Perspectives

Q&A

MODERATED BY
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Phyllis Johnson (USDA, Beltsville, MD): We are moving into a third generation of genetically enhanced crops. We can control the part of the plant in which a gene is expressed so that an insecticidal protein is present in the leaves but not in the edible portion. Does that change the regulatory or the ethical context, and, if so, how?

Gregory Jaffe: On the regulatory angle, it is a positive step because you can control where the protein will show up. You may have different containment and segregation issues, but some of the same food-safety issues and some of the same regulatory issues still need to be addressed. Containment risks to the environment can be reduced, but I don't think they will be eliminated.

Lea Thompson: Greg, you said in your presentation that if there were to be mandated pre-market testing that the FDA would take control of that. Can you explain that to us? Even for animals?

Jaffe: The USDA will continue to deal with environmental crop-safety issues. The FDA has no expertise in agriculture and I don't think anyone would want to see that agency regulating agriculture and how crops are grown. The FDA has expertise in food issues and will continue to regulate food safety.

Thompson: So, would all pre-marketing be done by the FDA even if it dealt with animals?

Jaffe: If you were genetically engineering an animal and you were going to put that in the food, then yes, you would want approval by FDA that the product is safe to eat. Right now that is the case for animals, but not the case for crops.

Audience member: Lycopene is listed in about 400 articles, indicating that it is good for your health and particularly for prostate cancer. How can a commodity group use that as a sales tool, for citrus for example?

Jeffrey Burkhardt: This is one of these claims that you see in health food stores all the time when it may not have been substantiated by anybody that matters. If they want to claim that lycopene is going to solve prostate cancer then pass the ball to Greg. But let's see if it really does help prevent or deal with prostate cancer, and market it accordingly.

Thompson: Expect some reporter at your door asking for the clinical test results to prove it.

Phil Berger (University of Idaho, Moscow, ID): Mr. Jaffe, you are calling for an increase in regulations, some of which may be beneficial. But if you think about it, the only product currently in production that is deregulated that is not from a private sector source are papayas in Hawaii. Traditionally, the source of germplasm for our growers has been the agricultural experiment stations. We are very interested in producing crops generated through biotechnological processes. The reality is that we really cannot easily afford to deregulate these crops now, and with additional regulations you will basically lock out the traditional sources of germplasm for the United States and most of the world. So, my question is: under the different regulatory framework, how do you propose to pay for it?

Jaffe: Even though we seek a stronger regulatory framework, there are ways to address minor crops and ways to address research at universities and agricultural research stations. We need more publicly funded biotechnology research. Too much is being done by industry, which is where the products are coming from. We are losing a lot of the promise of biotechnology by not having more publicly funded research. There are ways to set up regulations to help with additional burden in terms of testing for food safety where original funding comes from the government. There are programs, for example, for pesticides under the IR4 program that allow pesticides for minor uses with funding for the testing. There are ways that you can set up mechanisms within a regulatory structure that can give incentives to those types of products and also help pay some of the costs if the public institution has no return on investment.

Charles Arntzen: The concern should also be for smaller companies. Increased regulatory hurdles are an entry-barrier. If new products are to enter the marketplace, we have to keep that factor in mind also.

Jaffe: To some extent what I am calling for is not necessarily a raising of the bar. Part of it is a public perception thing and part of it is a legal authority thing

for the agencies. They already have this deregulation and permitting processes and so forth. Part of it is actually making them work.

Thompson: Greg, aren't you saying that, indeed, many of the companies that are producing these products are already going through this process because they have to do it for other countries?

Jaffe: Right. That's what I am saying. Especially the food-safety aspects, where we are adding more in terms of data requirements. These companies are already doing huge numbers of food-safety studies. I am not sure more studies should be done, but I think that the FDA should be reviewing those.

Arntzen: I believe we already have a costly process in place. I am not saying that there is anything wrong with a costly process, but it is driving a few very large companies such as Monsanto, Dupont, and Dow to carry new products into the marketplace. And the strategy for those of us in the universities, or with small biotech companies has to be to partner with someone who has the global regulatory expertise, *etc*. Now, I really don't see us going back on that, but I also would not like to see us go any further in making it impossible for somebody out of an ag experiment station to introduce a new product that has real value for the consumer.

Thompson: This is an issue that everyone in this room cares about. Susan, I wonder if you could enlighten us about how important is this kind of premarket testing to the consumer. After all, if the consumer won't buy, you are wasting your time.

Susan Borra: I don't think consumers are aware of premarket testing. They have an assumption of safety. They feel that if something is on the market then it is safe. Until there's a challenge to that presumption, they probably won't think about it very much.

Thompson: Shiriki, any comment as to where consumers are on all this?

Shiriki Kumanyika: I was reflecting on my experience a few years ago on the Commission on Dietary Supplement Labels where we were trying to clarify what the regulations were and the different nutrition-support claims and health claims. Unfortunately, I agree with Sue. For example, I don't think that the disclaimer on the labels is noticed by consumers who have decided to use the supplement. There are just so many disclaimers, whatever is on the label is so much verbiage. If something comes down the pike that is the dietary version of "Phen-Fen"-type problems (phentermine-fenfluramine combination), I think we will be in big trouble, because a lot of people trust that it wouldn't be out there if it weren't safe, if it weren't good for you.

Thompson: So often all of this happens in a crisis mode, such as with StarLink™, and the more crises there are, the more people are going to be concerned and the more they are going to call for testing or regulation. It doesn't take much to turn the consumer around when there is a real problem. I see that all the time. I cover crises in the food area and have been stunned, frankly, to see how quickly consumer opinion can be turned—not that the consumer at this point would know whether there is something biotech in the food they are eating anyway. I think it is something that everyone needs to be concerned about, because, once again, if people won't buy it you are wasting your time.

C.Y. Hu (Oregon State University, Corvallis, OR): Jeff, you mentioned that biotechnology will provide benefits only if scientifically and legally successful and they garner consumer acceptance. I am wondering, as a scientist, shouldn't we consider legal and consumer aspects before we take on any project.

Jeffrey Burkhardt: Yes. I think that's right—your responsibility is to do what you do. But there is almost a relay-race mentality. The scientist does his thing, runs his leg, then hands it off to the research administrator or to the company developer, who hands it off to the marketer, who hands it off to the government regulator. Everyone is back there clapping hoping that the guy finally crosses the finish line with the baton. They have a stake in the final outcome. A stake, sometimes financial, and certainly a stake in terms of their participation in the development. Even if you are doing basic theoretical science, you have a stake and some degree of responsibility for the outcome. We have got either the "cast it to the wind and hope it flies" mentality or the "relay-race" mentality. Maybe more so for the research administrators than for the bench scientists, but we all need to do more conceptualizing of what we are about, or perhaps we should actually be watching and monitoring, to the extent that we can, products as they move from the laboratory or the research assistant's spot in the lab out to the market. We can't expect a first-year research scientist at a major state university to know everything there is to know about social responsibility of research scientists, but we can expect more than we do.

Barbara Schneeman (University of California, Davis, CA): The major thrust we have seen, using biotech for nutritional and health improvement, has been by adding the nutrient or bioactive compound to the food, in a sense making the product comply with the dietary guidelines. I would like to hear comments from the consumer perspective and the public-health perspective regarding the value of that kind of approach, versus other approaches, where biotech might be useful to help the consumer comply with dietary recommendations.

Kumanyika: I don't have an example in mind of an approach that would be based in the product that would help the consumer comply, unless you are talking about, say, a cookie that could make you stop eating it when you have had too much. One could go in that direction: things that lose their sensory properties at a certain point! A more coordinated approach may be needed among food technologists about products in general, rather than considering particular products. That is how we got into the problem with something as simple as lower fat but higher in calories. A coordinating panel could look at a grouping of foods and ingredients being added and consider how that meshes with what policymakers expect to be in that food—because if we did make big shifts we would need to adjust the dietary guidance. But, I can't think of ways in which you would work directly with the consumer, unless you are looking at appetite control.

Borra: Biotech may provide changes to the food supply that will be helpful for public health. However, macronutrient issues are now of greatest concern, for example the obesity issue in America.

Schneeman: In the case of golden rice, one or two nutrients are added to rice in a region of the world where the people obtain 75% of their energy from rice. The problem is probably just that—75% of the energy comes from rice, and adding two nutrients won't have a big impact. That's what I mean by the nutrient-focused approach—modifying the product rather than asking the question of what else needs to happen for the population to have a healthful diet?

Arntzen: The golden rice story is one that warrants discussion of what caused it to happen. As you'll recall, almost all the funding came from the Rockefeller Foundation after an intensive study by multidisciplinary groups who cared about nutrition and plant molecular biology and defining what was possible. The decision to put genes for carotene enhancement in rice was made with under-served populations of the world in mind. If you planned a similar product for the United States or Europe, you'd be laughed off—why would you bother doing it? You have to keep that in perspective.

I don't know why people focus on biotech. There are other technical approaches that don't involve genetics, *e.g.* DHA or omega-3 fatty acid supplementation of baby food. It took ten years of activity, eight years longer than it took in Europe, to get that supplementation in, even though there was abundant nutritional evidence that it was good for children to have DHA supplementation. Why did it come? Well, finally one company adopted it and the other infant-formula companies couldn't avoid it—they added so as not to be pushed out of the marketplace. Low-cholesterol eggs, produced by feeding chickens various things, were a non-event in the marketplace. And stanol esters

in Benecol® margarine—to lower cholesterol—hasn't had a significant impact on that segment of the marketplace. The problem in the United States is that we have an abundant supply of food with people interested in eating what they like, not necessarily what is good for them. And we have a whole bunch of claims out there. Probably the only successful area has been low-fat foods, because it was an opportunity for the food industry to make proprietary technical advancements and lower the fat content and substitute, usually, carbohydrate content in its place. It has been a good marketing niche. It doesn't take a lot of advertising and there is some proprietary advantage. Lycopene from Texas A&M requires a lot of education and there is no incentive for the food industry to invest money unless they can get a proprietary advantage. I would not focus on biotech. There are things we can do with biotechnology, but by and large there are so many other things we could do based upon other food-processing technologies that would be easier, faster, and cheaper. With respect to nutrition we have a tremendous opportunity in the developing world. The DOMI program—Diseases of the Most Impoverished—is funded by Bill Gates, and nutrition is popping up on their radar as something to focus on; they are considering all sorts of things, including biotechnology.

Thompson: Shiriki, one of the big things that has come to the marketplace in the past five years has been WOW® potato chips, which are marketed as being low fat. Are people buying them?

Arntzen: Why would someone eating potato chips care about a health claim? You're eating salted fat—

Thompson: But you can eat the whole bag—

Arntzen: I think the people who respond to health claims are the same people who belong to health clubs or they jog religiously, *etc*. They care about their health. And they don't eat potato chips. They eat tofu.

Kumanyika: I think a lot of people are using alternative foods that don't have the consequences associated with the regular form. I have no data on how much they are selling, but if they are on the shelf, I assume that they are selling. I have noticed, however, that, depending on where I shop some products are absent. There are neighborhoods in Philadelphia, where I live, where there is a high profile for WOW® and that type of product, and other neighborhoods where I go there are none in the store because the demand probably isn't there. There is an interaction between having some of these things available and the consumer creating demand. Sometimes people can afford only the generic choice and will be unable to buy something healthier because it is three times the price. There are interlocking aspects.

Borra: I understand that the no-fat potato chip has not survived in some marketplaces because it hasn't done well. For some reason, it didn't fill a consumer niche; perhaps the taste profile wasn't right. But your comment is interesting: "You can eat the whole bag." That's the issue—that should not have been the selling point.

Maggie Powers (Powers and Associates, Inc., St. Paul, MN): I own a health communications firm here, and I appreciate Sue's work with consumer messages, because I think that is what is ultimately going to get them to listen to us, to have a positive impact. Shiriki, do you have a comment based on the obesity information you provided, regarding children developing type-2 diabetes. Recently, in a school district in Pennsylvania, notices were given to children who were obese. I found that fascinating. It gets into policy issues. We give out notices concerning other diseases prevalent in school systems—my children bring home such notices—I am curious as to your thinking.

Kumanyika: Obesity is one of the chronic diseases that is much more socially than biomedically defined. Even though from a public-health point of view we can look at body-mass index and say your weight over height squared is such and such, consumers have different definitions. Parents, as the CDC is finding out, define obesity in their children in terms of how the children function psychologically and physically, not in terms of their weight for their height. So, we have some things to learn. We were asleep at the wheel and this was an epidemic before we noticed it. It will take a lot of social and cultural reflection and intervention to see how best to address it without stigmatizing the children or their parents. But, it is definitely something that we will have to address, which is why some of us favor environmental solutions, such as placing those kids in schools that have a physical ed class. Thus, without labeling anyone as obese, they find themselves in more active play and with a different school lunch.

Audience Member: Greg, some people would argue that food risks associated with the process of genetic engineering are dwarfed by other kinds of risks, such as bacterial-borne diseases and contaminants. If that is the case, how can we justify a presumed increased cost in the regulatory system associated with mandatory approval, and would those dollars be better spent in other ways?

Jaffe: I tend to agree with you that biotechnology is not number one in a list of food risks, in fact it would be fairly far down on the list. My organization contends that biotech foods are safe to eat. However, there are public concerns. NABC has been addressing these for many years at their conferences. Public perception, public acceptance issues are commonly written about in newspapers. Also there are *some* food-safety risks with the technology, and you solve

both of those problems through a mandatory approval system. Whether it is number one on your priority list, public-acceptance issues are under debate worldwide. There are ways to design a system so that it would not be much more expensive than it currently is, and that is what we are attempting to achieve. With user fees, for example, the cost can be borne by the developer rather than by the government. The system that is in place is already costly.

Sraddha Helfrich (University of Minnesota, Minneapolis, MN): Although there are so many ways in which we can manipulate DNA, it is important to bear in mind that humans are spiritual beings. Food is often at the heart of the spiritual and cultural experience across the globe. As scientists in positions of power, how do we respectfully engage in dialogue with people whose very cultural identity may be threatened by our science. I wonder if this is even an appropriate question.

Thompson: I think it's very appropriate.

Kumanyika: Can the ethical justification be extended to the process, not the outcome? In research on humans, we have to go through institutional reviews to determine whether such is justified—is it worth the human burden? When I think about this issue and about tying up the regulatory system, then I wonder how do you justify creating products just because you can, and then there is a burden to regulate them. You can imagine tying up the entire system with product development that might not have been vetted for a positive outcome. I wonder if there's a pre-approval process for product development that can include some of the concerns that you are raising.

Burkhardt: Isn't that what interaction with peers is supposed to be, in the basic sense, beyond sharing the results of the latest experiment to sharing the values and norms of science? There would be a pre-vetting process, if you will, if people would talk to each other about what they are doing and what they are planning to do. So, if someone says, "I want to make a tomato with legs," and someone says, "No, don't go there"—that would be the ideal communication system, within a university department, within a research laboratory, within a corporation, or among those entities. More directly pertaining to your question, one of the things that I am sick of hearing is the totally inappropriate response to the issue you raise: "They just need more information. Consumers want information." Well, if you gave them the information they wouldn't know what to do with it. With people from a very different culture, a very different set of ethical or religious convictions, you don't give them more information and say, "If you understand this you'd understand us." That's disrespectful at best. The alternative is to acknowledge that, in fact, they don't buy into our reductionistic, corporate, *etc.,* approach—you can run down the list of every complaint

that has been made about modern science. They don't buy into it, and you cannot make them, as much as many of those present may want to make them buy into it, you cannot force them to believe that this is the best way to go in all cases. That's where respect ends.

Barrie Froseth (General Mills, Golden Valley, MN): Can you give us some specific examples of outstanding communication or education of health and nutrition. On one hand we have the paradigm of "five a day for better health" driven by an industry group, and on the other hand we have CSPI going after specific cuisines, most recently pizza.

Thompson: I am going to interrupt and ask this room: how many of you have used the nutritional facts information that is shown on products? Almost everybody in the room. That is a very successful label. Food manufacturers and processors in this country came kicking and screaming about that label, yet everybody appreciates and uses it, and everybody is better informed as a result of it.

Borra: We don't have good communications on nutrition. If we did, we might not have such a problem with obesity. We need to find new and better ways to talk with consumers about nutrition—that's the key. We are trying all kinds of new communications approaches—sitting down and talking with consumers: "What are you dealing with in your life and how can I make my nutrition message fit?" With my professional nutrition colleagues, we have tended to tell people what they should do: "You should be doing this because I know the science and I know it's right." We have to change that approach. How many people eat according to the Food-Guide Pyramid in this country? Very few. We haven't gotten through with those messages. There is much work ahead to figure out the best way to communicate with consumers.