Technical Risk Assessment and Regulations

Co-chairs: Rebecca Goldburg, Biologist, Environmental Defense Fund
William F. Greenlee, Pharmacology and Toxicology, Purdue University

Products of agricultural biotechnology, such as field tests of genetically engineered crops or foods derived from genetically engineered crops, may pose risks to ecosystems or human health. However, the traditional risk assessment paradigm, developed to assess the carcinogenicity of chemicals, is not easily applied to products of agricultural biotechnology. Thus it is necessary to develop new risk assessment approaches in order to assess the risks of many agricultural biotechnology products.

After making scientific assessments of the nature and magnitude of any risks, regulators and other decisionmakers must elect a course of action. This risk management process often involves weighing risks and benefits of a particular product. The process can be difficult for agricultural products (e.g., pesticides, whether genetically engineered or not), since many of the individuals who bear direct risks from these products may not be the primary beneficiaries of the products.

Workshop participants set out to identify issues and make recommendations concerning risk characterization and risk management in agricultural biotechnology. Participants were first split into three groups to identify important issues. From the large number of issues identified by all three groups, participants selected, by vote, three issues for further discussion. The selected issues were essentially consecutive steps in the risk characterization and management process:

Identify hazards of process/product
Measure risks and establish scientific standards
Balance risk and benefits

Workshop participants then divided back into three groups, one for each issue, to develop recommendations. These three groups reported their recommendations to the workshop as a whole, and all participants were given an opportunity to discuss the recommendations before they were made final. The third group noted that risk is a part of life, and many participants felt that consideration of biotechnology products should somehow involve benefits as well as risks. Balancing risks and benefits for agricultural biotechnology

products can be extremely difficult, however, especially when risks and benefits are not, for the most part, borne by the same individuals or groups. No specific recommendations were agreed upon for balancing risks and benefits.

RECOMMENDATIONS

Identify Hazards of Process/Product

The National Academy of Sciences should study and develop strategies for hazard identification in agricultural biotechnology.

Regulators have extensive experience identifying the hazards of synthetic chemicals, but this experience is not always directly applicable to agricultural biotechnology products.

More input is needed from the scientific community to develop hazard identification methodology for agricultural biotechnology products.

Legislative gaps should be filled (e.g.,fish, shellfish).

Regulatory agencies, in some instances, lack the authority to adequately address risks of agricultural biotechnology products. Fish and shellfish present a clear example of such a gap. No agency has a clear Congressional mandate to regulate either the risks of releases of genetically engineered fish and shellfish or to regulate the safety of fish and shellfish (genetically engineered or not) for human consumption.

Land-grant universities need to address issues such as sustainable agriculture, family farms, and pesticide use, for which biotechnology now serves as a lightening rod or even a surrogate focus.

Some agricultural biotechnology products are the focus of considerable criticism or opposition from individuals who believe that these products may exacerbate existing trends in agriculture. Many issues about the structure of agriculture, (e.g., the loss of family farms), merit public debate. Unfortunately, few obvious forums are now available for public discussion of these issues. As a result, in some cases biotechnology products are serving as the primary vehicle for debate.

Government officials need to develop integrated approaches to regulation that incorporate knowledge of product and process.

As has been noted by many others, risk assessment of biotechnology products should be based on the characteristics of the products and not the fact that biotechnology was used to develop the product. Nevertheless, knowledge of the process used to develop a product can sometimes help form the questions asked in risk assessment or aid in decisions concerning which products to assess (e.g., in assessing the safety of a drug, regulators often consider the process used in its manufacture because the process can affect the presence of impurities in the product). Regulation

of biotechnology products should be based on science and the law, and not on ideological avoidance of all references to biotechnology.

Measure Risks and Establish Scientific Standards

Tools (appropriate test systems) should be developed to evaluate the potential hazards of three classes of organisms: animals, plants and microorganisms.

Scientific guidelines need to be developed to ensure that any ecological or human and animal health risks of agricultural biotechnology products are adequately addressed. The following are examples of areas that may merit the development of such "tools:"

Animals
- -containment/ecological effect of releases
- -human safety of expressed products
- -unforeseen metabolic effects

Plants
- -containment/ecological effect of releases:
  - altered disease/insect susceptibility,
  - weediness, and
  - outcrossing.
- -human safety of expressed products
- -unforeseen metabolic effects

Microorganisms
- -containment/ecological effect of releases:
  - colonization,
  - pathogenicity/toxicity to nontarget organisms, and
  - frequency and impact of gene transfer to other microbial species,
- -unforeseen metabolic effects

Models should be developed to assess the toxicity and allergenicity/antigenicity of expressed products as part of developing risk assessment guidelines.

It also should be noted that it is impracticable to measure any and all potential unforeseen effects. One can only look for specified unforeseen effects of particular concern.

Public Assessments of Benefits and Risks

Cochairs: Ted A. McKinney, Community Affairs & Contributions, DowElanco
A. Ann Sorenson, Center for Agriculture and the Environment, American Farmland Trust
with Patrick A. Stewart, American Farmland Trust

The purpose of this workshop was to establish an understanding of the underlying reasons for public concerns about agricultural biotechnology. This was accomplished by dividing the 28 participants into three smaller groups to discuss issues and possible solutions followed by an open group discussion in order to reach consensus. Over the course of two days, the often spirited discussion revolved around public perceptions and ways in which to respond to the public's need for credible information.

MAJOR THEMES

Discussions centered around two interrelated themes that came into sharp focus later on in the workshop. Both dealt with public perceptions of biotechnology. The first was a possible paradigm shift in the way the public thinks about the benefits and risks of biotechnology. The perception of the group was that there is no longer an unquestioning acceptance of the social paradigm in which humans are seen as dominating the planet and its resources. It is being replaced by an environmental paradigm, in which the public perceives limits to growth. Biotechnology's place in this new paradigm has not yet been determined, but its perceived role may affect its acceptance.

The second underlying theme that emerged from the workshop was that of the potential of biotechnology to bring about change. With the introduction and development of biotechnology, society has been given a powerful tool to change its environment in unforeseen ways. This leads to questions about how society should shape itself and who should make decisions as to the form and extent of change. This has understandably raised public concerns. However, the workshop participants saw that decisions pertaining to biotechnology must be made because the technology cannot be suppressed, only channeled into desired uses. The participants further saw that if the public did not become involved in the decision-making process early on, the marketplace would make decisions in its absence.

These two themes are seemingly in conflict. On the one hand, many people are fearful of new technologies and express an increasing desire for

nonintervention in the ecology of the planet. On the other hand, biotechnology offers the possibility of more controlled and targeted interventions into the environment, minimizing negative side-effects. Ironically, even as science has developed a technology that can change the environment, the public's perception and acceptance of biotechnology has turned away from the promise of benefits, and focused on risks associated with technological change. Technical analysis of benefits and risks is no longer sufficient to assure acceptance of biotechnology. Increasingly, an appraisal of the public's perception of those risks and benefits by stakeholders must be considered as well.

STAKEHOLDERS

The participants felt it was important to define who the stakeholders in public assessment of risks and benefits associated with agricultural biotechnology are. The stakeholders fall into five broad groupings:

- Government: Local, state and federal level policymakers in the legislative, executive/administrative and judicial branches.
- Universities/Research Organizations: Groups providing the scientific knowledge and information on which policy decisions are often based.
- Special Interest Groups/Organizations: Groups with an interest in preserving or changing the social and economic status quo. These include environmental groups, farm groups, industry/trade organizations, health groups, unions, religious groups and others.
- Corporations/Organizations Funding Research: Organizations creating products and technologies to serve their constituents/consumers.
- Consumers/The Public: Individuals directly affected by the production and consumption of biotechnology.

ISSUES

Workshop participants identified three major issue areas in public perception of agricultural biotechnology: personal issues, societal issues and process issues. Intervention to influence public policy can take place at any of these levels.

Personal Issues

Personal issues deal with how an individual views the impact of biotechnology on themselves. Personal issues identified by workshop participants included: food safety/health, economic impact, environmental/animal health, and the spiritual/moral-ethical dimensions of genetic engineering.

Food Safety/Health: Questions about the safety of food manipulated through genetic engineering and its impact on human health are of particular concern for the agricultural biotechnology industry.

Economic Impact: Individual concerns over the economic impact of agricultural biotechnology center around possible positive and negative impacts on jobs and the introduction of new products into the market.

Environmental/Animal Health: Individuals are becoming increasingly aware of negative impacts to both the environment and animals. The perception of agricultural biotechnology's role in ameliorating or aggravating current conditions will influence the acceptance and use of agricultural biotechnology.

Spiritual/Moral-Ethical Dimensions: Some individuals seem to have a "gut reaction" to biotechnology, not necessarily connected with religious beliefs, that no amount of scientific knowledge or data will change.

Societal Issues

Societal issues deal with ties between society and its leaders, and the strength of those ties. Again, in no particular order, the participants identified the following issues:

Trust: Public involvement in policymaking has increased in the past two decades. Citizens are increasingly suspicious that policymakers, who they see as manipulated by private interests, may be trying to manipulate them. This leaves them wondering who to trust with decision-making and who to turn to for credible information. Debate over the scientific accuracy of information also has contributed to a basic distrust of authority.

Motives: The public also has developed a distrust of some individuals and groups on the basis of their motives. They perceive an imbalance between those who bear the risk and those who benefit in society. The brunt of this distrust has been directed at industry because of its necessary focus on profit-making.

Socioeconomic Concerns: There was concern over the possible impacts of biotechnology on the socioeconomic structure of groups and communities. The possibility of concentration of ownership of food production through control of biotechnology is disconcerting to some. The potential impact of agricultural biotechnology on small and medium-size farms, and its possible contribution to the loss of a traditional way of life, is of special concern.

Process Issues

The third tier of concern was that of process issues, or how policies are made and who makes them.

Public Policy: Questions over public policy on biotechnology focused on who determines policy, who should determine the policy, and how policy should be implemented. There was an expressed need to find a process of technology control with which the public is comfortable and involved.

Public Understanding of Agricultural Biotechnology: The issue of public knowledge was seen as going beyond that of agricultural biotechnology to science and technology as a whole. Participants felt that lack of

public knowledge was understated by most people and that some people simply are not concerned or likely to ever be concerned about the impacts of biotechnology on their lives. In spite of this, there was a desire to distribute accurate information ranging from the technical aspects, the socioeconomic impacts and the moral/ethical concerns of biotechnology.

Public Attitude About Biotechnology: There was a two-pronged question about the public's attitude concerning agricultural biotechnology and how to assess it. The public currently receives information from competing channels: special interest groups, media, government, industry and university sources. Because these messages often conflict, public attitudes about biotechnology are shaped by what appears to be the most trustworthy source. It is at this point that information moves from being a scientific issue to being a political issue.

Process and Value of Measuring Public Response to Risk: The value of measuring public perception of risk was questioned for two reasons. First, gaps between the public's statements of what it would do and what it actually does always exist. Second, even if such information were known, changing public attitudes is difficult.

What Does the Public Think vs. What is Known: There was a belief that the majority of public decisions are made on the basis of emotion and limited information. This is of great concern to researchers and industry who must deal with a public that cares little about science and must attempt to bridge the gap between science and the public's understanding of it.

SUMMARY STATEMENT

After much discussion, workshop participants agreed on the following summary statement on public assessment of risks and benefits of bio technology:

> We recognize that technical assessment is not the only factor in public acceptance of technology. We recognize the need for better understanding of personal and societal values. We also recognize the need to understand the factors influencing public attitudes about biotechnology and biotechnology-derived products on the part of stakeholders.

RECOMMENDATIONS

On the basis of the preliminary discussions, the combined group developed recommendations for dealing with personal, societal and process issues. These objectives address the concerns outlined in the group's summary statement:

Develop and implement methods of identifying and monitoring public understanding of and awareness about issues and potential changes being brought about through biotechnology.

Greater support is needed for social science research through multiple methods such as surveys, informal information gathering, expanded dialogues between stakeholders, public forums and content analysis.

Place additional emphasis within education and the educational process on defining, assessing, and understanding risk and decision-making under uncertainty.

Expand the capacity and commitment of the scientific community to more effectively communicate with the public.

Expand to an ongoing dialogue about the implications of the knowledge being generated.

Place additional emphasis on science education in kindergarten through twelfth grade.

Expand public dialogue and discussion about the forces of change being generated by biotechnological developments beyond traditional channels (the Federal Register, Public Comment, *university extension services, etc.) in order to reach the public at the grassroots level.*

Broaden involvement of stakeholders in identification of priority needs to be addressed by biotechnology.

Public Values: Benefits and Harms

Cochairs: Rosetta Newsome, Scientific Affairs and Information, Institute for Food Technologists
Lilly-Marlene Russow, Philosophy, Purdue University

The workshop began with clarification of the topic of the workshop, and howit might be separated from the other topics. It was noted that the concepts of benefit and harm—particularly the latter—were considerably broader than the more specific idea of risk. "Risk" tends to invite a focus on health and safety issues, while benefits and harms extend beyond these specific concerns. Nonetheless, it was clear that the topic is very broad, that nearly every question about biotechnology is a question about public values, and hence that any attempt to predetermine the focus of the workshop would restrict the discussion too much. Two themes were repeatedly emphasized: 1. public values grow out of attempts to acknowledge and balance the values of diverse individuals; and 2. the whole issue of public values must consider the process by which values are shaped, expressed and recognized.

IDENTIFYING ISSUES

The participants were asked first to identify, and then to prioritize, topics of greatest concern. The results were as follows. Issues are listed in the order they were assigned as the result of vote, with comments voiced by participants and examples of topics within specific issues included under each general heading[1]. Topics are reproduced exactly as formulated by the workshop, since in many cases there was substantial debate about the wording. The results of the voting upon which the ranking was based are included. The first issue, identified below, ranked considerably higher than the others[2].

[1] The summaries under the heading "Elaboration/Analysis of Major Issues" reflect only the initial discussion. The workshop discussed the top-ranked issues in more depth on the second day; the discussions are summarized under the heading "Other Issues."

[2] Each participant was asked to list all seven topics in order of importance. Each list was then weighed, with the issue listed first receiving a "1", the second a "2", and so on to the last, which received a "7." Since there were sixteen participants who voted, there was a possible range of 16-112 points, with the lower numbers representing the issues judged more important.

Who should have the right or power to make decisions that have broad social implications? (29 points). Participants decided to consider the question of who ought to have a voice, rather than simply to ask how decisions are currently made. Participants pointed out that public institutions are poorly funded and need to be empowered, and that a sharp, reductionistic divide between science and technology and other sources of value (e.g., religion or spirituality) exists. More generally, this topic encompasses the questions of who sets research agendas, who shapes and controls the regulatory process, how the food-production system is determined and controlled, and who decides what products are available.

What criteria are used to assign value to new biotechnology? (53 points). The discussion began with a look at how the public views biotechnology and other "new" technologies in contrast with familiar products and processes. Some view new scientific discoveries as "progress," and "new" as equivalent to "better" or "improved." However, at least since Hiroshima, others express increasing numbers of questions, and perhaps skepticism, about the wisdom and value of some so-called "advances."

How safe is safe enough? (59 points). This discussion began with the observation that people today have different expectations about safety than they did earlier; they are more likely to raise questions about the safety of everything from food to playgrounds than they were fifty years ago. Although safety is only one factor in public value, it is important enough, and complex enough, to warrant careful consideration. Participants noted that there were conflicting ideas about what is included in judgments about safety. Perceptions of safety were tied to control in that something one can choose to avoid (e.g., bungee jumping) is less likely to raise serious safety concerns than things that are more difficult to avoid (e.g., drinking water). It was also pointed out that there are discrepancies between what people say they want and what they are willing to pay for, but that economic and class value systems were important factors to keep in mind. The importance of avoiding an elitist structure was emphasized: safety should not be a luxury limited to those who can afford to pay for it. On the other hand, concern about safety rarely overrides basic needs—one participant mentioned that people starving in Sudan, or even getting canned food from a soup kitchen, are less likely to worry about insect damage or contamination than affluent Americans.

What communication is needed among all citizens affected by biotechnology? (65 points). Preliminary versions of this topic were phrased in terms of information, but people soon changed to a discussion of communication in order to emphasize the need for true dialogue and the importance of avoiding an arrogant "us vs. them" attitude. Specific questions noted under this general heading were: 1. what sort of information consumers need and want; 2. the concept of "informed consent" and what that standard requires;

and 3. what sort of information regulators and legislators need in order to reach decisions.

How does biotechnology affect distribution of assets, incomes and power? (73 points). In general, public values will vary according to who wins and who loses through biotechnological advances. If large corporations are perceived as profiting while small family farms are perceived as harmed (as the bST/bGH controversy is sometimes portrayed), biotechnology is more likely to be viewed as harm. A more specific subheading under this issue had to do with the impact of biotechnology on the structure of the food production and distribution system.

What is the environmental impact of biotechnology? (85 points). There was little initial discussion of this issue, but subsequent comments indicated that it included, among other things, affect on the type and quantity of pesticide used, water quality and biodiversity. On the issue of biodiversity, one participant pointed out that more thought must be given to the choice of plant species used, e.g., to develop substances such as plastic substitutes. Choosing alfalfa rather than corn as a 'host' for example, the participant said, would be beneficial in that it would help stem the tendency towards monocultures and their attendant problems.

How should concerns for animals be taken into account? (93 points). There was considerable debate about the wording of this point. Some people wanted to describe the issue in terms of a contrast between concern for animal welfare and animal rights ("Should animal welfare be expanded to include animal rights?"). Others felt that terms like "animal rights" were prejudicial and unclear, and that a broader and more neutral description of the issue would be preferable. By majority vote, the form given above was chosen by the group.

Elaboration/Analysis of Major Issues

The workshop was then asked to break into two subgroups to explore the two issues identified as the most important topics. Each group was given one topic, and asked to identify: 1. barriers which hindered the group from addressing the issue effectively and appropriately, and; 2. recommendations about how to deal with the issue and the associated barriers. The barriers and recommendations developed by each subgroup were then presented to the entire workshop for discussion.

Who Should Have the Right or Power to Make Decisions That Have Broad Social Implications?

The subgroup which discussed this highest-ranking issue began by identifying the various sorts of "players" in the process of evaluating biotechnology. The following were identified: 1. regulators (including legislators

and regulatory agencies such as USDA, FDA, etc.); 2. developers (industry, scientists, granting agencies, academia); and 3. consumers (including both consumers in the literal sense of people who buy a product and also people seeking other benefits, such as environmental groups). The news media were also cited as players which can wield significant influence.

Next, the group identified the following barriers:

—Exactly what people want to know is not always known.

—Not everyone wants to get involved; some people want someone else to make the decisions. Consumers typically are overwhelmed; scientists typically want to be left alone to focus on their own work.

—Current procedures for gathering views and disseminating information are too formal to be widely effective (e.g., most people do not read the *Federal Register).*

—A common base of shared knowledge cannot be presupposed.

—In determining value, the scientific processes which are learned, the investigative tools which are developed and the advances in basic science, not just the concrete products of biotechnology need to be considered.

—The complexities of diverse cultures and value systems need to be understood and respected. This will affect, among other things, choices about whether, when and how, to compete with other countries in the international marketplace.

—Although the current political forum in which policy is shaped is supposed to be democratic, questions are raised concerning how democratic it is in practice.

Recommendations

Finally, the group offered two recommendations:

Increase the opportunity for "friendly" participation in the formal process. A system is needed which encourages and fosters broad participation, and which really listens and responds to input from all stakeholders.

Congressional hearings, by contrast, are often unfriendly, and people who testify often leave with the feeling that their input made no difference.

Real discussion (as opposed to mere dissemination of information) needs to be promoted among broad and diverse audiences.

NABC meetings represent a valuable first step, but do not represent the diversity of positions and values that must ultimately be included.

What Criteria are Used to Assign Value to New Biotechnology?

The second subgroup identified barriers and made recommendations regarding this second major issue. Barriers fell into two major categories. Several examples are identified in each category.

The first category of barriers or complexities in defining value or public good concerned the heterogeneity of people affected by biotechnology and public values. Religious, ethnic, economic, age and educational differences were all thought to effect how people judge the benefits and harms of biotechnology. Specific biotechnological developments will rarely be perceived similarly by all segments of the population. Moreover, people differ with respect to their willingness and/or ability to accept risks.

The second category of barriers related to information, and the difficulty of getting information into a public forum early enough. Full and free exchange of information is often hindered by concerns for intellectual property rights, the proprietary interests of an industry and competitiveness between industries, the desire of scientists to keep findings to themselves until their work has been published, and regulatory restrictions on discussion of products under regulatory review. It was suggested that there is a possible "window of opportunity" for earlier exchange of information after a patent has been granted, yet prior to marketing. This suggestion was countered by the observation that the restrictions of the patent process limit this potential "window." Participants recognized that within the current system, a significant investment, both public and private, is made before public value is fully established.

Recommendations

The group then offered several specific recommendations to help overcome the problems inherent in dealing with the heterogenicity of the public. While the general theme reflected an encouragement of broad public involvement and consideration, these items were considered more as examples than as a complete list. The following suggestions were identified:

Be sensitive to religious concerns and provide information in food labeling accordingly.

Develop information which is clear and understandable, so as to be accessible to people with a variety of educational backgrounds.

Assess the social/economic impacts of specific biotechnology applications at the earliest stage possible.

Specifically, applications should not adversely impact individuals in the low income sector, e.g., applications that would raise significantly the cost of foods should be avoided.

Establish a societal "minimum acceptable risk level," recognizing that some products or processes might be too risky to be acceptable at all; and identify risk levels of acceptable applications to enable individuals to make personal decisions about risk acceptability.

To deal with information barriers, the group suggested:

Land-grant universities and extension offices be singled out as particularly appropriate forums for discussion and dissemination of information.

However, effective functioning in these roles requires increased funding, more attention to and respect for extension activities as part of the original mission of land-grant institutions, and more autonomy from industry support.

More attention be given to the "window of opportunity" (see above).

Information should be exchanged and made available as widely as possible during this period, and consideration should be given to modifying the processes and regulations to allow for better exchange of information as soon as possible. Thus, open forums (designed to encourage personal communication and dialogue, not promotion) during the early stages of development before beginning marketing, need to be fostered. This would require, among other things, clarification of restrictions on discussion of patent applications under review and products under regulatory review.

Finally, participants offered a variety of additional criteria likely to arise in various applications of biotechnology. This list is not to be interpreted as recommended standards or criteria to be formally incorporated into the approval process, but rather, items which warrant consideration as early as possible in the developmental process. The difficulty of accurately projecting impact of various applications was recognized, though. The first point mentioned in this regard was the need to *pay attention to both long-term and short-term impact,* people evaluate a product on the basis of what its impact maybe in twenty years as well as what it maybe now.

Other criteria mentioned were: *impact on the food supply*—nutritional value, food quantity, quality, variety and cost, and *impact on the structure of agriculture.* With regard to agricultural structure, concerns were: Will the application accelerate vertical integration and the role of farmers in the decision-making process and will it impact the sustainability of the process? Is government support required? Impact of the new development on current products and on food production were also offered.

Environmental concerns generated another set of possible criteria. Water quality, sustainabililty and biodiversity were a few of the concerns that were highlighted. *International effects* also were mentioned, including competitiveness and impact on Third World or developing nations. Finally, *economic and social considerations* were brought up again, with particular emphasis on concern for equitable distribution of financial gains.

OTHER ISSUES

The detailed discussion of the two most important issues did not leave much time to pursue the other topics that had been identified during the first session. Nonetheless, some of the lower-ranking topics (e.g., the environment) had been taken up in the course of discussing one or both of the first two issues, and some discussion of the third and fourth issues (safety and communication) was possible. The variety of participant comments on the third and fourth issues are detailed below.

How Safe is Safe Enough?

Several barriers were noted. The first was short-term versus long-term safety considerations. A related point emphasized generational considerations, and the fact that people are often willing to take risks for themselves, but not for their children. (Alar was cited as an example of this point). Second, the public is increasingly unwilling to trust science and industry, and to view assurances from these sectors with suspicion. Next, the tension that often arises between public safety and individual freedom and choice was mentioned. Laws requiring motorcycle helmets, and New Jersey's short-lived attempt to prevent restaurants from serving soft-boiled or sunny-side up eggs were cited as examples. Finally, the apparent failure of our educational system to provide people with an adequate understanding of scientific methods and the limits of science, for example, was cited.

Recommendations

These problems gave rise several recommendations:

The need for better education at all levels, beginning with kindergarten.

The need to avoid absolutes when talking about safety.
Nothing is simply or absolutely safe, and this requires open communication about levels of safety.

It is necessary to take a much broader perspective when considering safety.
One should attempt to evaluate the whole process, source as well as outcome. In considering *Salmonella* contamination for example, all stages of the poultry and egg production process are to be evaluated, not just egg preparation and consumption practices.

What Communication Is Needed Among All Citizens Affected by Biotechnology?

This last issue addressed the need to improve communication. The main point conveyed here was the need to communicate on an effective, personal level, which requires, among other things, listening to public concerns as

well as providing information in an appropriate way. Educational levels and vocabulary were two factors that should be kept in mind. Realism is always necessary; practitioners must listen to real situations expressed by the public. It also was recognized that many individuals exhibit a narrow vision or focus on their own specific agenda, and that communication may be hampered by people's unwillingness to get involved, or doubt about whether they should really care about these issues.

Recommendations
To address these problems, the group recommended:

Better support for land-grant institutions and extension offices.

Better education programs at the K-12 levels.

More strenuous efforts to support scientific societies (e.g., Institute of Food Technologists) with information for broad dissemination.

Public Communication About Risk

Co-chairs: Karen Bolluyt, Agricultural Information Services, Iowa State University
David Judson, Gannett News Service

MISSION

To provide society the information it needs to evaluate the potential risks and benefits of agricultural biotechnology.

BACKGROUND

Certain basic principles can guide all involved in public communication about risk as it relates to biotechnology.

Opinions about risk vary from one perceived risk to another. Peter Sandman, professor of environmental communication at Rutgers University, has described "outrage factors" that drive personal assessments of risk. Communication about any perceived risk should include an analysis of the risk in light of factors that influence personal perceptions of risk. According to Sandman, these include: 1. individual control in assuming risk (voluntary vs. involuntary exposure); 2. fairness or the extent to which a risk is distributed equally; 3. morality or the extent to which technology or behavior not only poses a risk but is perceived to be evil; 4. dread, e.g., the belief that the potential damage may be catastrophic or may cause a fatal, lingering illness; 5. familiarity, as illustrated in the difference between fear that peanut butter may contain carcinogens or the fear that irradiation may change foods in undesirable ways; and 6. trust as earned or lost in all areas of organizational behavior.

Some elements of modern technology help cause increased perceptions of risk. These include: 1. the improved ability to detect toxic substances (one part per quintillion); 2. new technology that is not understood except by people with exceptional skills or highly specialized education; 3. knowledge of catastrophes or instances in which technology believed to be beneficial proved to be harmful (e.g., thalidomide); 4. experts disagreeing during litigation, hearings or other widely publicized public discussions; 5. growing production and distribution systems that increase the potential for technologies and products to affect millions of people each day, thus increasing the chances for catastrophe; and 6. growth in knowledge and the accompanying growth in awareness of gaps in knowledge (How valid are methods of risk assessment?).

Categorizing some perceptions of risk as "irrational fears" interferes with risk communication and is a counterproductive substitution for thoughtful

exploration of issues/answers. "Many risk experts insist that 'the data' alone, not the 'irrational' public, should determine policy. When a risk manager continues to ignore [outrage] factors—and continues to be surprised by the public's response of outrage—it is worth asking just whose behavior is irrational." (Sandman, 1987)

The long-term view for risk communication is that society and/or consumers determine the success or failure of new technology and new products. This long-term outlook should drive communications plans and activities.

In the United States a majority of people express some belief that biotechnology in agriculture can benefit them and express some support for the development of biotechnology. The public strongly expresses a need/desire for information about biotechnology and for the opportunity to be involved in decisions about the use of biotechnology in the development and use of products.

Communication is not the easy task of message distribution once the difficult decisions about financing, research, development, marketing, etc. are made. It is a crucial, complex, continuous, circular interchange that should be a central part of all planning and budgeting. In general, communication plans and efforts have been inadequate.

RECOMMENDATIONS

The workshop participants prepared recommendations on three topics: communication content, credible communication, and circular communication. Some recommendations were made for more than one topic, but each is reported only once here.

Communication Content

Communication should contain more than facts. Opinions and values should enter the communication mix at every juncture, and that is taken into account later in this report. The following recommendations regarding factual information were made:

Communicate in specifics as much as possible.

Focus on specific products or technologies, risks or benefits.

Focus on what a product/technology will mean to specific audiences.

Use simple language (old, short words).

Prepare to be brief and concise about key ideas and information, and be prepared to provide detail (probably written).

For all sources of information, identify the source's qualifications and affiliations.

Base information on sound science.

Credible Communication

Beginning with the assumption that credibility must be earned and conferred, that it can not be claimed or bought, the following recommendations were made:

Provide full disclosure of information about benefits, risks, and the assumptions on which the information is based.

Be clear and forthright in describing biases or financial interests that an audience should understand to evaluate information and opinions from various sources.

Provide product information and 1. provide, or 2. make it easy to obtain process information.

Do not simply state conclusions; provide background information about how conclusions were reached and distinguish between opinion and fact.

Use language and concepts that the audience understands.

Clarity is credible. People are more likely to be suspicious of what they do not understand.

Choose spokespeople carefully, considering each audience and using the audience's criteria for trustworthiness.

Build bridges with key groups by identifying people who can serve as liaisons.

All members of most groups will not become experts in biotechnology, so they identify a trusted group member or liaison who is knowledgeable and they rely on him or her for guidance.

Circular Communication

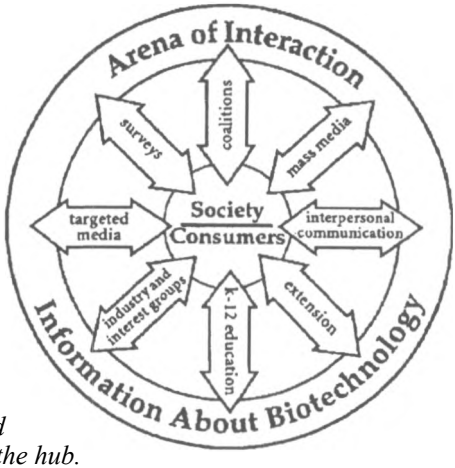
If one accepts the proposition that the consumer will be one of the primary determining factors in the process of acceptance, then there are two critical communication questions to be addressed: 1. How do we provide the information consumers need? and 2. How do we develop and maintain effective feedback from consumers? This process is complex, but it has a circular nature that provides points of reference for plans and actions. These points of reference are: 1. provide information for the forum of pubic debate; 2. listen to the feedback in the ensuing dialogue; and 3. go back to point one. The following recommendations for establishing circular communication are made:

Listen more than you talk.

All participants should make special efforts to listen attentively, with the goal of understanding the facts and beliefs behind various points of view. A corollary to this is that multiple sides of an issue should be presented during meetings/discussions.

Adopt the wheel model for risk communication. (right)

The hub is society/the consumer. The spokes are conduits for information flowing to and from the public, and the rim is the arena of interaction containing multiple sources of information and opinion. Any poorly functioning part of the wheel will have a negative impact on the whole.



Identify the stakeholders at the rim of the wheel, and key individuals and groups among the general public at the hub.

Deciding whether an individual or group belongs at the rim or in the hub will be a useful part of communication planning.

Identify the communication channels.

Define the role, the costs and the importance of each channel, and develop communication plans accordingly. Among the channels that might be used to exchange information are the following: K-12 education, land-grant institutions—particularly their extension services, interpersonal communication, mass media, targeted media, coalitions, focus groups and surveys, consumer behavior, organizational boards, and formal or informal opinion leaders.

The following were selected recommendations for channels of communication:

Increase funding for such programs as "Ag in the Classroom."

Science teachers' associations should be invited to cooperate in planning educational programs.

Provide scholarships for teachers and students that could bring them to university and industry labs as interns or workshop participants.

Take advantage of all opportunities to build coalitions. Bringing together groups that disagree often works.

Areas of disagreement are based partly in misunderstandings and lack of information. Common ground and common goals often can be identified. Such coalitions can become credible communications channels because they do not represent a single point of view.

Share new and existing information from focus groups and surveys as widely as possible.

This is one efficient way to identify problems and issues early and to build general understanding of biotechnology and of public opinion and behavior.

Use the land-grant model for coordinating communication.

Cooperative Extension might be empowered to build and coordinate cooperative agricultural biotechnology communication programs.

Identify and use opportunities for interpersonal communication.

Several decades ago, research on the adoption of innovations pointed to the importance of interpersonal communications for decision-making. Recent research on risk communication indicates that human behavior has not changed in this regard. This inefficient channel for communication may be the only effective channel/best channel in many instances. Organizations should make interpersonal communication (i.e., listening and talking) a strategic part of communication plans.

Use mass media and targeted media to reach audiences and to elicit responses from them.

Media relations strategies have changed considerably with the growth of special interest publications. There never has been any such creature as "the general public," but media targeted at specific groups have increased in importance while many "mass media," (e.g., daily newspapers) have decreased. The role of mass media and more targeted media as sources of facts and as mechanisms for calling attention to issues also has remained relatively stable since the time of the adoption-diffusion studies of the 1940s.

Use the body of communications research on the role of these communications channels to plan risk communications.

Advise organizations and institutions to incorporate diverse points of view into their leadership.

This should begin with The National Agricultural Biotechnology Council.

Recognize the importance of informal and formal leaders.

For many issues, formal and informal leaders are sought out for their opinions. Sometimes they are in decision-making positions, but not always. They are, however, channels for information. Special efforts should be made to understand how they obtain information and to keep them informed.

Communication about biotechnology is a complex process that requires equal attention to facts about the science and understanding of human behavior. It requires planning, resources and respect for the consumer. It can be frustrating. Poorly executed, it can create ill will and a great drain on resources directed at damage control. It should receive careful as the attention from the beginning of any efforts in biotechnology.

REFERENCES

Sandman, P. 1987. Risk Communication: Facing Public Outrage. *EPA Journal.* 13:21-22.