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WORKSHOP REPORT

HERBICIDE TOLERANCE IN CROPS

Preparation of NABC for the workshop on herbicide tolerant crops (HTCs) began with a meeting at Iowa State University (ISU) during October 1990. Participants were invited from academia, federal and state government and other selected organizations to conduct a benefit/risk assess-

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ment for the introduction of herbicide tolerant crops in Iowa. The report of that meeting served as a background paper for this workshop. See page 179.

This workshop differed from the one at ISU in three important aspects: 1 - Only a few of the participants in Sacramento had attended the meeting at ISU. Consequently, the workshop at NABC³ was essentially an independent evaluation of HTCs. 2 - There was considerably less time available at NABC than at ISU, which restricted the topics that could be discussed. 3 - The participants at NABC chose to devote a large fraction of their time to a discussion of appropriate government oversight of HTCs.

The first step in the workshop process was to list comments that one or more attendees considered to be important with regard to HTCs.

The wide array of comments reflected the broad range of interests and opinions among the attendees.

The second step was to select from the list a limited number of the issues. Eight major issues were identified and the attendees individually ranked their importance. The eight issues are listed below in their order of interest to the group as determined by vote of the attendees.

- 1- Will HTCs modify herbicide use in agriculture and forestry?
- 2- Risk assessment relative to human and environmental concerns.

- 3- Socioeconomic impacts.
- 4- How will HTC be regulated?
- 5- Public perception of HTCs and responsibility for HTC education and appropriate use.
- 6- Use of public research funds to develop HTCs.
- 7- HTCs effect on food safety.
- 8- Effect of HTCs on crop management by farmers.

The first four issues were clearly the most popular; therefore, with the limited time available, the attendees decided to consider only those four issues. The attendees were divided by individual preference into four groups and each group discussed one of the topics. Each group was asked to a) clearly describe the issue, b) define the goal that the group wanted to achieve relative to the issue, c) provide recommendations on how to achieve the goal, and d) describe the criteria by which progress toward the goal would be evaluated. Summaries of the reports from the four groups are provided.

Issue 1: There is controversy about how HTCs will modify herbicide use. Despite the controversy, there was general agreement that the primary goal of research should be to ensure that HTCs result in the safer use of safer herbicides. It was also considered important to ensure that the use of HTCs should be compatible with integrated pest management systems of weed control. It was also considered important to ensure that the use of HTCs does not divert efforts away from integrated pest management systems of weed control. With new technologies becoming available to farmers, only one of which is HTCs, farmers must learn how to integrate the various options into the best management plan for their farm. Optimum weed management strategies should rely on integrated approach, which may include crop rotation, cultivation and the minimum use of chemicals.

To attain the goals defined for HTC development, it was recommended that *field research studies should be conducted that compare alternative weed control strategies*. The studies should consider how HTCs will affect the overall production system, including soil conservation practices and minimum tillage systems.

It is recommended that *HTC research should be focused on herbicides with the following attributes: low toxicity to non-target species, including humans and wildlife; low residues in the environment, including ground wa-*

ter, surface water and air; nontoxic residues in the crop and food; low use rates; appropriate degradation (breakdown) to benign breakdown products; cost effectiveness; compatibility with alternative weed management strategies; compatible with technology improvements in the way the herbicide is applied; and increased reliability of weed control accompanied by improved crop yields. It will be important to investigate whether the use of certain HTC's would increase worker or consumer exposure to a herbicide. The group did not discuss whether research on HTC's should occur in the public as well as the private sector.

Success in achieving the goals of the safer use of safer herbicides and ensuring that HTC's are compatible with integrated weed control systems would be measured by the identification and development of economical weed control systems for farmers that also are beneficial for society.

Issue 2: There is a need to identify any health and environmental risks specifically associated with HTC's.

Issue 3: The socioeconomic impact of HTC's should not be a regulatory criterion for product approval by government agencies. Information concerning the socioeconomic impact of HTC's should be publicized to permit consumer choice and any requisite governmental mitigating effort.

Issue 4: There is a lack of regulatory policy to regulate some aspects of HTC's.

The reports of the groups that considered issues 2,3 and 4 are presented collectively, since all three issues concerned the regulatory process. Participants first agreed that any health and environmental risks associated with HTC's need to be identified and that criteria to assess these risks should be developed. Examples of possible risks include the transfer via pollination of a gene conferring herbicide tolerance from a genetically engineered crop to a related weed and the safety as food of crops genetically modified to tolerate herbicides.

The group made three recommendations concerning possible health and environmental risks. First, *environmental data for HTC's should be evaluated on a case-by-case basis.* The biology of the crop, the nature of the genetic modification and the characteristics of the herbicide the crop has been genetically modified to tolerate should form the basis for evaluations. Such evaluations should be performed in a reasonable time frame. Second, *the federal government should, on an ongoing basis, use public funds to construct a database from information obtained from small-scale field tri-*

als of HTCs. The database would be used to codify data relevant to questions concerning environmental risks and to identify knowledge gaps. Third, *guidance should be provided to ensure that seed companies and other institutions developing HTCs ensure the food safety and quality of the crops.* Some participants cited guidelines developed by the International Food Biotechnology Council¹ as appropriate.

For both the first and third recommendations, participants felt that the impact on the cost of products and the development of minor versus major crops should be considered.

Participants agreed that regulatory policy covering some aspects of HTCs is lacking. Although the group did not discuss precisely which aspects of regulatory policy needs to be clarified or established, the group agreed that a fair, timely process clarifying or establishing regulatory policy is needed. Participants recommended that *a policy stating what is regulated and who regulates it should be articulated by January 1, 1992.* (This date may seem ambitious, but many participants felt a pressing need for regulatory policy.) Within a reasonable time after a regulatory policy has been articulated, the regulatory process should be "tested" with a specific HTC which is ready to go through such a process.

The group set three general criteria for such a regulatory process. First, the regulatory process should provide meaningful opportunities for public input. Second, the regulatory process should allow industry to proceed in a fair and timely manner. Third, as appropriate, responsible health and environmental safety reviews should be conducted under the regulatory process.

Participants also agreed that the *socioeconomic impacts of herbicide tolerant crops should not be a "fourth criterion" for government regulatory approval for product commercialization,* as has been proposed in the European Community. Products should be judged on the first three criteria: human and environmental safety, quality and efficacy.

The group made two recommendations concerning socioeconomic impacts of HTCs. First, *government institutions that already deal with socio-*

¹ International Food Biotechnology Council. *Biotechnologies and Food: Assuring the Safety of Foods Produced by Genetic Modification.* Printed as a supplement to *Regulatory Toxicology and Pharmacology*, Volume 12, December 1990.

economic concerns may wish to consider the socioeconomic impacts of herbicide tolerant crops and if appropriate, mitigate any impacts. (Examples of mitigating actions currently employed by the government range from providing unemployment compensation to subsidies for new enterprises in adversely affected communities to antitrust actions that reduce or redistribute market shares.) Second, public discussion of the impacts of HTCs, including their socioeconomic impacts, should be fostered.

WORKSHOP REPORT

BIOLOGICAL CONTROL OF PESTS

Biological control methods have significant potential to become important tools for managing populations of agricultural pests. However, in spite of over 100 years of use in the United States, biological control has made little impact as a viable alternative strategy for pest control. It is clear that biological

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control has not been a significant national priority and there is no coordinated national program in place to enhance its development and implementation. The main objectives of the workshop were to develop strategies for a national effort on *how to make biocontrol work* and to propose recommendations for implementation of these strategies.

The workshop brought together approximately 45 individuals with different backgrounds: industrial, environmental, and consumer groups, universities and regulatory agencies. The participants were asked to project their vision of how they thought biological control should be part of our agricultural future. From these discussions, some broad perspectives emerged.

The most important broadly-shared vision was the hope that the use of biological control in pest management would increase significantly in the coming years and reduce our dependence on chemical pesticides. Furthermore, several individuals mentioned the importance of the use of biological control as part of an integrated pest management system. Most of the individual visions that did not explicitly mention this broad perspective focused on issues and problems that hitherto have prevented biological control from becoming an important part of pest control.

While biological control practices offer an environmentally-friendly alternative to chemical pesticide use, numerous constraints have prevented bio-based technologies from becoming an important means of pest management. The participants identified four major areas of concern within biological control that deserved separate attention: 1) technology, 2) regulation, 3) commercialization and 4) adoption. In addition, it was agreed that there is an overall lack of advocacy to get biological control on the national agenda.

The group was divided into four subgroups, each focusing on one of these areas of concern. Each subgroup was charged with developing goals in the different areas and recommendations to achieve those goals.

TECHNOLOGY

Important technological issues are:

- the lack of sufficient knowledge of the potential for biological control to be commercially viable (i.e. efficacy, market potential, production technology, etc.);
- the lack of strategies and fundamental knowledge underlying the productive use of biocontrol mechanisms; and
- insufficient funding to overcome these hurdles.

There was general agreement that there was insufficient knowledge on mechanisms of biological control at the genetic, molecular, population and ecosystem levels. The goals set on the technological level were to provide sufficient funding and/or develop incentive schemes that would encourage research on the viability of biological control for the grower and commercial producer and on existing defense mechanisms in nature.

Recommendation T-1: Establish and maintain basic and applied research programs to address scientific issues.

These research programs should focus on the following areas (in order of priority): 1) host-pest-biocontrol agent interactions, 2) ecological relationships between the target pest, its environment, and biological control agent, 3) host resistance mechanisms and 4) compatibility of biological control agents with chemical agents in integrated pest management (IPM) programs.

Recommendation T-2: Provide public funding and incentives for 'public good' (commercial products) types of biological control.

Recommendation T-3: Provide incentives for 'private good' types of biological control.

Various options that were mentioned in the workshop discussions, without necessarily being agreed upon by the group as a whole, included diversion of money from the Clean Water Act and establishment of a pesticide tax. These revenues would be used for field demonstrations of biological control. For 'private good' incentives the following ideas were proposed: an 'Orphan Drug Act' for small market biopesticides, research and development tax credits, clear and concise regulations for field testing and registration of biocontrol agents, and lowering capital gains taxes to help research and development investments.

REGULATION

The following goals should be set in developing the regulations for biological control agents:

- establish clear-cut regulatory procedures for all biological control agents;
- establish risk-benefit based regulation; and
- establish guidelines permitting exemptions for interstate movement of cultures of biological control agents for research purposes.

Therefore, the following regulatory recommendations were forwarded by the group and listed in order of priority:

Recommendation R-1: Redefine regulatory procedures by: 1) defining agency responsibility for organism groups; 2) defining criteria/characteristics representing risks and benefits; and 3) establishing a fixed time for regulatory decisions on field test applications.

Recommendation R-2: Improve communication by: 1) facilitating access to federal/state regulatory procedures; and 2) establishing voluntary mechanisms to share results of safety tests between investigators and between federal and state authorities (such as the National Biological Impact Assessment Program data base in the USDA).

COMMERCIALIZATION

There are three major impediments to the commercialization of biological control technologies:

- biological control agents are not sufficiently reliable and available for commercialization;
- incentives to commercialize the biological control products are not sufficient; and
- product cosmetic quality standards of the consumer are too high.

Therefore, incentives to increase the use of biologicals and minimize these barriers are necessary. A number of policy options were discussed in the group and it was agreed that they should be evaluated on criteria such as their effectiveness in achieving the goals, their ease of adoption, their political feasibility, their cost and their impact on the international competitive position of the U.S. farmers. From this discussion, the following recommendations were adopted:

Recommendation C-1: Set up national research centers to develop biological control methods with local/cooperative, clearing houses for basic and applied information on and the delivery of biological control agents.

Recommendation C-2: Modify crop support programs to encourage diversification and provide insurance premiums against crop loss to farmers who use biological control agents.

Recommendation C-3: Develop programs to change the lack of tolerance for imperfections at all levels of the marketing systems.

ADOPTION AND IMPLEMENTATION

The most important issues needed to be addressed in this area were:

- The lack of information on biological control strategies. Potential users do not understand which alternative options exist — or could become available — and how they should use them.
- Economic constraints. Existing biological control practices often have a cost disadvantage.
- Distributional problems. The overall access to and availability of the agents is limited.

Several initiatives were recommended that could overcome these problems. The first initiatives focused on transmitting information on alternative biocontrol technologies. An important criterion in setting up these programs should be the ability to demonstrate the efficacy of the biocontrol technologies.

A second group of initiatives would enhance the access to biological technologies and their availability. For this purpose, marketing and distribution systems should be developed. It was suggested tying this into established IPM programs.

Finally, it was argued that incentive mechanisms should be developed to make biological control technologies more cost effective. Suggestions were: 1) to set up 'shared risk programs', which would reduce the increase in production risk that the farmer incurs by using biocontrol agents 2) to provide inexpensive insurance for programs under testing and evaluation and 3) to tax chemical usage to reflect its total social cost and use these revenues to support biocontrol adoption programs.

The selection of these programs should be based on a thorough evaluation of the environmental costs of the technologies they promote and on their financial sustainability, both from a government (taxpayer's) perspective and from the producer and farmer's point of view.

The group agreed on the following recommendations:

Recommendation A-1: Establish a national program for the promotion of biological control. This included: 1) developing educational and informational materials and their distribution and 2) establishing demonstration projects on farms.

Recommendation A-2: Establish programs to reduce the initial cost disadvantage of biological control agents over traditional pest management techniques. This could include taxing pesticides/users and use of the revenues for these programs.

CONCLUDING REMARKS

Four issues emerged throughout the subgroups as important for the development and increase in the application of biological control in the coming years. The first was the *lack of leadership* in the area of biological control as a whole. It was the feeling of the workshop attendees that biological control has to get to the national agenda and, for this to happen, advocacy is necessary from academicians, legislators, and other public policy makers. Secondly, everyone agreed on the need for *effective and reasonable regulatory procedures*. Third, the establishment of a *tax on pesticides* to provide government revenues for the promotion of biological control applications was raised in all subgroups. Finally, there was a

strong need identified for an increase in *government funding* in the public arena (research and extension) and the establishment of (*financial*) *incentives* for an increase in supply (industry) and demand (farmers) of biological control agents.

A number of problems were not addressed in the short time the workshop group was together; and several issues were deferred to a “debate continues” category. Among these were the questions on how to manage resistance to biological control agents, approaches and problems associated with narrow genetic resources, the definition of biological control, and patentability of biological control agents.

WORKSHOP REPORT

TRANSGENIC ANIMALS

The possibility of transferring sections of genetic code into the genome of an animal—creating thereby a new genetic resource for a species—has been among the most exciting and dramatic applications of biotechnology. To date, there have only been a few laboratories attempting to apply

transgenic technology to farm animals. Although commercial application of transgenic animal technology for enhancing the quality or quantity of the food supply is not imminent, it is not too early to begin discussing the social and ethical issues associated with transgenic animals.

The workshop on transgenic animals included representatives from public and private research organizations that are either conducting or contemplating research on transgenic animals, representatives from several public interest groups, and several individuals interested in the politics and policy issues associated with biotechnology. There were not participants whose interest was defined in terms of opposition to transgenic animals, nor were there participants who expressed concerns that would

rule out research and development of transgenic animals. This fact is important in evaluating the consensus statements that are summarized below because they do not reflect the view of the groups that would be most likely to oppose the development of transgenic animals.

Participants in the workshop on transgenic animals listed several dozen topics for discussion. These topics were summarized into the following four headings:

- 1) Anticipation and management of unintended consequences
- 2) Socioeconomic impacts

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- 3) Funding-priorities and participation
- 4) Food safety and consumer acceptance

Participants divided into four subgroups to work on these areas. Each subgroup was charged with constructing a statement of the issue, defining the goal sought, and identifying strategies for accomplishing the goal. Subgroup reports were reviewed by the entire workshop.

In general, these discussions did not generate a high level of controversy or emotional intensity with respect to transgenic animal research. The workshop group felt that, since transgenic research is in the early stages, it would be some time before issues associated with the development and application of transgenic animals would become public. The group agreed broadly, at this juncture, that more basic research on the techniques and potential of transgenic animals in agriculture would be required before it would be possible to conduct well informed discussions of the social, ethical and policy issues that might one day be associated with transgenic animals.

In the following workshop summary, each of the four areas is discussed, with general conclusions drawn in the final section.

UNINTENDED CONSEQUENCES

Issue—Unintended and unwanted consequences of technology are most often the source of social and ethical problems. Aside from food safety and socioeconomic dislocation, both discussed below, transgenic animals maybe associated with several broad categories of unintended consequences. First, there is the possibility of environmental risk, including impact upon genetic diversity, animals as disease vectors and effects upon wild populations, as well as pollution that may be associated with animal production. Second, there are issues associated with the well-being of the animals themselves, both in terms of their health and in terms of their ability to lead relatively tranquil lives. Third, there is the possibility of consequences not readily anticipated.

Goal—Animal genetic research should be conducted to enhance human and animal well-being at an acceptable risk to animals, humans and the environment.

Strategies—The workshop discussed three strategies expected to help achieve this goal.

- 1) *Adequate funding.* If there are sufficient public funds to conduct research in the area of transgenics, the group felt that many of the worst problems of unintended consequences could be avoided by reducing the pressure to rush to market and by supporting research on risk, including frames of reference.
- 2) *Responsible science.* The second strategy stresses use of peer review panels, such as current animal-care committees, to assure that research on transgenics follows existing rules both for containment of recombinant DNA experiments and for animal welfare. This strategy requires open disclosure of the peer review and enforcement process. It will succeed only to the extent that the public is aware that these procedures are in place, and has the opportunity to express concerns to the appropriate bodies.
- 3) *Quality science.* The third strategy is to bring scientific resources to bear upon anticipating and assessing unwanted consequences. Both unwanted and beneficial outcomes can be anticipated through the development of model systems. For this strategy to succeed, there is a current need to place transgenic research within the framework of basic, rather than applied, research. Once models have been developed, it will be possible to conduct cost/benefit assessment of future transgenic research.

SOCIOECONOMIC CONCERNS

Issue—Can transgenic animals be used to enhance the quantity and quality of animal products in an efficient, sustainable manner (i.e., economically, environmentally and socially sound)?

Goal—To minimize the negative and maximize the positive socioeconomic impacts of transgenic animals and their products at the local, national and international levels.

Strategies—There are four key steps that must be completed to achieve the goal.

- 1) Determine the type of transgenic animal/product, the time frame in which it will be developed and adopted, and where and how it will be used.
- 2) Identify direct economic consequences (good and bad) of adopting transgenic animals/products. It will be important to include second

and third order consequences, i.e., downstream effects of transgenic animals.

- 3) Identify possible environmental benefits/costs associated with the use of transgenic animals/products.
- 4) Identify segments of world society that are affected by transgenic animals technology. This step includes involving society, developing public policies and conducting research on the socioeconomic impacts of transgenic animal technology.

FUNDING

Issue—Transgenic technology is merely a research and technological tool. As such, it should not be singled out as a special priority for funding. Rather, basic animal genetic research funding should be increased, because an increased knowledge of animal genetics will help increase the welfare of humans and animals.

Goal—Public funds should be used to increase the genetic knowledge base.

Strategies—There are three separate, but mutually inclusive, ways to go about securing this goal.

- 1) Preferably, funds will be distributed by peer review through competitive grants with public participation during the decision-making process.
- 2) Fund secondary and undergraduate education in animal genetics.
- 3) Public policy should encourage industrial funding for animal genetic research, with public participation and oversight.

FOOD SAFETY AND CONSUMER ACCEPTANCE

Issue—How can modern animal genetics be used to enhance the quality and safety of food, while minimizing the possibility of unanticipated deleterious effects? The existing research and regulatory systems should be more effective in building public communication, confidence and acceptance of food derived using biotechnology.

Goal—Ensure the safety and quality of food through modern genetics and develop (public) consumer communication that assures decisions are made on an informed basis.

Strategies for assuring quality and safety—

- 1) Meet consumer needs with enhanced quality and safety of the product. It will be necessary to produce products through modern animal genetics that are attractive and desirable to consumers, and to create a “market pull” for new products.
- 2) Conduct research to avoid unexpected consequences affecting food safety. It is important to clearly and demonstrably conduct research in parallel that looks for and avoids unexpected safety or quality problems with animal products derived through modern animal genetics.
- 3) Use biotechnology to assure food safety and quality. It will soon be possible to use the modern tools of biotechnology, for example for microbial probes contamination, to enhance the safety and quality assurance programs in food inspection.
- 4) Include transgenic animals in the broader context of animal molecular genetics. Since the application of transgenic animals may raise concerns, the subject should be discussed as part of the overall program of research and the products resulting from the use of modern animal genetics; transgenic animals are only one of the tools used to achieve the desired new products.

Strategies for improving consumer information—

- 1) Enhance the credibility of the regulatory system. Trust in the regulatory system to assure a safe and wholesome food supply has eroded. Research and changes in policy should be explored to improve the performance and image of the regulatory system.
- 2) Expand dialog with the public, including consumers, K-12 and college. The public image of the food supply is greatly influenced by what children learn in the classroom and what the consuming public is exposed to in the media. There should be a balanced effort to expand two-way communication with the public regarding concerns about the safety and wholesomeness of new products and processes from transgenic animals.
- 3) Early in the research and technology to produce products from transgenic animals, the public should be consulted to determine consumer acceptance of the products.
- 4) The results of safety and socioeconomic research should be discussed publicly. Elsewhere in this workshop, participants emphasized the

need to conduct parallel research to minimize socioeconomic impacts of the results of research on animal molecular genetics. A corollary to this issue is to conduct parallel research to assure that unanticipated results are minimized. The public should be made aware of these efforts as a part of the overall communication process.

CONCLUSIONS

In general, workshop participants concluded that public issues associated with transgenics were not urgent, primarily because applications of transgenic technologies as they affect agriculture and the food supply seem remote at the present time. It was expected to become more prominent. In this connection, it will be important to determine whether existing guidelines for treatment of research animals are adequate to assure the well-being of transgenic animals.

WORKSHOP REPORT

ANIMAL GROWTH PROMOTANTS

The following four issues evolved from the workshop on animal growth promotants (AGPs). There was consensus in identifying the important issues and goals with respect to AGPs. Divergence of opinion occurred in how they might be addressed. The order of the goals does not signify their

importance. No discussion as to the relative rank or importance of each occurred.

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issue 1) We need to assess the compatibility between broader social, value, political, economic, cultural and spiritual dimensions and the technology.

issue 2) We need to assess the *process* by which animal, human and environmental safety issues of AGPs are evaluated in order to possibly improve that process.

issue 3) We need to provide access to the information on the risks and benefits to the groups affected by the specific AGP.

issue 4) We need to eliminate international regulatory disparities with a goal of free/fair trade.

THE BROADER SOCIAL ISSUES

The first goal was the most controversial in the sense that it was the most difficult to reach a consensus on. There was strong disagreement about introducing broader social issues as a "fourth hurdle" to technology assessment. However, *agreement that some assessment of the broader social impact should take place at some point* arose from the following issue developed by a workshop subgroup: "What are the social value, political, economic, cultural and spiritual systems that are the context for new technologies; recognizing that 1) animal growth promotants are not unique and 2) all technologies are expressions of the system in which they are developed?"

This issue reflects the observation that technology is a product of the culture, the values of its developers and/or the society from which it evolves. The cultural context and values in which technology is developed is often not acknowledged as influencing that technology. Hence, technology is not value-free. This created conflicts between groups affected by the technology who may have different values. Thus there is a need to recognize values in technology and its applications, and when other values might be inconsistent with that technology. There was some contention whether or not major incongruences exist between social value systems and technologies, and whether it is possible to agree on a definition of "compatibility."

An example of actual conflicts is development of pork products in a Moslem country. Other conflicts of values may not be so obvious. Thus, a consensus was obtained for the goal of "identifying and measuring these broader social factors," and that the best way to accomplish this was via research.

Disagreement occurred as to who should do the research, whether public or private funds should pay for it, and how it should be applied. Within the subgroups, it was felt public funds would be most appropriate because of the need for a balanced public approach. When discussed by the entire workshop, however, some participants felt private funds may be appropriate in some cases.

A recommendation by the subgroups to incorporate these social impact assessments into technology evaluation and institutional decision making met with a great deal of controversy. Generally, agribusiness industry representatives, producer groups and university natural scientists felt socio-economic assessment would prevent research and/or product development if it were applied as a criterion. One participant was concerned that socio-economic assessment could mean "social critics are free to operate without restraint and do not have to measure up to any standard," rather than peer reviewed socio-economic research. There was also disagreement as to when such analysis ought to occur and who ought to do it. It was pointed out that it may not be feasible to do research on impact assessment before product development, or prior to product release. Particular concern was raised in the discussion over whether to analyze these issues prior to or after approval of the products, and also pre- or post-product development.

Some social impact assessments are currently being done, however, in an ad hoc manner. One participant pointed out that farmers make an ad hoc assessment through their purchasing decisions, which reflect a variety of social values. Concerns and questions were raised about whether current assessments by researchers are being done appropriately, and how they should be done. How and when the information from the assessment should be disseminated was also a concern, as was who should do it and how it should be funded.

EVALUATION OF THE REGULATION PROCESS

Safety and regulation issues were combined to form an issue: "*The process by which animal growth promotants are regulated for human, animal and environmental safety should be assessed for possible improvement.*" The issues were originally expressed separately: "assurance of product safety" and "is the regulatory process to evaluate AGPs applied appropriately, correctly and legally?" However it was determined one could not do one without the other, so the issues were combined.

There was no consensus about what ought to be improved or how it might occur. However, concerns included: credibility of decisions made by regulators; the definition of safety levels; the timeliness of the process; the openness of communication; the timing of public input; and the disclosure of information versus proprietary rights. The subgroup premise to this issue is that two major concerns of consumers are price and safety.

The methodology proposed to accomplish this goal is to a) identify the concerns of the different constituencies, possibly in a meeting or via a survey; b) brief the groups on the regulatory process as they each may not have a complete overview of the process; c) develop a white paper that reflects the concerns of the groups with subsequent feedback in order to reach a consensus; d) develop solutions for the identified concerns.

Seven groups of constituents were identified: regulators, consumers; industry; producers, academia, researchers, educators; and legislators and environmentalists. One critique of this process is that it might take too long. Another was the difficulty of handling a lack of consensus and the level and timing of communication among the constituents.

There was a lack of consensus in the workshop about the wording of the issue: "should be assessed for possible improvement" versus "could be im-

proved." Some felt more comfortable with the latter because they thought improvement was needed. The former working was adopted, however, indicating a lack of consensus about the need for regulatory improvement.

Other concerns arising from this issue were whether the Food and Drug Administration is funded well enough to do its job. Some participants had questions about how technologies and products should be regulated, how to make the process more credible, and how might the good aspects of the regulatory process be communicated to the public to improve credibility of the regulatory agencies.

INFORMATION ON THE DISTRIBUTION OF RISKS AND BENEFITS

Consensus was easily reached for another issue, "*Access to the information on the risks and benefits should be available to the groups affected by AGPs.*" However, there was no consensus on who should acquire the information, when it should be done, and whether it should affect regulatory restrictions.

The methodology proposed involved research, education and public policy. "Credible" research would identify the specific groups affected to determine potential risks and benefits. A public education program would disseminate the information and public policy would be set to insure that relevant, credible, objective, nonproprietary information would be available to all.

The word "objective" was a point of contention (as it was in Issue 4). It lead back to Issue 1, in which "objective" information depends upon the values of the individuals or institutions supplying and receiving the information. Along a similar vein, concern was expressed over individual opinions and values dominating risk and benefit standards. Some felt there is a need to develop a *systematic* way of obtaining and disseminating information of risks and benefits. One person expressed concern over information "carpet-bombing," i.e., the ability of groups or individuals to dominate information dissemination about animal growth promotants, presumably through the media.

INTERNATIONAL REGULATORY DISPARITIES

This issue stemmed from concern about who is making decisions for whom. The issue is "*International regulatory disparities affect trade and developing country economies.*"

The methodology proposed to accomplish the goal of eliminating disparities is: a) establish an international dispute settlement mechanisms such as GATT; b) conduct research in a neutral, independent setting such as international research centers; c) establish objective international standards such as CODEX; and d) educate consumers possibly using UN/FAO funds.

Disagreement occurred over the goal of "free" trade versus "fair" trade. Some felt "free" trade would benefit countries and industries with large market shares that are able to undercut smaller industries and countries through "unfair" trade practices. In particular, the potential of large, developed countries to overwhelm smaller, less-developed economies was a concern of some. One person stated that free trade is means to a goal and not an end in itself.

The methodology proposed by the subgroup raised some controversy as to who ought to pay; whether any international body is really "neutral;" and whether objectivity of standards is possible given the many assumptions and models required to make assessments. In particular, the neutrality of CODEX was questioned. Questions were also raised about how to establish neutrality and to develop objective standards.

SUMMARY

Many of the situations, concerns and issues emerging from the animal growth promotants workshop transcend the topic of AGPs and even biotechnology, and deal with the broader issue of technology appraisal. There was a consensus that the issues are rarely product specific and that future workshops might be aligned to reflect this.

General concerns voiced by the workshop include the uncertainty of the new technologies, the availability, source and communication of information about AGPs, and trust or credibility in institutions, the regulatory process and the media. These themes of uncertainty, information and credibility emerged in many of the issues, from regulation to labeling.

Another recurring theme was perceptions and values. It was recognized that different constituents have different perceptions and values. However, value judgements were invariably placed on whether these perceptions or values are “good” or “bad.” As an example, many scientists perceived science as “objective.” However, it was pointed out that science is a product of the assumptions made, choice of experimental design, choice of research model, and choice of statistical analysis used, all of which are subjective decisions.

The conflict between perceptions and values was most evident in participants assumptions about the role of agriculture, and hence agricultural policy and research in our society. Production maximization, profit maximization, sustainable agriculture, and providing top quality food and fiber were all evoked as goals of agriculture. Some viewed production maximization and profit maximization as equivalent, however this is incorrect, unless input prices are zero. Profit maximization and sustainable agriculture were seen by some as divergent goals in agriculture, despite the fact that unsustainable practices are not profitable in the long-run and agriculture is not sustainable unless it is profitable.

Agriculture is varied and involves many people and institutions with different cultures and values. Different approaches are likely to exist and to be encouraged. However, without some agreement about the role of agriculture, it is unlikely that a consensus can be reached on substantive issues of agricultural policy and public funding of agricultural research with respect to AGPs. In particular, some interested groups will continue to feel disenfranchised, expressed by an overriding theme of “who is making decisions for whom?”

The animal growth promotants workshop had representatives from universities from a variety of disciplines, from agribusiness industries, producer groups, environmental groups and consumer groups. Two groups conspicuous by their absence were regulators and individual producers.