WORLD FOOD PRIZE SYMPOSIUM
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Good I have the... Now you know a little about my... nefarious background. Anyway, I'm very pleased to be here. A few of you may know me as someone who might be characterized as a critic of biotechnology and certain other developments in modern agriculture and food production. And I was invited here today to talk a bit about the topic of this session, "Is the Credibility of Science at Risk?" Now, obviously, that's a really broad topic, even if you narrow it to agricultural biotechnology.

And in thinking about this session, I didn't think I could it justice, and so what I've elected to do was to present to you two histories, two stories, two case studies of things that have gone on in the U.S. regulatory system to do with the interaction of science and oversight of biotechnology products and help you think, at least from my perspective, about some of the issues about the credibility of science and biotechnology.

In the interest of time – we're very short on time – I've cut one of those cases I was going to look at, which had to do with BT corn and monarch butterflies, an issue I'd love to talk about to people afterwards or in question and answers. And I'm going to focus my presentation today on issues of food allergy and genetically engineered food and talk a little bit about the development of some of the science, or lack of development of the science to deal with some of these issues. And I'm going to, as I said, give my presentation as a bit of a history or a chronology of events.

The issue of food allergy and genetically engineered crops really started in 1992 when the Food and Drug Administration raised the issue in its 1992 policy for genetically engineered foods, saying the companies must label genetically engineered food, if they contain genes or proteins from the 8-10 most commonly allergenic foods, things like peanuts and tuna, for example, and the company cannot demonstrate that they introduced proteins that are not allergenic.

FDA's policy got truly widespread press coverage, and the allergy provisions were widely criticized as inadequate. A lot of folks, such as myself, pointed out that there are a lot allergens that come from foods that aren't so commonly allergenic and could conceivably come from nongene sources where genes are introduced to genetically engineered food. And the issue was raised rather widely.

In 1994 FDA, in response to this criticism, and other U.S. agencies decided to convene a scientific meeting on food allergy. It was a great meeting, a few days long, but FDA did absolutely nothing to follow up on the meeting, except to publish the transcript of the meeting. Industry did a little bit more to follow up. In the mid-1990s the biotechnology industry recognized the ... of scientific tools to assess whether or not a protein added to a food via genetic engineering is an allergen.

Just in case some of you don't have a background on these issues, the issue comes from the fact that all know food allergens are proteins, and of course genes code for proteins, and so every time, or almost every time, a new gene is added to a crop with genetic engineering, a new protein is added, and there's some small chance that the new introduced protein may be an allergen. And that can pose some health issues for people, particularly because, well, people who are food allergic right now avoid things they might be allergic to, for example kiwi fruit, by simply not buying or eating them. If an introduced protein is in a genetically engineered food, a consumer might not be aware of its presence.

Anyway, in response to these concerns, industry developed a decision tree methodology to guide decision-making on the allergenicity of proteins introduced to foods with genetic engineering. And this decision tree relied on the biochemical characteristics of the introduced protein, to guide government decisions about whether a protein is more or less likely to be allergenic. So it was really the cornerstone of the decision tree approach, was to look at the stability of the protein under the conditions it would be found in the gastrointestinal tract, because allergens as a whole tend to be relatively stable proteins because they have to survive the GI tract in most cases and move into the bloodstream to cause health problems.

In the meantime, research at the University of Nebraska showed that the concerns about food allergy in genetically engineered foods were real. In 1996 the University of Nebraska food scientists published a study in the *New England Journal of Medicine* showing that soybeans engineered to produce a Brazil nut protein were allergenic to people who were allergic to Brazil nuts. And this study was done at the behest of Pioneer Hi-Bred here in Iowa, which, to its credit, after the results became apparent, stopped moving the soybeans along for its commercialization.

Worth noting, however, this demonstration of allergenicity was only possible because the University of Nebraska scientists happened to have frozen blood serum from Brazil nut allergic people in their lab freezer. So they were able to take an extract of the soybeans and look for what are called antibody antigen reactions and look to see whether the soybeans were allergenic. But this sort of testing isn't generally possibly, because for most proteins introduced to food with genetic engineering, there is no lab freezer full of blood from people who have allergies to the relevant sources.

A few years later, by 2000, around 45 genetically engineered crops were commercialized in the United States for use as food. And only one of these crops, Aventis StarLink corn, did not fulfill the criteria of the industry decision to breed. All the others did, and the government said, put them on the market. However, at the Aventis's request, EPA registered StarLink in 1997, but Aventis agreed to limit the use to animal feed and industrial products. In 1999 Aventis petitioned EPA to allow the use of StarLink corn in human food, and in February 2000 EPA held a science advisory panel meeting that concluded that evidence... inadequate information to support a registration for the use of StarLink corn in human food.

In the meanwhile, the National Academy of Sciences, or really the National Research Council, had a panel committee, including myself as a member, who were working on a report to do with genetically crops and reported a number of conclusions. One of them, which I'll allude

to here, was that the tests in industry's decision tree for allergenicity either are indirect, not as involved, adverse effects or otherwise problematic for testing novel proteins that have not previously been components of the food supply. Priority should be given to the development of improved methods for identifying potential allergens in test-protected plants, specifically, the development of tests with human immune system end points and of more reliable animal models.

This conclusion was quite strong, coming out of the National Academy, and it really reinforced what many of those of us in the NGO community have been saying since 1992, that we don't know how to test for allergenicity, we're putting a lot of crops on the market, it's unlikely that any particular crop would be allergenic to consumers, but it is a possibility, and you have to have a methodology to test it if we're going to continue to develop biotechnology.

So, of course, in September 2000, as everyone in this room knows, I'm sure, StarLink corn was discovered in Taco Bell taco shells and in time a host of other foods. And the StarLink contamination got heavy press coverage throughout the U.S. and abroad through the fall of 2000 and became a real issue for U.S. corn exports to Asia. In November 2000, EPA convened yet another scientific advisory panel on StarLink corn, and the panel concluded that there was a medium risk that StarLink is allergenic and recommended investigation of reports by consumers that they'd had an allergic reaction to corn products.

Finally, in winter 2000 the industry began formal discussions of the developing animal models for testing allergenicity. You know, when most chemicals are tested for their toxicological effects, it's done through the use of animal models, which are a much stronger way, generally, of looking at the effects of a chemical than simply making some guesses about its effects based on its structure and biochemical characteristics and so on.

In April 2000 Aventis petitioned EPA a second time to allow StarLink corn in human food. And in June 2001 the CDC and the Food and Drug Administration found that 17 allergic reactions to corn that were reported by consumers do not appear to be due to StarLink but ended their report with some language about the fact that they don't want to be stuck in the position of doing the testing in the future – there's got to be a way of looking at allergenicity from the beginning.

Well, where are we now with the issue of allergenicity in StarLink corn? In July 2001 yet another EPA science advisory panel concluded that there is inadequate evidence to support the approval of Aventis's second petition, and to EPA's credit, the agency denied the petition.

Finally, in December of this year the U.S. government, along with the National Institute of Environmental Health Sciences, could consider that part of the government, is going to convene a meeting, another meeting, the next one since 1994, on the allergenicity of biotech food, take a hard look at some of the underlying issues.

And this fall an industry group is considering providing grants to academic researchers to look at some of the issues underlying allergenicity.

I would like to say that this experience really shows to me that some of the issues that have been raised about the safety of biotech foods and biotech talks more generally, although I haven't gotten an opportunity to talk about some of those issues, really have been short changed scientifically in the regulatory decision process. And if we want the science of biotech to be credible, there has to be credible science underlying the safety.

Finally, I thought I'd conclude by providing a quote from former Secretary of Agriculture Dan Glickman, which was provided to the St. Louis *Post Dispatch* in January of 2001 after he was out of office, and he was reflecting on his experience at the U.S. Department of Agriculture. And he said, "What I saw generically on the pro-biotech side was the attitude that the technology was good and that it was almost immoral to say that it wasn't good. There was rhetoric like that, even here in this department. You felt like you were almost an alien, disloyal, by trying to present an openminded view on some of the issues being raised."

Now, I don't consider myself anti-biotechnology at all, but I do think that it's important that folks who are biotech... spend some time focusing on some of the concerns that have been raised about biotech and developing a better science to address many of these concerns.

Thanks a lot.