Paper presented to the Regulatory and Public Policy Perspectives Workshop

ANDREW JORDAN
Director
National Cotton Council
Memphis, TN

Agricultural biotechnology represents a new range of tools for production and processing, and for numerous new agriculturally based products. This year's conference — *Agricultural Biotechnology and Environmental Quality: Gene Escape and Pest Resistance* — is on a topic of great importance to all. This workshops deals with public policy and regulations. Collectively you represent diverse interests, ranging from state and federal regulators, agribusiness providers, public scientists, educators, and farmers and other users. Interests as diverse as these typically generate healthy debate. We can expect that a discussion about regulating environmental impacts of gene escape and pest resistance will be no exception.

Discussion during the first workshop session has to do with pest-derived resistance to transgenic plants; the second session will consider gene escape. I have been asked to set the stage for both.

REGULATORY AND PUBLIC POLICY

As one who represents cotton farmers and processors, I am sensitive to the specter of unnecessary regulations. Having said that, I will concede the necessity for more regulations in cases where there is a clear inadequacy for protection of health, safety, environment, and economic well being.

The cotton industry has firsthand experience dealing with costly regulations. Most recently we supported the sound principles of the new Food Quality Protection Act (FQPA) because we agreed that reform of pesticide and food safety regulations was essential because the old regulations were archaic and unreasonable, and made little sense from a risk-avoidance standpoint. The act eliminated the Delaney Clause, an eccentric provision in the old law whose origin was driven by emotion rather than scientific merit. We embraced the

basic proposition that pledged a more sensible and more holistic approach to decisions about pesticides and food safety.

Given assurances that the new act would be better for all of us, we were disappointed to discover that execution appeared to differ markedly from expectation. In our view many regulatory decisions in implementing the new act were arbitrary and without merit. Furthermore, there was no clear plan for implementing the new law.

Confusion abounded. This chaos proved to be burdensome to farmers. It was expensive in terms of denied access to important agricultural chemicals, costly due to untimely decisions (sometimes after crops had been planted and materials purchased), and unsettling with respect to the cloud of uncertainty for planning a year-long pest management strategy. It was clear the decisions were not based on improving diet and reducing risk to human health but instead were made to fulfill the passionate needs of some individuals.

Of course, there are those who disagree with me because of a different experience, agenda, bias, emotion, or understanding of risks and benefits. There are those who consider theirs a noble cause and are immovable in their conviction that some products should be regulated out of existence.

While I seem to belabor the point of regulation, it is for the following purpose: We will be discussing public policy and regulations affecting transgenic plants. I foresee a path that potentially could parallel development of pesticide regulations in complexity, and in emotional attachments to positions. No doubt, decisions of federal agencies regulating real or perceived hazards become bitterly controversial. One person's passion for purity will be pitted against another's desire to provide basic human needs. Economic benefits will be challenged by perceived risks, and interpretation of one expert's facts will go against another's interpretation.

GOALS

We will have made a major contribution if we succeed in providing early enlightenment to the debate on regulation of transgenic plants. We need to strive for reliability and objectivity in the scientific assessment of pest resistance and the environmental effects of gene escape. In our hearts we may desire to be impartial, but there is no escaping the fact that by necessity there invariably will be subjective evaluations.

Another of our goals should be to identify those institutional mechanisms that best form a constructive partnership between science and government. We should consider whether we could create alternative public policy mechanisms to support the goal of acceptable risk demanded by society. Rhetorically, can this technology be used without the burden of over-regulation? Can it be done with no regulation? Perhaps not. So if regulations are deemed necessary, let's ensure that the rules are based on the best available scientific knowledge.

The public policy-setting task is complicated even further by the unavoidable

collision of conflicting interests that impact most important regulatory decisions. The fact that costs and benefits of regulatory policies fall unequally on different groups makes the task a daunting one.

Resistance and Gene Escape

The plenary speakers presented interesting ideas. They set the stage for discussion if not debate. While each of us has a notion as to our level of agreement with the speakers, our aim is to discuss these topics in the context of public policy.

Dr. Gould made a good case as to why he thinks that alternative protein toxins will be hard to identify. He also discussed the alternative refuge/high dose approach endorsed by many scientists. I will want those of you from industry and academia to help elucidate whether you think Dr. Gould's theories are sound. If I understood Gould correctly, he said (to paraphrase) that we will be wasting effort looking for alternative *Bacillus thuringiensis* (Bt) proteins.

Dr. Beachy discussed resistance to virus infections in transgenic plants. He cited studies that suggest that specific transgenes may be more likely than others to develop pathogen-derived resistance. In that light, I will want to hear your opinions as to the significance of those studies.

The afternoon plenary speakers presented interesting but disparate views. Dr. Nickson asserted that biotechnology could be an environmentally responsible way to meet increasing requirements for feeding a hungry world. On the other hand Dr. Ho presented an entirely different view. While the title is long, it appropriately captures Dr. Ho's emotion. While we individually may disagree with Dr. Ho, we must recognize that hers is an opinion shared by many around the world. Those beliefs represent issues that must be considered and responded to in an appropriate and science-based manner as we debate public policy.

Drs. Gould and Beachy suggested uncertainties in our knowledge gap about resistance. Drs. Nickson and Ho, while not corroborating deficiencies in information, clearly disagreed on whether biotechnology would help feed and clothe the world or whether the gains from biotechnology are only short term. If we are to believe any or all of our plenary speakers, we must accept the fact that there are uncertainties. In the absence of good research to sort out answers to these questions, a cloud of doubt and mistrust will shadow this new technology. Good sound research is key to addressing the risks and benefits of transgenic plant technology.

In the meantime we must decide in the context of public policy how to deal with uncertainty with the information now available. Agreeing that there is no such thing as zero risk, our challenge will be to help set a framework of decision making to establish a level of acceptable uncertainty. Given that the best of scientists don't always agree, we must decide which science is dependable and how to generate acceptable risk models.

Questions for Discussion

- What potential risks do resistant pests pose to society? Are they real or perceived?
- What are the social costs of the wrong decision or the wrong regulation?
- By what mechanisms do we weigh consequences of over-regulation vs. under-regulation? Are they social, economic or political? All of the above?
- Whose best interest are we regulating for — how do farmers fit into the equation? Do they really have a say?
- What conditions would warrant a regulatory strategy that is as permissible as possible early on, monitored for effect, and then adjusted to respond to the expanding experience base?
- Conversely, what conditions would warrant a strategy that is "highly restrictive early on, followed by strict laboratory research, and then loosening of regulations if new information dictates"?
- What are the consequences of wrong decisions? Are they catastrophic, or can eco-systems recover?
- The EPA convened a Scientific Advisory Panel for Bt products. They agreed that BT is an important IPM tool and that we need to protect the technology. Can we make an informed recommendation as to the proper ratio of transgenic crop to that left for refugia? What's magic about four percent, 20 percent, or even 50 percent?
- As we are dealing with resistance or gene escape, who is responsible for monitoring? Is this a public responsibility? An industry responsibility? A farmer responsibility?
- Is our reliance on population models appropriate?
- In absence of definitive field data, can we appropriately extrapolate laboratory data to the real world? Under what circumstances should these data be extrapolated, and where should they not?
- I would like to hear discussion on how to best quantify benefits of transgenic technologies compared with the risks. In doing so, we need to answer the questions as to how benefits and risks are measured and assessed. Can risks identified with this technology be reduced to levels acceptable to the public?
- Finally the last question: Who should be responsible for deciding the future of plant biotechnology, and how does the public participate in this decision-making process?

In conclusion, there is no doubt that the task facing this technology is awesome. Plainly, there are questions; some more important than others are. We will not have the last say, but what we do at this conference will make a difference. If I were to summarize all our goals into a single objective, it would be to promote understanding of the issues.