

## REMARKS ON REGULATING GENETICALLY MODIFIED FOODS IN THE UNITED STATES

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{1} I would like to thank the Richmond Journal of Law & Technology for inviting me this afternoon and for organizing this forum. I've never been on Crossfire, and it's easy to see why Val has, so I probably won't be quite as entertaining. In fact most of what I wanted to say this afternoon has already been said in one form or another. Val just stole the last one with the Watson and Crick Fiftieth Anniversary. What I want to do is maybe give you more of a sense of perspective and then go over some of the facts.

{2} In public perception, agriculture biotechnology is an infant industry. The public perception is accurate with respect to realizing the potential of the technology. We've taken the first tentative steps, but we don't know enough either about the technology or the genomics of plants, animals and microbes to do more than toddle in the general direction we want to go while making new discoveries with each step. In the 10,000 years that we've been cultivating plants and domesticating animals, we only discovered the science of selective breeding 140 years ago, and we only discovered how to target molecular level breeding several decades ago.

{3} The public perception does not conform to reality with respect to our experience in regulating the technology. Watson and Crick, as Val has already told you, discovered the molecular structure of DNA exactly fifty years ago in 1953. The U.S. regulatory structure for the use of biotechnology was established seventeen years ago with the publication of the Coordinated Framework in 1986. The Coordinated Framework is based on a simple premise. It was thoroughly examined and debated at the time, and as recently as 2002 was re-examined and determined to be fundamentally sound. The premise is that the risks presented by agricultural biotechnology are no different in nature and scope than those presented by conventional plant breeding.

{4} The Coordinated Framework established a regulatory structure based on the existing responsibilities and authorities of the U.S. Department of Agriculture (USDA), particularly the Animal and Plant and Health Inspection Service (APHIS), the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA). To greatly oversimplify the respective roles of each of these agencies, USDA is responsible for protecting animal and plant health and safety, EPA is responsible for regulating the use of pesticides and toxic substances, and FDA is responsible for ensuring that new food products do not contain toxins or allergens and for ensuring the safe production and use of pharmaceuticals and veterinary drugs.

{5} It's important to note that biotechnology is a process, not a product, and our regulatory system is designed to regulate products. So we regulate the products that are developed through biotechnology and not the process of biotechnology itself. In the seven years that we've had commercial production of agricultural biotech products, there have been three significant regulatory problems, all of which have been mentioned here today I think. One of those involved a product that was commercially



released, and the other two involved products still at the research and development stage. All three were essentially enforcement problems, but they do provide valuable guidance about improvements and enhancements to our regulatory structure.

{6} First problem was Starlink. Starlink is the brand name for a Bt corn variety that was released for commercial production in 1999. Starlink corn was approved by EPA for uses in animal feed, but not for human consumption because there were concerns that it might contain a potential allergen; this has been discussed somewhat already. In September 2000, Starlink corn was detected in taco shells sold in grocery stores. Starlink corn was grown on less than one percent of total U.S. corn acreage in 2000. The incident led to a recall of nearly 300 food products and resulted in a 21% decline in U.S. corn exports to Japan, our top market. Even though Starlink has been pulled from the market, residual amounts remain in the U.S. corn supply. Despite the fact that the residual amounts that remain in the corn supply are down to trace amounts, the economic and trade impacts continue.

{7} U.S. exporters have to test every shipment of corn to Japan for the presence of Starlink. In December last year (2002), Japan's Ministry of Health detected Starlink in a shipment of corn destined for human consumption and immediately announced an increase in testing requirements to a level that will make it very difficult for U.S. exporters to continue selling corn to Japan for the near future. In retrospect, the approval of Starlink for feed use but not food use was a serious mistake. As a condition of approval, EPA required Aventis, the company that made Starlink, to control the distribution of Starlink through a series of contractual arrangements. This failed for a variety of reasons, but in large part because too many of the companies selling the seed and too many of the farmers planting the seed did not understand the restrictions and in some cases were never informed about them. EPA has since determined that it will no longer issue split approvals for food and feed.

{8} The second problem was Prodigene. Prodigene is small company based in College Station, Texas, and they do research on the production of pharmaceutical and industrial products in plants, primarily corn. Companies conducting research frequently perform field trials, which have to be authorized by APHIS either through a permitting process or a notification process. Last fall APHIS inspectors conducting routine inspections of field trials in Iowa and Nebraska discovered serious violations of the permit conditions. The problem was similar in both situations. Inspectors found volunteer corn plants growing in or near the test sites in which the experimental corn had been grown in 2001.

{9} The permits require that tests sites be monitored for at least a year after the actual field trail for any volunteer plants, and those plants have to be removed before they tassle, which is the point they begin to produce and spread pollen. In the Iowa situation, APHIS determined that pollen from the volunteer corn may have contaminated adjacent corn fields. APHIS required Prodigene to purchase and destroy all of the contaminated corn. In Nebraska, the volunteer corn plants were found in soybeans planted on the test site. Again, APHIS required the company to purchase and destroy all of the contaminated soybeans. All of which is potentially going to cost the company about three million dollars, the largest fine APHIS has ever imposed.

{10} The third problem involved a research project at the University of Illinois on pigs. Scientists there have been inserting cow genes and synthetic genes into pigs in an attempt to increase the growth rate of the animals. These experiments were being conducted under FDA's rules for new animal drug investigations. The offspring from the altered pigs were examined to determine whether they inherited the transgenes, and if not, the offspring were sold for slaughter. This was a violation of FDA rules since all offspring of the genetically altered pigs were considered themselves genetically altered.

{11} This situation did not result in the recall of potentially affected meat products because FDA

determined that based on the available scientific evidence, the proteins produced by the genes in question would present no risk to public health. However, the incident did highlight the need for tighter control over animal research. Most of the animal research is currently being conducted by universities. Commercialization of any transgenic animals is most likely still years away. Nevertheless, we need to guard against the possibility of unauthorized products entering our food chain.

{12} The lesson from these three problems with our regulatory framework is essentially that our coordinated framework has worked very well. There has not been a single documented case of human illness from consumption of food products derived from biotechnology. Fears that we are creating uncontrollable super weeds have not been realized. Monarch Butterfly populations have not been decimated by Bt corn. What these cases do demonstrate is that we need to be constantly vigilant and we need to keep up with the changes in the technology.

{13} We believe we've demonstrated our ability to safely manage the risks from the first generation of the products. We understand the risk, and we've developed effective risk management techniques. By the first generation of products, I mean largely those products that have agronomic traits, traits that are beneficial to farmers more so than consumers. The challenge that lies ahead is in managing the risk of products that are not intended to be introduced into the food system. These are the products that were involved in the Prodigene situation and the pigs at the University of Illinois.

{14} Our objective in regulating these products is containment. We want to keep them out of the food system. I think everybody agrees that this should be our goal. It turns out that concurrent with the Prodigene situation, certainly not as a result of it because most of this discussion started well in advance, a very interesting debate has developed over how we regulate pharmaceutical and industrial products. Greg Jaffe referred to a number of the issues that his group has been looking into, and I think that fairly reflects what a number of other groups are concerned about, as well. Just to give you an idea of what some of the issues are in this debate, a number of people have said, "We shouldn't be producing these products in food crops, it's too dangerous, we don't want to risk contaminating the food supply." There are a variety of reasons why this research is done in food crops, and I will let the scientists debate this for you, but that's something that's not going to go away sometime soon. There's a lot of pressure from the processed foods industry on that score.

{15} You may have also read that there was pressure at one point to not allow these products to be produced in the major crop production regions, such as Iowa and Illinois. A certain Senator from Iowa, who happens to be very powerful, decided that wasn't particularly a good idea. In fact, scientifically it makes no sense. Political boundaries really have no place in a scientifically based regulatory system.

{16} Another issue is whether we should have thresholds; whether we should allow some adventitious presence of these products. The U.S. Government does have a Federal Register notice out now on the whole issue of adventitious presence, but it specifically excludes these products. We need to figure out how we are going to deal with adventitious presence of unapproved first generation products, the Bt corns and the RoundUp Ready soybeans, before we start tackling the more difficult issues that are going to create more widespread consumer concerns.

{17} A similar issue is how we are going to deal with economic risk. One of the issues that is being widely debated in the agriculture community right now is RoundUp Ready wheat. Monsanto has already put the application into the U.S. Government for approval of RoundUp Ready wheat. The wheat industry is actually debating this issue in Washington tomorrow. There are many wheat growers who would like to use the product, and there are probably just as many wheat growers who don't want the product commercialized because they're afraid that it will cause them to lose markets in Japan,



Europe and elsewhere. Obviously, the food industry has a great voice in this debate. Wheat is an interesting one because it would be the first bulk commodity agricultural crop that's intended primarily for direct human consumption. The corn that we are producing now in biotechnology is largely for animal feed. The same is true for the soybeans, but wheat would be the first one that's intended primarily for direct human consumption.

{18} Again, that's not a scientific issue, it's more of a public perception issue and it's an economic issue. Right now our regulatory system doesn't allow for decisions to be made on the basis of those issues. Another issue in this debate is that no matter what we decide on any of these issues -- we could all agree here right now today with the exception of Tony Van der Haegen on what we're going to do about these -- we still have to convince our trading partners. We can set an adventitious presence threshold of 5%, 2%, 1%; if I can't sell it to Tony and our colleagues in Europe, it doesn't do us any good, because if we cut off our exports, our agricultural industry is dead.

{19} You may have noticed as I've gone through this list that a lot of the things we're talking about affect primarily bulk commodities. These issues arise when we're dealing with things like corn, soybeans and wheat. The reason is because we cannot segregate these products to meet zero tolerance requirements, which is what most, if not all, regulatory systems in the world have right now for unapproved products. If a product is not approved in the United States, it's not allowed on the market, period. There's no tolerance for it, and that's true in almost every country. We can't segregate and that was the lesson from Starlink -- once you've commercialized something, it's in the system, you can't keep it out, not to a zero tolerance.

{20} So, in conclusion, I haven't even covered animals or insects or the mosquitoes that somebody's working on -- there is a whole range of issues that I have barely touched on, and this forum will barely touch on these issues. For those of you who are students and who are interested in this area, it's a fascinating field and we're barely scratching the surface. Despite everything you've heard here today, most consumers in this country trust the decisions that are made by regulators. That's a trust we have to earn and protect, but it's a trust we can't afford to live without.

{21} Finally this technology moves very quickly, and we as regulators have to keep up with it. We have to be adaptable, we have to be flexible, and we've got to stay ahead of it. We can't afford to get in a situation where we have products getting into the market that we decide aren't safe, because that would kill the technology and it would seriously damage our regulatory system and that's something we just cannot afford. Thank you.

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