Genetic Engineering and Specialty-Crop Improvement

Q&A

Moderator: Dan Lineberger
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Tom Redick (Global Environmental Ethics Council, Clayton): I wrote a book on labeling issues and so I just wanted to correct points made by Greg Jaffe. Connecticut is likely to sign. The other two up in that part of the world, Maine and Vermont, are stuck at the house level where a lot of these bills die; the Senates and governors may not comply. Alaska is labeling only fish and there aren't any GE fish so nothing will happen in Alaska until the FDA finally gets off its butt. Thanks.

Chris Wozniak (Environmental Protection Agency, Washington, DC): A question specifically for Dennis Gonsalves although Tony Shelton certainly could address it as well, or Roger Beachy. The point was made earlier on that the technology is there for a lot of these specialty or minor crops to reach their full potential in the marketplace. The transformation techniques are in place; that's not an issue. Traits are available. Promoters are available. Yet we still don't see a lot of these on the market. We see virtually none. You pointed out that, in your development of papaya, things went fairly straightforward. We do, in fact, have European plum with plum pox resistance registered by an ARS scientist, Ralph Scorza, who did the regulatory work on his own. My question to you is, if the technologies are in place and we see that the regulatory system seems to have worked here, then what is holding it up? Or is it the regulators and these were just two anomalies?

Dennis Gonsalves: This was back in the 1990s—actually the process that we went through was pretty straightforward. We didn't do anything that was out of the ordinary. My personal bias is that a number of people are rationalizing themselves from moving forward and, you know, with the papaya it wasn't so much about whether we were going to make money. As public-sector scientists, our goal was to help. We got no support from the industry—they don't make much money. It did not cost that much. It was almost like getting a series of grants. So, to answer your question, I think some people are gun shy.

Craig Nessler (Texas A&M AgriLife Research, College Station): There's a big difference between deregulating coat protein or another known protein from a foreign protein. The allergenicity questions have been raised but I don't know that they are legitimate. Now you can just use RNAi—you don't have to express the protein at all—which may influence the speed of deregulation. Animal tests on safe proteins from other plant species will still have to take place.

Gonsalves: We went through Japan—people will say that it's the strictest country—but they never required us to do animal tests. They were concerned about allergenicity, food safety, we had to do a lot of bioinformatics, and we had to do gastric juices tests, which are pretty simple. But they never required animal-feed tests, perhaps because it's very difficult to draw firm conclusions from such studies.

Roger Beachy (Global Institute for Food Security, Saskatoon): Dennis or Tony, have you ever worked up the numbers for what it would cost if you needed to do each of these per Craig's suggestion? Have you gone through what it would take to register a product that requires animal testing and a lot of the environmental tests that are now sort of expected for all crops? Do you know what that number is? Chris, maybe you could clarify what it takes to deregulate something novel? Not another Bt, not from RNAi, but from something else? Or maybe someone at a private company can provide an estimate.

Wozniak: I'd like to clarify that question because this is something we've tried to address before. As you probably know, Nick Kalaitzandonakes, in Missouri, has some pretty good data, but even he will admit that a lot of the information that is put under the heading of "I had to do this to get this registered or deregulated" are really things the company would do themselves anyway for their own peace of mind. Remember that even though—as Greg pointed out—the FDA system is voluntary, the onus is still on the person entering the food or feed into the marketplace for its safety. They are personally responsible for that. So, even if you had no regulation and you were putting out, say, a *Bt* corn, or whatever, are you telling me that you would never do an animal-toxicity test? If you have capital investors putting millions of dollars into a large company, for their own peace of mind they would want to know, "Is this going to be an allergen?" "Can it be a toxin?" Some of these tests are expensive, but some of the allergenicity checks can be done on your laptop in 30 minutes.

Beachy: We are talking about specialty crops that have markets not in the hundreds of millions of dollars. We are talking about markets that are considerably smaller.

Wozniak: Right, and I will address that in my presentation, but the real difficulty for me is coming up with that number. If you look simply at the tests that are sort of mandated—and Dave Heron can also address this from APHIS's standpoint—you could go to the third-party laboratories and get their costs for doing the tests and you could also get all the background information that isn't a data generation kind of test, plus the consultants' fees. You could do all that and put this all into the proper format, and come

up with a realistic number. But the numbers I have seen to date, from Nick for example, 10, 12, 14 million, I think are way off base. I don't know if Dave Heron is here, if he wants to try to address that from the APHIS standpoint.

Beachy: It would be really interesting exercise to have that done from the Canadian side and the US side, because the Canadian process is built on food safety. That is their benchmark for release or not. It would be nice to have that available for those in the public sector and land-grant institutions—to say, this is what it will take to release a new pepper, or whatever, to farmers. If that number is a high hurdle, what is that hurdle that we have to overcome? What is the role of the experiment station? Or the state? Or the farmers, in helping it happen? In Canada, the farmers take an active role in support of research. Including developing varieties—farmers pay. Maybe the time is ready for us to do things in a different way and realize that those who will benefit—the farmers—will pay for product development. Maybe their royalty stream will be lower, whatever the number, but think of it differently. We ask about how we move it forward; maybe this is in the mix. Because, right now, it seems that we don't have a sense of what it's going to take to get a new product out. It's a barrier even to getting experiments done. We could just do it by mutagenesis and work for 10 years to get it finished.

Wozniak: Well I have some things to present, some things where I think you can mop up the corners a bit.

Gonsalves: We had a conference a while back at the University of California, where we asked the same question about specialty crops. My thesis is you've got to get other crops of this size commercialized, so people get used to it. Even if you lose money on it. I told the University of California, maybe the dean should contribute $200,000 to $300,000 to get a technology like virus resistant, or whatever, that is already developed, then get a sociologist to do the work to get it deregulated and commercialized. Then you actually can analyze the philosophy, the whatever it takes, because it takes actually doing it before you know how to go. With Japan, a lot of it was when to argue and when not to argue. You just got to do it and then you can get numbers. But, if you don't do it, then nothing happens. Like I said, there is no reason I should be talking at this conference. We did this in 1998—my goodness, there should have been other crops commercialized since then.

Wozniak: I'm waiting for that Roundup Ready tomato.

Alan McHughen (University of California, Riverside): When Dennis and I took our products through regulatory approval back in the mid and late 1990s, the costs were not outrageous. As Chris suggested, most of the information required by the regulators were data points that we would have measured anyway just in our regular due diligence, looking at allergens, looking at anti-nutritional factors that are naturally occurring in that food product in the first place. So we had the majority of the data already. The additional cost over and above the cost of doing that due diligence was relatively affordable. Frustrating sometimes, but certainly affordable.