Session 4: Perspectives from Relevant Groups

Q&A

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Scott Thenell (Thenell & Associates, Walnut Creek): Tom, earlier you asked about identity preservation[1] and whether I thought that would work. Obviously, the Soybean Association has identity preservation; can you give us an idea about the additional costs?

Thomas Redick: They have what they call the eleven-point plan for keeping things separate in soybeans. Soybeans are self-pollinating, but there are all kinds of opportunities to commingle in the chain. The premium for that is a negotiated element, so additional costs you incur depend on your own farm, whether you have a guild, and so on. Maybe you are growing white corn for FritoLay and are part of a network contributing to a dedicated elevator. So, $.40 a bushel is just one example. It could be more, it could be less. Definitely, if you are going to go to a specialty preserved chain of commerce, the costs of identity preservation mean that the grower is not going to do it unless there is something in it for him. It could be a 10-year contract that he's guaranteed. That could do it, if you have a guarantee that every year they are going to buy what you grow. But, usually, you need something per bushel to sweeten the pot before you are going to agree to a fully identity-preserved production system.

[1]Page 218.

Ralph Hardy (National Agricultural Biotechnology Council, Ithaca): In the pesticide area they have special exceptions for certain crops, called IR-4. It's also my recollection that there is some harmonization between the Canadians and the United States in IR 4. Does that concept have any relevance to any of these specialty crops we are talking about?

Redick: Yes. When we did the Accord, we first talked to folks involved in IR-4 because they have their own data-compensation system with USDA oversight. That was designed mainly for specialty crops to ensure they get the active ingredients they need when they go generic. So, that was driven by a need for chemicals to go into the right places where they are needed—whether they are generic or not—without worrying about overseas approvals and data and whether issues have been resolved. So, there are plenty of models to be followed, and the Accord will be filed this summer. I think the final steps will be done and we'll have a document that folks in the specialty sector may also use for patents that have expired.

Roger Beachy (Global Institute for Food Security, Saskatoon): Are there any opportunities for North American identity preservation that would ease some of this? Are there products that could be from Mexico, the United States and Canada that that could be called out, without need to worry so much about other exports to other countries?

Redick: I think you could produce a crop in a closed-loop and assure the stakeholders who matter that this has been produced in a closed loop, not commingling with the export chain of commerce. The trick is going to be to find the place to grow it, where it's not going to just automatically—

Beachy: But are there products that have enough market to do that?

Redick: A high-oleic soybean that came out in 1999 was grown in a closed-loop but never made the market because of the cost. So, there's no guarantee that the identity-preservation cost will justify the new event that you are introducing in a specialty crop. In the soybean sector at least, everything has been grown for major market approval. In corn, they only have two markets they care about. So their board has voted only Canada and Japan, not even Mexico. And Mexico has actually allowed that because they eat so much of our corn and feed so much of it to their animals. So, it's possible that carrots could be more like corn than like soybean. Maybe there's not a big export market for certain crops. Maybe there are governing stakeholder groups that say, "We want the innovation." There are models out there for doing it with just a couple of key markets.

Beachy: Then I have one more. Has there been sufficient validation from the market on the heart-healthy oils? Will consumers pay more for them? I just don't know how that consumer research is going. And does that pay for segregation?

Redick: That's the great untested question. There are issues too like glycosylation of omega-3s. CAST has actually written a paper on that question. So there's a lot of tough science before you're going to find on these specialized oils meeting scientific nutritional equivalents. I don't know that every one of those is guaranteed. Actually I've heard people say that a third of those might actually find the market. Soybean oil economists project that you really have to meet certain levels of marketability to get in the niche. But the high-oleic soybean that is coming out now—they are looking at 25 percent to 50 percent of the market share because it can fry fast food better and deliver a heart-healthy benefit—called Plenish® and other names. They think they are going to get a good market share. The soybean check-off is putting a lot of money into making that happen, so we'll see if the market accepts it.

Allan Eaglesham (NABC, Ithaca): Mary Ann, are wild blueberries more effective than cultivated blueberries and, if so, do you know why?

Mary Ann Lila: Yes, because they are more concentrated they withstanding more stresses. In some ways it's like the organic vs. non-organic argument. But yes, plants in the wild accumulate more phytoactives.

Bolormaa Jamiyansuren (University of Minnesota, Minneapolis-St. Paul): Dr. McHughen, you mentioned that people who were against GMOs do purchase GM products after seeing the price. I am gathering information on GM products in terms of being cheaper or more expensive then conventional or organic products. Can you give a reference to that? Or did you do a study on that?

Alan McHughen: The studies have not been properly done, or at least not for several years. In some of the early academic studies prices were equal so consumers making a GMO/non-GMO choice didn't have price as a consideration. We need to do more of that and have prices reflect what consumers will see in the marketplace. Presumably, if the GMO has a benefit to it, at least agronomically, the price should be lower because of the increased efficiency of production. Of course, this will also help to sell more of the product. At least for those people who have an open mind, if they see good quality at a lower price then they will be inclined to purchase. We did see this early on in the UK when GM tomato paste was on sale for a short time. Unfortunately, the cans of tomato paste were of different sizes so even though the genetically engineered tomato paste had a lower price, consumers couldn't make a direct comparison. But the GM paste was less expensive and, apparently, that is what many consumers chose to purchase. But we will be able to answer this only when we have multiple products in multiple markets and really see how the consumers treat them. But I'm convinced that the vast majority of people don't particularly care how the product was made as long as the price is good and the quality is good.

Jamiyansuren: Dr. Lila, you convinced us that blueberries are very good. In terms of the blueberries and green tea, your slides indicated statistically significant improvement in the treatment group compared to the control group. I wonder about a human factor; if a very healthy man happens to be in the treatment group might it produce a better result than with the control group?

Lila: They were all high-performance athletes across the board. I was working with ASU, using their standard experimental design—all high-performance athletes.

Bill McCutchen (Texas AgriLife, College Station): Jim, can you tell us the exact date on which we will be able to use the technology you were talking about—homologous recombination—to make changes in specialty crops without going through regulatory processing? A little joking, but how far away are we from being able to make those types of changes?

Jim Flatt: Most of my insights in this case are gleaned from our work in algae as really simple plants and plant models. We have been successful in developing HR homologous recombination methods for several of the algae. But, I can say that this is very species-specific and has required a lot of work to get there. I do think it's possible, although efficiencies vary among the couple of species that we have used to develop the genetic tools. One of the things that is beneficial here, though, is in terms of developing some of the nucleases to make double-stranded cuts in DNA. We have benefited in our work from the ability to make these very specific modifications, in trying to improve the efficiency of that process. I wish I could give you the exact date; it's probably still several years off. Certainly, we see some glimmers of hope at least from our work.

McCutchen: Do you see the possibility, using viral vectors for delivery within the plant for homologous recombination? In other words using that as a carrier or other symbionts?

Flatt: Sure. If we can deliver the DNA or RNA we're usually able to get good expression. Irrespective of the method of delivery, if we have the right sequences we should be able to ultimately make the desired changes. But, we've not specifically worked with viral vectors so I can't speak any more definitively on that.

McHughen: This illustrates an important concept that we haven't really discussed: developing methodology to circumvent regulations and this is a problem when your regulations are triggered by process rather than product. Lots of new technologies have been developed since the dawn of recombinant technologies and some of those may be captured by current wording in the regulations and some of them may not. But, really, the question is whether our environment and our society adequately are protected from real threats to our health and to our environment. We can't achieve that based on a process trigger because we are always going to be playing catch up. When harm is caused, it is due to the presence of products. So, let's change our regulation so that they are product-triggered and not have

to worry about work-arounds or companies that may be interested in trying to invest in a way to avoid regulations. I'm in favor of sensible regulations—not no regulations.

Beachy: First, I endorse what you just said Alan. I'm curious as to how we take the information that you gave us, Mary Ann, about benefit and validation of beneficial attributes of horticultural specialty crops, and then using that to amplify, through synthetic biology, metabolic engineering, to enhance specialty crops. A number of us have worked in that space. At the end of the day though, the consumer needs to pay more. How far off are we before consumers will actually pay for a beneficial attribute? A lot of people have spent money in this space, even analyzing consumer attitudes and found out they want more but don't want to pay for it. Jim, how does that affect what you decide to do in the company, because it's all costed by likelihood? Do you delay certain things for the next five years until attitudes change? How do you see this moving forward to really have good products?

Lila: We've been talking through this whole conference about regulation holding things back and in the case of specialty crops and health you almost wish there was more regulation on what the media say and what they put out there. People who have serious problems with health or suspect or are paranoid about that, will pay. They will pay extra for something that is validated. Maybe they don't understand the science, but if they feel it is validated and substantiated you will get the extra premium. I can't put a number on it.

Flatt: Yes Roger, that is a great question and I'll address it in a couple of respects. When we embarked several years ago on our food efforts, we actually spoke with a number of very large multinational, both commodity as well as consumer packaged, food companies and a couple of things that those discussions bore out—the first is that the more visionary companies definitely saw that there would be growing acceptance of these methodologies in particular if they provide benefits that consumers can recognize. I think this is the point Mary Ann was making. So, again, to the extent that there is a validated clinically proven health benefit or a reduction-of-risk benefit or a performance nutrition benefit, there is certainly abundant evidence that consumers will pay for that, and oftentimes it is less important how that is produced. Having said that though, companies are very sensitive with their image and perception and have asked us to, as we are developing our products, to be able to provide them in two forms if you will have it, one that will essentially allow them to provide choice to their customers as well as deal with regional worldwide sensitivity. So, in some markets it's acceptable to produce that product through a GMO whereas in other markets you are still looking at identity-preserved sources. One of the things that we have been working on is how we can do bioinformed sorts of classical strain or cell-line improvement. And so we've had some progress there but, of course, you are still limited in the complexity of problems you undertake. We guide our product development making sure we can meet both of those needs. Because, again, you can't bet the whole farm—especially if it's a smaller development stage company—on producing a technical success but a market failure.

Ralph Hardy (NABC, Ithaca): At NABC 22, at the University of California, Davis, there was discussion of what was adequate proof of efficacy of some of these entities. One of the examples that was used was Activia yogurt. The European scene has required an efficacy hoop that is almost impossible, as I understand it, to exceed. That barrier is: it has to be proven the same as a drug. What guidance would you give in terms criteria to be used in the United States and Canada to be appropriate demonstrations of efficacy?

Lila: Hard to say, but definitely moving to the clinicals is the important thing, which they are doing more and more now. We had such a long drought of just cell-culture studies, which—I'm not downing those—certainly get to some answers, but they don't get to the answers that you really need to make a claim. Even when you do have validated repeated clinicals, you still have regulatory hurdles to pass through. But I think that clinicals—clinical trials—have to be the gold standard to validate a product or a technology.

Flatt: Mary Ann, in a prior life you were involved in a lot of nutritional research and one of the barriers in doing good research was just really the limited amount of money and the large base size for a clinical population. One of the trends that we have seen, in speaking with various nutritional researchers around the country, is using bioinformatics to carefully select and screen the test population so that you can get very meaningful data from a much smaller sample set, which helps get you a much more homogeneous test population with fewer subjects and allows you to draw definitive, statistically valid conclusions. I think that is something that we will see growing and hopefully will help.

Beachy: When you make those selections of population you do it for a variety of reasons; do you include microbiome in those populations that eventually would be your test case?

Lila: Because it's becoming more and more—

Beachy: It makes your selection of who that test case is more expensive to evaluate.

Lila: It does, but individualized nutrition is part of it, and what works on one population will not work on another.