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Workshop Report

The charge to the workshop participants was to identify and examine issues arising in regulatory treatment of animal biotechnology. This charge was addressed in an open forum in which free-ranging discussion among individuals with different perspectives was strongly encouraged. The two introductory talks by Martin Terry, Vice President for Scientific Activities, Animal Health Institute and Margaret Mellon, Director, National Biotechnology Policy Center, National Wildlife Federation, gave rise to an initial discussion. The approach taken by the group was to list relevant issues, group those issues into three basic categories, discuss the issues category by category and develop shared issue statements or recommendations. The issues raised by various members of the groups are listed below according to category. While consensus was not sought nor achieved on the specific issues listed, 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 this arena. Common themes of agreement did emerge and these were captured in the form of four issue statements or recommendations that represent points of consensus and, as such, they highlight important underlying concerns in this arena. The three basic categories discussed are as follows:

THE REGULATORY PROCESS *(how the process works)*

This section deals with: 1. How the system works; 2. The issues in formulating and implementing regulations; and 3. Where there are gaps in the system that are of potential safety and/or environmental risks. The following issues and gaps have been identified:

Research Stage

The National Institute of Health has not adopted Appendix Q which contains guidelines for contained research on transgenic animals. These guidelines would be helpful for Institutional Biosafety Committees and others. There are no mandated guidelines/regulations for industrial research of animal biotechnology.

Clinical Testing of Drugs
No obvious shortcomings were identified.

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;
- —Implementation of "Guidelines for Research Involving Planned Introduction into the Environment of Genetically Modified Organisms" developed by the Agricultural Biotechnology Research Advisory Committee (ABRAC) should govern agricultural research;
- —Absence of mechanism to deregulate similar genetically modified organisms that have been proven to be safe based upon previous case studies;
- —The inability to gain access to some information on health and safety of products because of "confidential business information" designation.

Large Scale/Commercial Release
There are no oversight mechanisms, guidelines or regulations for large scale commercial release:

- —Of products of animal biotechnology;
- —Of second to nth generations of transgenic animals;
- —Impact of the production system for the environment (e.g., genetically modified organisms replacing indigenous populations).

Regulatory Assessments (current regulations that relate to animal biotechnology)

Animal safety: the current regulatory system for drugs and therapeutics appears to satisfactorily cover animals that receive or are altered by biotechnology.

Food safety: foods of animal origin are regulated by USDA's Food Safety Inspection Service and the FDA's Center for Veterinary Medicine for safety, quality and efficacy. The gaps that are currently not covered include disposition of transgenic animals such as: Should they be reviewed case by case? Should transgenics receive prolonged testing before slaughter? Should fish, seafood and wildlife not be covered?

Efficacy: the efficacy of drugs is regulated by the FDA. Should transgenic animals used as pharmacoreactors receive special attention?

Market Place
Should consumers have the ability to make choices by knowing when they are purchasing products resulting from animal biotechnology?

ANIMAL BIOTECHNOLOGY REGULATIONS AND PUBLIC INVOLVEMENT

(who is involved in regulations)

The Public's Role in Debate

There should be representation of broad interest. The access to information and participation in debate should be improved for interested persons.

A dear definition of process (where input and questions, etc. can be integrated) should be known so that those wishing to participate could do so. Channels for participation may vary across agencies.

Possible mechanisms for improved access include:

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 To Be Considered

—Role of states and industry in debate;
—Public education and who has responsibilities for keeping the public informed;
—Communication and knowledge can lead to choices by the public; and
—Labeling products developed through biotechnology.

TECHNICALLY BASED REGULATIONS VS SOCIAL/ETHICAL/ECONOMIC IMPACT CONSIDERATIONS *(What is the basis for regulations? Why are decisions made?)*

Regulatory Impact

The goals of regulations include:

1. Safety of the public and environment;
2. Safety and efficaciousness of food;
3. Quality assurance of products; and
4. The safety and welfare of animals.

Regulations can impact not only in the U.S., but also on international trade as well as trade relationships with third world countries. Patenting, however, impacts as a socioeconomic factor.

Information and Consumer Choice

Consideration was given by the group to the level of information available for consumer choice:

—Is there a need for labeling which would provide the public with a way to reflect their individual values?
—Should labeling be voluntary or mandatory?
—What information should be made available?
—What are the criteria for labeling?
—Can labeling be used as an education device? Concerns voiced by participants included complexity of labels, definitions, etc.

The group acknowledged early on that many groups of people (e.g., minorities, farmers, industry) were not well represented in its deliberations; the workshop's report stems from a lower diversity of backgrounds than might

be wished. Nonetheless, a wide diversity of positions relative to animal biotechnology regulations were represented. It is the hope of the group that its recommendations may contribute to positive actions and that its listing of issues may stimulate further debate in many other forums.

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 leading to the recent FDA food safety decision as falling short of the goals for an acceptable process.*

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.*