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# *Workshop Highlights and Recommendations*

NABC 4 featured four concurrent workshops focusing on areas of concern in agricultural biotechnology: Animal Well-Being, Links of Animal Biotechnology to Human Health, Meat and Animal Product Safety and Regulatory Issues. In the workshops, participants were asked to define and prioritize national issues, reach consensus where possible, and to develop recommendations. The diversity of participants helped to insure that a wide variety of issues were raised; at the same time, diverse values and goals often made consensus difficult. Consequently, workshops were also charged with identifying areas of disagreement both of fact and perception. The following highlights are from reports prepared by workshop co-chairs and reviewed by all participants in those workshops. Any inaccuracies are the result of editing and not the responsibility of the original writers. Full versions of the workshop reports and summaries, as well as background presentations, can be found in Part II starting on page 23.



## *Biotechnology and Animal Well-Being*

The workshop began with a wide-ranging discussion about the concept of well-being. Participants decided that the discussions should be limited to the well-being of animals involved in biotechnology: farm animals and experimental animals. Many felt that new technologies create new problems and raised new questions.

Individual participants listed 15 questions about biotechnology and animal well-being. It was observed that the emergence of biotechnology coincides with greater concerns about animals, increasingly cognitive views of animals, increased distance from agricultural and draft uses of animals, and urbanization and romanticization of animals. Technology is colliding with changing morality. Genetic engineering feeds into these concerns because of the general concern that the manipulation of genes could lead to unnatural beings.

By this point in the discussion the participants were quite polarized. To move the discussion forward it was suggested that some of the fundamental

concerns might be identified. Among the 16 listed were: whether it is ever acceptable to utilize animals for human use, whether animal biotechnology poses unique questions about animal well-being and whether biotechnology is qualitatively or quantitatively different from what has come before.

Following an intense discussion on the concerns, individual participants identified some possible harms and benefits to animal well-being that arise in the context of biotechnology. A highly unrepresentative straw poll was then done in order to see which of these possible harms and benefits the participants most wanted to discuss. The four possible harms (1. diverting resources away from improving traditional husbandry practices; 2. loss of genetic diversity; 3. proliferation of genetically defective animals who suffer disease as models; and 4. thinking of domestic animals as human artifacts), and the four possible benefits (1. removal of genetic defects from animal populations more rapidly; 2. better understanding of animal well-being; 3. permitting increased disease resistance; and 4. more efficient production leading to the use of fewer animals) receiving the most support, along with the possibility that animal biotechnology may lead to healthier products for both humans and animals, formed the basis of much of the remaining discussion.

## CONSENSUS STATEMENTS

Weighing the broad spectrum of issues related to biotechnology and animal well-being, participants were able to reach agreement on four consensus statements:

*1. Biotechnology may contribute to animal well-being, but it is not the only approach to improving animal well-being.*

*2. There should be responsible, systematic investigation of the benefits and harms to animals that may be associated with biotechnology.*

*3. It is acceptable under some conditions to use animals for human use.*

*4. Animal biotechnology has the potential to contribute to the "three Rs" in animal experimentation: reduction, refinement and replacement.*

## RECOMMENDATIONS

*1. With respect to animal well-being, criteria should be developed for responsible research and application of specific biotechnologies in animals. The full spectrum of opinion should be represented in the development of these criteria. These criteria should be periodically reconsidered in the light of changing circumstances.*

*2. The benefits and harms noted should be taken into account in developing these criteria.*

*3. Animal biotechnology should not be used in ways that impose great costs in animal well-being while achieving only minor human or animal benefits. When there is the likelihood that a procedure will cause great suffering to animals, alternatives should be sought.*

## *Links of Animal Biotechnology to Human Health*

As a result of the advances made in molecular biology over the last decade, the fields of animal agriculture and human medicine have come to share a wide range of techniques and models. These profound changes in the research process have raised a series of issues with respect to the use of both farm and traditional laboratory animals in research. The discussions in this workshop focused on these issues.

### HUMAN HEALTH CONSIDERATIONS DRIVING AGRICULTURAL RESEARCH

In recent years, public concern about food safety and nutrition has played an increasing role in animal agricultural research. The public is also concerned about the disclosure of the contents of food and food products as well as about broader marketing issues (e.g., product claims).

In addition, new biotechnologies blur the lines between nutrition and pharmacy, making possible the creation of what have been variously called "nutraceuticals" and "pharmafoods." These products, often of animal origin, serve a combination of nutritive and therapeutic goals. They raise complex issues of regulation, food safety and consumer education.

### ETHICAL USE OF ANIMALS

Some argue that the use of animals as food or in research is itself unethical. Others argue that humane treatment of animals is the major concern. The workshop participants agreed that it was not clear just what is ethical. Moreover, they were concerned with methods used to accommodate the wide range of views on the subject found in our diverse society. They also questioned whether current guidelines on the use of animals in research, often written before the advent of the new technologies, are adequate morally.



### ANIMALS FOR BIOLOGICS AND THERAPEUTICS

The use of animals for the production of vaccines and therapeutics has a long history. Workshop members indicated that the widespread use of animals as living "bioreactors" to produce chemicals of value to humans differed from other uses of animals, (e.g., in food and fiber production). They expressed concern as to what, if any, ethical implications were associated with it. Moreover, the use of animals as bioreactors raises some practical questions. For example, there is the problem of what to do with the carcasses of these animals. Should they be allowed to enter the food chain?

Animal bioreactors also pose problems of containment, welfare and management, raising the question of whether it would be more desirable to have certain species earmarked for this purpose and not used for food. This, in turn, raised the issue of whether whole animals or cell cultures should be used for screening of therapeutic products.

## SOCIETAL CONTEXT OF SCIENCE SHARED BY AGRICULTURE AND MEDICINE

Research rarely takes place outside a larger social context. That context provides both the limits and opportunities for research. A central issue in this workshop was how (or whether) to integrate private and public research at the agriculture-medicine interface. Another key issue was the distributive aspects of this type of research.

The group also acknowledged that new linkages between the medical and agricultural sciences will be influenced by the current state of food, agricultural and medical policy. At the same time, the discoveries and inventions stemming from this research will have a considerable impact on food, agricultural, and medical policies. In addition, workshop participants wondered whether the current institutional structures (especially at universities) were adequate for the new linkages between agriculture and medicine.

Finally, there was a general consensus that greater public participation in the decision-making process was both necessary and desirable.

## RECOMMENDATIONS

*1. Stronger links need to be developed between agricultural and medical research relating to biotechnology. Among mechanisms to do so are centers, incentives for joint programs, funding, etc. This will require further integration and institutionalization of joint agricultural and medical programs. Such linkages will need to include an examination of the ethical, economic, social, institutional, and legal ramifications of these changes.*



*2. More resources from molecular biology should be devoted to genome and other research in an attempt to ultimately spare animals from direct use in research. It should be thereby possible to shift largely from whole animal to organ, tissue or cellular systems.*

*3. Explore the moral implications of the use of animals in medical and agricultural research. Issues in the area are currently inadequately examined, and thus, there is not yet an adequate moral framework for making decisions about this type of research.*

*4. Provide for education of and dialogue among all the participants in the debate.*

5. *Improve the agenda-setting process that insures that resources are properly allocated and that all interested parties are involved in the allocation process.*

*6. Improve the guidelines to aid in determining appropriate circumstances for patenting animals, tissues, and cell lines.*

## Meat and Animal Product Safety

Workshop participants identified 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. Participants also discussed the promise for new biotechnologies to produce diagnostic tools for food safety testing of animal products.

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. 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. 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

In the area of use of transgenic animals to produce pharmaceutical agents for use by humans, the major safety concern was that these "pharm" animals may enter the human food supply, but before they do, their safety must be assured.

1. *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 consensus in the group as to how extensive the data base would be and what it would contain.



In the area of animals administered recombinant DNA products: 1. hormones; 2. vaccines; and 3. direct-fed microbials; there was consensus that the regulations under the National Environmental Protection Act (NEPA) and the testing protocols for vaccines were probably adequate. FDA has the authority to regulate direct-fed microbials, but the group felt it has not been doing so.

2. *FDA should investigate direct-fed microbials more carefully in the future when applications for recombinant products are received.*

Another concern expressed was about long-term consequences of breeding transgenic animals. The concern here is the unknown potential for unexpressed genes to cause other changes in animals that may not be expressed for several generations.

3. *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

*4. Recognizing that animal products are the major source of microbial contamination in the food supply, the use of DNA probe assays and immunoassays for the detection of pathogens is to be strongly encouraged.*

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 group also discussed how genetic markers offer the potential to improve the healthfulness and safety of the food supply.

*5. Research and application of these tools should move ahead rapidly. They endorse continued research on the use of the genetic makers techniques.*

DEFINING FOOD SAFETY

Some participants argued the present definition of "safe," relative to foods, is too narrow, ignoring quality issues as well as the fact that food safety is a social construct. 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, but there was no agreement about whether the mechanism should be separate from, or integral to, the present system.



6. *The larger issue here is how to define food safety.*

COMMUNICATING WITH THE PUBLIC

This section of the report and recommendations are premised on a consensus agreement that the public has a stake in maintaining public institutions provided they are responsive to public needs. 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 which were endorsed by all workshop participants.

7. *There is a body of knowledge about communications that scientists should use to improve the dialogue with the public.*

*8. 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.*

*9. Interdisciplinary work between the biological and social sciences should be promoted and recognized as critical if serious progress in this area is expected.*

*10. 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.*

*11. 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.*

*12. The public, starting at the elementary 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 the group suggested that 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.

## Regulatory Issues

The charge to the workshop participants was to identify and examine issues arising in regulatory treatment of animal biotechnology. Free-ranging discussion among individuals with different perspectives followed. While consensus was not sought nor achieved on the specific issues identified, these issues were deemed worthy of consideration by one, some, or many of the members of the group, and as such help to illustrate the range of concerns in the regulatory arena. Common themes of agreement did emerge and these were captured in the form of four issue statements or recommendations at the end.



The following issues and gaps have been identified in the regulatory process:

—At the research stage, there are no mandated guidelines/regulations for industrial research of animal biotechnology.

—In field testing, there are no regulations for release of fish, wildlife, insects or pets; for micro-organisms in livestock feeds or for zoonotic pathogens of animals and humans. Also there is no mechanism to deregulate similar genetically modified organisms that have been proven to be safe based upon previous case studies;

—Implementation of the ABRAC developed guidelines should govern agricultural research in the area of field testing;

—There is an inability to gain access to some information on health and safety of products because of "confidential business information" designation.

—In the food safety area there are gaps that are currently not covered by any regulations including disposition of transgenic animals and whether fish, seafood and wildlife should be included.

—In efficacy testing, the issue of whether transgenic animals used as pharmacoreactors should receive special attention from FDA was raised.

Recognizing there should be representation of broad interest, the public's role in regulatory debate was discussed. Possible mechanisms identified for improved public access included: 1. legislation regarding public participation in regulating decisions across the board; 2. publication beyond the *Federal Register*; 3. improved representation in decision-making processes; 4. open forums; 5. research on opening up scientific decision-making process; and 6. rebuilding public trust and regulatory transparency.

Other issues considered were the role of states and industry in the debates, public education, and communication. Consideration was given by the group to the level of information available for consumer choice.

Workshop participants also considered technically based regulations vs social/ethical/economic impact considerations. They noted that regulations can impact not only in the U.S., but also on international trade, as well as trade relationships with Third World countries.

## RECOMMENDATIONS

*1. The regulatory gaps delineated deserve serious investigation. NABC may wish to establish a committee or other mechanism to assist this investigation.*



*2. A more acceptable policy-making process for rules of broad applicability would be clearly understood or known (not ad hoc), transparent, and participatory. The group viewed the process by the Council on Competitiveness in the Office of the Vice President, leading to the May 26, 1992 FDA food safety decision, as falling short of the goals for an acceptable process.* (Editor's note: At the final plenary session, a recommendation was made by those present (no opposition was voiced) that NABC respond urging future processes of policy development be open and include all interested stakeholders. NABC sent letters to Vice President Dan Quayle and the heads of HHS, FDA, EPA and USDA.)

3. *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?*

*4. 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.*