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Remarks on Food Safety in Dealing With Genetically Modified Foods

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REMARKS ON FOOD SAFETY IN DEALING WITH GENETICALLY MODIFIED FOODS

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{1} It's nice to be here, and I appreciate the opportunity to talk with you all. It's my first time in a School of Law and you certainly have more wood in your rooms than we do in laboratories, so this is a different experience for me. I'm a food microbiologist by training, so to me, food safety means *Salmonella* and cantaloupe and viruses in cruise ships. With genetically engineered foods, it's a little bit different because the effects aren't as dramatic as far as safety issues as what I see in my daily professional life. Also, it's different because genetically engineered foods are clouded by so much emotion and hearsay; it is an emotionally charged topic. Today, I just want to talk about the product safety issues and not get into the environmental ones, such as containment.

{2} When I first started to get involved with this area of food safety, I realized how little I knew about farming. I had fairly good grasp of biology from being a grad student and working in the lab, but I was really ignorant about farming and the science of farming. I thought "Well it's just basically you put the seeds in the ground, it rains and at the end of the season you harvest the crops and that was pretty much it." In getting into this, and looking at agricultural genetics, I learned that science in this area has been going on a long time, and the techniques we're talking about are really based on what's come before. It's more a continuum, not voodoo, black magic and just beyond the laws of physics, biology and chemistry.

{3} To begin, traditional foods, so to speak, are ones that are generally recognized as safe; they've been consumed for a long time, and we trust them. You have to realize that these traditional foods aren't one-hundred percent safe, as they can have natural toxins and carcinogens and there's a dose relationship there. So these foods are not one-hundred percent risk-free, and on top of the toxins and carcinogens, you have to recognize there are also allergens in food. For example, peanut allergies can be quite devastating, as people can actually go into anaphylactic shock after tasting a peanut, so you don't want to mislabel foods if peanut proteins are present. In all of this, you look at the conventional foods and note that when it comes to breeding and some of these other established genetic methods, the foods simply aren't tested. It's sort of a trust-based relationship. So I think one thing that helps in looking at this area is not to look too narrowly, but with a broad look at the history of the technology. And, like me anyway, you can start to appreciate things in the past and understand what's occurring now.

{4} The general consensus of scientific panels that I've seen is that when dealing with the technology of GE foods, there are no hazards particular to these modern molecular techniques. These genetic techniques have been based on prior work, so the scientists know the foundation and different levels of application. It's a continuum, as I mentioned earlier. These methods are no inherently less safe than the conventional methods that we continue to use.

{5} Before I get to the conventional methods, I just want to outline very briefly the safety evaluation for this segment of foods. I think the mentality of the FDA and the USDA has been to look at the food product. Granted, you realize the process that it took to deliver the food, but the focus should be in the composition of the food. If there is anything deleterious with the food, then you deal with it. This becomes especially important when you're trying to compare conventional food with a food that's been genetically engineered. It thus becomes a system of dealing with substantial equivalences, a term which has generated some controversy. You compare the genetically engineered counterpart with it's parent, or the traditional product, and focus on the changes and differences between the two foods. This method is used to structure the safety assessment, but this gets into food law and regulation, and I know there's quite a few people in here that know more about that subject than I do.

{6} The focus is on how the food looks, its composition, and the make-up of the food itself, considering both intentional effects and unintentional effects. The safety of the introduced genetic material is assessed, and one asks "What are you putting in there?" Most of these modifications are relatively simple, with either one gene or just a few genes inserted, and the technology is nothing relatively different than it was 300 years ago. Looking at the DNA, the source of the DNA is determined, as well as the size of the DNA that's inserted, the number of copies that may be inserted into the host genome, and the location of the insertion. It is also important to note the base sequence of the insertion. For comparison, about ninety different bacteria have their entire base sequence known.

{7} More importantly, DNA by itself is not toxic. DNA is in foods, we eat foods, the DNA is hydrolyzed, and the DNA is broken down like nearly everything else we eat. It's really the gene product that's the key and where issues can immerge, like allergenicities. It becomes crucial to look at substantial equivalence by looking at the parent and the traditional. You look at the composition, the structure, and the amount that's expressed in the food. I mean there are issues with acrylamide in baked products, and acrylamide is a carcinogen. This has nothing to do with genetic engineering, but the point is it's been there apparently for who knows how long but in such a low level that our bodies detoxify it, and apparently it's not an issue in human health and safety. So the amount is important, along with a comparison to known toxins and non-nutritional factors. The Cry proteins cause human allergies. Thus, you can compare their structure, the function, their amino acid sequence, and certain other traits, and you can predict outcomes.

{8} So it's not as if these products are untested, because they are tested. Again, some of these things are rather straight forward and have been around for some time. Regarding thermal and digestive stability, this is another factor that's examined because when something is allergenic, it is not broken down by the body. Thus, it's those that aren't digested that become an issue. You want to understand how a potential allergenic protein deals with thermal processing since so many foods are heated.

{9} As for unintended effects, even in the sloppier, conventional genetic modifications, you usually don't see unintended effects, because if they're that substantial, usually the offspring are not viable, and in cases in using recombinant DNA technology, none has been documented. Is there one-hundred percent guarantee that this will never ever happen? Well nothing can be guaranteed one-hundred percent.

{10} Now an example of an incident of unintended effects that actually involves a conventional genetic modification; it deals with Lenape and Atlantic potatoes. In this case, it involves conventional plant breeding, this was not recombinant DNA technology. A variety of potato known as Lenape was

being prepared for commercial release as a potato we would all eat. It was found that it had a very unusually high glycoalkaloid content. Green potatoes usually mean high solanine content. In the case of the Lenape, even though it was conventionally bred and its *immediate* samples or tissues before it did not have this elevated alkaloid content, this specific potato did. It was realized that the undesirable trait skipped a generation. In this case, even though further breeding with the Atlantic potato had acceptable low amounts of this alkaloid, the Lenape from this particular cross had these unintended effects. Again, this doesn't often happen, but in this case, thankfully scientists were aware of it and this variety of Lenape was never commercially released.

{11} Allergenicity is part of the key issue with food safety of genetically engineered foods, because again, if you take a protein that's allergenic and put it into a food unintentionally, that food could be mislabeled or somehow find itself on the plate of a person who's watching what they eat because they have an allergy to certain food proteins. Now what the FDA does is look at the source of the gene, what you're engineering, and the amino acid sequence compared with the homologous structure of known allergens. The FDA might also look for digestive stability to determine whether or not a particular protein is allergenic.

{12} One example of a mishap involves recombinant soybeans where workers, in order to make the soybeans nutritionally more complete, decided to reduce protein deficiencies in this crop. The researchers, who didn't know too much about foodborne allergies or that segment of science, decided to take Brazilian nut proteins, not thinking that quite a few people are allergic to nuts, and genetically engineer a new soybean. This new soybean was never released because someone asked them if they knew about human allergies to nuts. It was like, "Oh!" and so they checked it and found the soybeans did contain the allergenicity. So, while this plant was never released, it is an example where you do want to check and you do want to make sure a GE food doesn't contain an unintentional allergen, because if it's not labeled, people not meant to consume it could consume it.

{13} I'm not a psychologist, but I am very much aware through teaching students and interacting with various people, that when it comes to this segment of foods, as I mentioned, there's a wide range of responses. Part of it is just the fear of the unknown; part of it is people not understanding where their foods came from or how they were made. In my line of work, I deal with college students, and I frequently ask them, "Do you drink beer?" A few will say yes, and I will say, "Do you know how it's made?" Usually, I don't get a correct answer. There's just a lack of understanding, and there's a trust for how things are made. Now, in the area of genetically engineered foods, there's a lot of "bru ha ha" about whether you should trust people that delivered food to you, asking if the food is a wholesome, safe, etcetera.

{14} There are also a lack of visible effects. It's true many of the early modifications dealt with production issues, but now you see such products as golden rice, where scientists are trying to stabilize the genes to insert beta-carotene so that they can deal with nutritive diseases around the world. You see more about golden rice than you do about a pesticide-resistant soybeans, since there the value of pesticide resistance just isn't recognizable to most American citizens.

{15} There are many different websites out there with a lot of information, a lot of misinformation, and a lot of anti-this and anti-that. There's one about Nutri-Sweet, and of course it has nothing to do with genetic engineering, but one site says that Nutri-Sweet causes brain tumors. Talk about obvious fabrications – you have to be careful here.

{16} What about Mad Cow disease? Mad Cow disease, which has nothing to do with genetically

engineered foods, first occurred in the mid-1980's, and the European governments did an extremely poor job in handling it. Now granted, prions were not well studied at that time. The governments understand a lot more now, but European countries and their citizens lost a tremendous amount of faith in their governments as far as making correct decisions. So when genetic engineering became an issue again, the citizens voiced "You couldn't get Mad Cow right so how are you going to get this right?" I was with a group in Amsterdam and most of them were food technologists. I did talk to them about food technology in Europe and GE's, and most of them were resigned to the fact that things are pretty much flat regarding research and development in the area of genetically engineered foods.

{17} As of now, little, if anything, is going to be accepted in Europe regarding GE foods, regardless of the quality of the data you submit because the people don't want to hear it. As far as any documented safety issues, the Europeans in Amsterdam noted there were none. Some at the table got really lit up about Monsanto and how the company handled the situation, because of their arrogance and how they treated European citizens – as if the consumer knew nothing about anything. Monsanto just lost a tremendous amount of credibility, and quite a few at the table, most of whom were from the UK, were losing their temper about it.

{18} These scientists also saw a brain drain, as they see a lack of funding for molecular microbiology, in general. Thus, PhD's have to go somewhere else because now many European countries and their governments aren't politically willing to promote some of these technologies which are so unpopular. In Europe, to me, the climate from what I've heard is just so much different from here, but that might be a point that the panel can take up.

{19} One more thing, on a bit more personal note and as something I'll have to get over sooner or later, is that some say microbiologists are anal retentive. Well, I guess I am, but genetic modification happens all the time – it's life. We live because of genetic modification, and there's all different kinds of genetic techniques that have been used a long, long time. Granted, people didn't always know what the methods were doing and didn't have nice jargon type names to describe them, but genetic modification is more than recombinant DNA technology. Other methods, like hybridization and induced mutation, have also been used to genetically modify foods.

{20} One of the things I thought about driving down here was organic foods, and that if we talk about organic foods, I should note that organic foods are not supposed to be genetically modified, but all our foods are genetically modified. So, the question becomes which genetic methods do we accept and which ones don't we accept as far as techniques that are "good or bad". Now granted the recombinant DNA technology would be one that is excluded from organic foods, but, for example, what about embryo rescue? When using embryo rescue techniques, is that acceptable for organic foods if you follow all the other guidelines? I don't know, where do you draw the line?

{21} Again, it's a continuum of methods as I see it, and not black or white, it's more gray because so many manipulations of our foods have been through selection of genetic mutants. You take male positive traits, female positive traits, mate them, produce offspring, keep the offspring that look good, and then do it all over again. We started with wolves, and we ended up with Mexican Chihuahuas and Irish Wolf Hounds through these kinds of genetic manipulations.

{22} One example of an alluded safety issue concerning foods derived from recombinant DNA technology is the tragedy that occurred back in 1989 where 37 people died from eosinophilia-myalgia syndrome. This is where I've seen some say, "Look – this is where GE foods kill you," but what actually happened involved a Japanese manufacturer who was very negligent. In this case the

manufacturer made changes to their production process to save money. What they did was they altered it, took out or modified purification steps; they deleted reverse osmosis and also some activated charcoal steps. Afterwards, the result was this intoxication syndrome caused by chemical impurities in the product.

{23} Now how recombinant DNA technology gets involved concerns the producing organism, *Bacillus amyloliquefacians*. This bacterium has been used for a long time to produce amino acids. The Japanese probably export 80% of the amino acids in the world – you know, that's one of their niches besides electronics and cars. Anyway, this industrial strain had been around and they modified it to increase amino acid production, but the modification and the engineering did not cause the tragedy. It was coincidental; many of these strains of bacteria and molds that the Japanese have used are modified through mutation that they've been doing since 1907.

{24} We've already heard about Starlink and Bt toxin, so we probably don't have to dwell on those examples too much. It just seems to me though that looking at what's going on in so many of the issues in GE foods are containment. You don't want mixing. I mean, you want segregation to keep foods separate according to whether they are genetically engineered and conventional. It's true, farmers in this country do not have the money and hardware and the systems to segregate large tonnage of many of these products until these issues came up with Europe, and now, you have to segregate to export foods to Europe. That's a curve ball that's hard to deal with, and farmers are trying to deal with it, but obviously the cat gets out of the bag on occasion and nothing is without risk, so you have these issues of containment as seen with Starlink. When it comes to actual issues of disease, or cancer, or the hard stuff, so to speak, I just haven't seen it. I'm not saying it doesn't exist, it just doesn't show up on my radar screen. It's sort of like *Listeria* in processed turkey or some other issues that will kill you in certain situations, in certain foods, and with certain consumers.

{25} As for safe products on the market, enzymes again are used in a lot of different industries. In the food industry, chymosin has been used since 1991. It's a genetically engineered enzyme. They took the genes from a cow and inserted them in *E. coli* K12 to produce this enzyme. The reason they do that is normally what you do with a conventional cheese is you slaughter a calf, extract it's stomach, and scrape out it's stomach and this extract contains the proteolytic enzyme, rennin, which you place in the milk to produce curds and whey. It doesn't sound very appealing but that's how cheese is made at least in the traditional sense. So, because of a lack of availability of rennin from the slaughterhouse, what they've done is they've taken the gene for rennin, inserted it into *E. coli* K12, and the enzyme is now being produced by a bacterium, often referred to as chymosin. Chymosin is cheaper, and it's also more pure. Of course they've compared the amino acid sequence from the cow to chymosin produced by *E. coli* and it works great and is safe. If you were going to have to label all GE foods, you'd have to label just about all cheese in the United States because that is pretty much what's now used.

{26} In closing, in looking at the techniques for genetic modification, taking DNA from different sources is a powerful technology. It is still in its infancy, we're still learning, we'll probably always will be learning, but it's something that is going to be here to stay. Those Europeans I was talking to at that lunch in Amsterdam all said that the Europeans will eventually get with it. I think basically a summation of their response is that we'll just have to wait a while for the Europeans. Genetic engineering is not going to take care of all the world's issues. We had six billion people in 1999 and we're going to have nine billion in 2030, so twenty-seven years from now we're going to have 50% more people. I mean Interstate 95 is crowded now, but it's even scarier what the future may bring. Recombinant DNA foods will help feed the world, but as far as alleviating everything, forget it – that's a Disney World fantasy.

{27} Finally, this can be scary, but the education and understanding of this technology and the foods and the regulation is something that we all have to continue to pursue. This slide is from a calendar and we have what appears to be a spider goat. What this slide is talking about is taking spider silk glands, and through genetic engineering making a transgenic goat, because you want to produce the spider silk for commercial reasons and have that desirable protein being excreted in the goat's milk. Someone who's not really understanding of this technology may take a step back when they hear about it. I mean this picture makes me think twice too. A lot of these issues are emotional, but you have to look at them objectively, look at the data, and try to understand what is an issue and what isn't, and that's how we'll get ahead and not hurt many people, but help them instead. We'll also hopefully be able to deal with environmental issues, but it's something that's challenging, which is why I guess your having a symposium on the topic. I guess I would say it's a good selection for a topic. So with that I will conclude. Thank you for your attention and again thanks for the invitation.

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