitz, Office of Biotechnology, FDA; Russell Cross, Administrator, USDA/FSIS; and John Frydenlund, Deputy Assistant Secretary, Marketing and Inspection at USDA, who felt that safety should be defined in terms of whether eating a product will cause injury or disease. They urged that scientific principles be used to; 1. assess the probability of foodborne injury to health; and 2. target foods where alterations associated with biotechnology might increase the probability of harm (e.g., allergenicity). A second view was represented by Dianna Hunter, a former small farmer and member of the Minnesota Food Association, who interpreted safety as "feeling confident about one's food." Factors that influence such confidence include whether the food is being produced and provided through a trustworthy source. Many participants agreed that nonscience factors (e.g., social, economic) can influence whether a source is deemed trustworthy and should be considered in the assessment of foodborne risk.

The 1992 meeting illustrated the need for biotechnology industries and high-level government officials to get behind the goal of increasing two-way communication where biotechnologists listen to the nature and shape of public and interest group concerns before formulating their messages about the safety, efficacy and benefits of biotechnology.

Regulatory Policy

A recurring theme in all the workshops was the need for clear regulatory policies for agricultural biotechnology whether for food, pharmaceuticals or animal use or release. In the workshop on Regulatory Issues, participants felt that pharmaceutical products have been foremost in the thinking of regulators who have concluded that the existing framework for biotechnology regulation is adequate and that all forms of regulation should stress product over process. Martin Terry, Vice President for Scientific Activities, Animal Health Institute, expressed the frustration of industry faced with different regulations depending on product classification as a drug or a food. He called the groups attention to both the debate on extra-label drug use in animals and the crisis in drug availability which currently besets animal agriculture. From the environmental perspective Margaret Mellon, Director, National Biotechnology Policy Center, National Wildlife Federation, argued a need for regulatory action, noting that there are several areas, including fish and wildlife, where animal scientists are undertaking biotechnology research in the absence of clear regulatory authority.

The group also discussed how process and point of origin have traditionally been important to consumer acceptance of agricultural products. Virtually every state claims that its soils, climate and farmers produce the best potatoes, onions, wine, pork or something. Furthermore, it was noted that the Food Safety Inspection Service (FSIS) has made decisions based on judgements that are not supported by risk-based reasons. For example, FSIS does not allow lungs to be used in meat products based on the cultural

judgement that consumers do not want meat products in which lungs are used—in the U.S. lungs are not classified as food. As such, participants felt that a decision to consider only risk-based regulatory policies for agricultural biotechnology leaves many questions unanswered, for example, labeling and product certification—another continuing theme that emerged in each workshop only to be shelved by each noting the need for a future NABC forum on the issue of labeling of biotechnology food products.

The 1992 meeting explored new issues and revisited several continuing issues. NABC 4 established a series of key understandings that should shape the direction of animal biotechnology research, product development, policy and administration for the coming decade. There was overwhelming consensus that greater public understanding of biotechnology processes and products and greater public participation in the decision-making process was not only desired, but essential, if agricultural biotechnology is, indeed, to be the growth industry of the 21st century.