Workshop Report: Regulatory and Public Policy Perspectives

Co-Chairs

Daniel E. Wueste
Clemson University
Clemson, SC

John Gentry
Clemson University
Clemson, SC

Calvin Schoulties
Clemson University
Clemson, SC

This workshop broadly discussed the issues of transgenic crops and the environmental concerns of gene escape and development of pests resistant to the transgenic pesticide. Risks of resistant pests, resistance management, benefits and risks, food safety, and communication were examined. Several key recommendations were proposed.

Risks to the Environment and Society posed by Resistant Pests

Many general questions and observations were made concerning the risk of pests, especially insect pests to a crop containing a transgenic pesticide, e.g., the *Bacillus thuringiensis* (Bt) toxin. If pests cannot be controlled, food and fiber crops will be jeopardized and may negatively impact society throughout the world. As a result, farmers may choose to plant crops that require an increased use of fertilizers and pesticides, which may negatively impact soil conservation and water use by increasing the amount of chemical runoff. In addition, the hazards associated with mixing and loading pesticides should be considered.

For example, if pests develop resistance to the Bt toxin transgenic crops, Bt microbial sprays will lose their effectiveness and Bt could be lost as a control measure. Growers faced with pests resistant to Bt would likely increase or return to the use of higher risk synthetic chemical pesticides. That will entail higher costs to growers, which would be passed on to consumers. A return to chemical pesticides is likely to be unfavorable to the environment and society in comparison to the use of Bt.

Communication

We must improve communication among the variety of groups concerned with or impacted by agricultural biotechnology, including academics, environmentalists, consumers, industry representatives, farmers, and others who use biotechnology. Many distinguish between the use of biotechnology to improve food and fiber production. However some crops, e.g., cotton, are both food and fiber crops making such a distinction difficult to impossible.

It is important to remember that the development of a pest-management system is an ongoing task; it requires constant adaptation to changes in pest-control technologies as well as response to the development of resistance on the part of pests. The problem of pest resistance is not new nor is it widely understood. Pests developed resistance to chemical pesticides before the use of biotechnology in agriculture. Communication is the linchpin to understanding.

Some people are worried that agricultural biotechnology will create super-pests. Are their worries unfounded? If so, this needs to be made clear because fear of this sort impedes progress. One participant stressed that not all fears are ungrounded. Those that are ungrounded should be identified as such and addressed through education and communication. Those fears that are based in reality must be responded to with safeguards. Sometimes we do not have adequate information to determine if the fears are legitimate and work should continue to define their legitimacy. Are there cases where public fear is based in reality and use continues anyway, or are there cases where public fear is not based on reality and the use is stopped? The alar scare may be an example of the latter.

Public perception is very important. It should be made clear that agricultural biotechnology is not the field of the proverbial mad scientist or of scientists driven by greed or other improper motives who ignore real dangers. With this last point in mind, it was stressed that research and development activities need to be monitored with the interests of public health and welfare and good science in mind. The system of monitoring these activities must be responsive to the changing needs of the public as well as to changes in scientific knowledge. In addition, the design of this system must include appropriate incentives.

Resistance Management

The major focus to minimize/delay the development of pest insects resistant to Bt toxin in transgenic crops is management of the planting patterns of the crops and monitoring for appearance of resistant insects. The group raised many questions: Who is monitoring for pest resistance to Bt and what is being monitored? Are farmers complying with regulation and licensing agreements? Is the development of resistance being observed? Are both being watched and if so, by whom? In this connection, the workshop participants expressed deep concern about the role of state regulatory agencies in terms of statutory authority and capability. Another question raised was whether the size of refuge set-asides will eliminate the participation of small farmers.

The answer to the first question was immediately provided: the US Environmental Protection Agency (EPA), the US Department of Agriculture (USDA), and industry are following up on the licensing agreement. Yet it was questioned whether auditing procedures and the enforcement tools are sufficient, and whether industry can adequately enforce its agreements with users. Currently, industry monitors efficacy by means of field sampling and comparing field susceptibility to baseline susceptibility levels. However, detecting resistance proactively is very difficult for large-crop acreage. There are at least two sources of difficulty here — field sampling itself and the sensitivity of the monitoring technique. Moreover, monitoring of this sort will not provide all of the information that is needed.

Education of growers of Bt transgenic crops is very important. If farmers know that the rules are not arbitrary or capricious, they are more likely to comply with them. The big picture — the whole-system— needs to be laid out for the users. It is important to develop close connections between public officials and private parties for the purpose of monitoring. Protocols for resistance detection should be revisited, reviewed, and revised as appropriate.

What degree of change in the level of resistance or level of crop loss is acceptable and how long should it be before additional control measures are taken? Should genes be re-engineered? Should crop insurance, which might prevent farmers from taking steps that are unwise or illegal in an effort to save a crop, be mandatory? These matters are of concern to all entities involved with the system, and action is required by all.

Farmers and industry should be willing to undertake monitoring because it is in their own best interest. Government involvement is important for the purposes of promoting trust and communicating to the public that what needs to be done is being done honestly, carefully, and in accordance with objectively rational standards. Government can be an honest referee. On the other hand, overly severe regulation based on misinformation may seriously hamper effective agricultural biotechnology.

A key concept here is product/technology stewardship involving all the stakeholders so as to establish trust and legitimacy.

Benefits and Risks of Transgenic Plants

Clearly, there are economic benefits for the producer and the end user, including the fact that a decreased use of conventional pesticides will result in substantial health benefits for farm workers. Others, both human and non-human, will benefit through enhanced air and water quality. Herbicide tolerant plants have a positive impact on crop management practices and soil conservation. In addition, production and equipment costs go down and control systems are simplified (mixing of chemicals for example, is less of a problem).

One area of risk is the creation of herbicide resistance in weedy relatives of the transgenic herbicide crop. The herbicide-resistance gene is transferred by the pollen of the transgenic crop to a cross-pollinating relative (weeds) in the area (gene escape). A similar problem could occur with insect resistance. There is a general concern about unintended effects of biotechnology as a result of gene flow or gene escape.

If out-crossing occurs, does it have negative environmental or social results, for example, in the form of super pests — new weeds, new viruses, new insects, and new and dangerous species? We need to know more than we do. The group agreed that there is a need to develop methodologies for measuring the probability of out-crossing and assessing its potential impact on the ecosystem, and defining an acceptable level of risk. In making these evaluations, one would consider sexual compatibility, geography (centers of origin), presence of out-crossing plants in the area of production of transgenic crops, and mechanisms of pollination (e.g., wind, hummingbirds, bees, animals).

Good Science

Good science is key to the successful use of biotechnology in agriculture. Scientific input should be sought at all levels of the decision-making process. Such input is essential, and is needed to answer such questions as whether another host crop can constitute a refuge and whether the extensive use of a bioengineered genotype will limit biodiversity. It is also essential that scientific input be free from bias. In the effort to guarantee that we have good science it will be necessary to avoid even the appearance of impropriety.

Legitimacy is very important. Once trust is developed it has to be maintained by continuous effort. One way to insure that effort is the involvement of stakeholders — producers, users, government regulators, and academics — in the decision-making process. Another way is adherence to high standards of professional and moral ethics. The integrity of the parties (people and institutions) and the integrity of the processes have to be maintained.

We need to find ways to incorporate value considerations in the decision-making process by encouraging more research regarding the social issues surrounding agricultural biotechnology. Not all decisions in this area turn on empirical, scientific determinations. Not all of the questions that have to be answered are purely scientific questions. Of this we must not lose sight.

Other Issues/Concerns

Other issues and concerns came up during our discussions. Thinking that they are worthy of consideration in any case and may be topics for future conferences, we record them briefly here: What are the risks and benefits of food quality enhancement by biotechnology? What about the development of plants to produce pharmaceuticals, and the genetic engineering of plants to make or be sources for polymers and industrial products?

Food safety

Concern about the risks of consuming transgenic crops already exists in Europe. One participant noted that labeling of genetically engineered products in Europe is not a safety matter; it is done to facilitate informed choice. Are such concerns shared by those in the United States? US regulatory agencies (Food and Drug Administration [FDA] and EPA) assess biotechnology products and evaluate industry data. In the US there is a need for more objective data and more communication.

One reason that labeling of genetically engineered plants might be necessary is to inform consumers of potential allergens (e.g., if genes from peanuts or brazil nuts were inserted into other plants).

Recommendations

1. *There should be scientific input into decision-making at all levels. Because it is essential that input be free from bias, an independently funded research institute should be established. This institute would conduct scientific and social/value research to provide information to fill in the gaps of regulatory policy and ensure that regulations are thoroughly debated for scientific and social soundness. With respect to the research to be undertaken in the values area, it was suggested that the ELSI (Ethical, Legal and Social Impact) research program of the Human Genome Project could serve as a model.*
2. *The EPA should be encouraged to continue working with scientists and industry to define the safety parameters of transgenic plants and determine how these plants are to be regulated. Regulations should be based on the transgene and the crop, using validated scientific field data, model, and laboratory findings. Work on methodologies for measuring the probability of out-crossing and assessing its potential impact on the ecosystem should continue. It will be necessary to define acceptable levels of risk.*
3. *Efforts should be undertaken to develop an appropriate network of product/technology stewardship involving technology providers, users, government regulators, and other stakeholders. Protocols for resistance management and detection should be reviewed and refined as necessary. At the same time, efforts should continue to be made to define acceptable levels of resistance. Also, regional cooperation must be increased, specifically with respect to regional pest management plans.*
4. *In order to achieve legitimacy for the decisions that come from the decision-making process, we must find ways to involve the public, producers, government, academics, environmentalists, industry, and other stakeholders in that process. Close connections should be developed between public and private parties to monitor and manage resistance.*
5. *Communication is critical. Communication must be initiated and maintained in accessible ways with targeted audiences. As an example, farmers are on*

the front-line for resistance monitoring and management. It is critical that they are aware of the reasons for regulations and that they receive assistance in compliance. Similarly, it is important to communicate with the general public to address and put to rest ungrounded fears. To be effective communication must not be a one-sided affair. Rather, it must be in the form of dialogues among concerned and impacted parties. Related to communication is the idea of developing trust among technology users, providers, and regulators. Effective dialogue will be a valuable tool for the achievement of this goal.

6. *We must find a place for value considerations in the decision-making process, for after we answer the question as to whether it can be done the key question of whether it should be done remains.*